

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.

The change in name reflected in this protocol from Moderna to Moderna SPIKEVAX® is a name change only. While this protocol includes updates to various sections including eligibility, handling and administration of the vaccine, there is no change to the vaccine formulation itself.

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.

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| 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 Data on the efficacy of the Moderna SPIKEVAX® COVID-19 vaccine against emerging variants of concern is evolving. ² |
| Eligibility | Individuals age 12 years and older without contraindications to the vaccine. |
| 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 |

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| 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. Once the vial has been entered (needle-punctured), it should be discarded after 24 hours. 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) 8 weeks apart.</p> <p>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 following completion of the primary series (see Booster Dose section of protocol below).²</p> |

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| 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><u>The additional dose for those immunocompromised should be 0.5mL.</u></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); |

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| | <ul style="list-style-type: none"> d. Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome); 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</p> | <p>Waning immunity over time and efficacy of vaccines against variants of interest and variants of concerns are two factors that have been examined in the context of booster doses. Current NACI recommendations include a booster dose of a COVID-19 vaccine after the primary vaccine series is complete.</p> <p>For all Nunavummiut ages 12 and up who have received a primary COVID-19 vaccine series (with a homologous or heterologous schedule using mRNA or viral vector vaccines) a booster dose of an authorized mRNA COVID-19 vaccine (Pfizer-BioNTech COMIRNATY[®] or Moderna SPIKEVAX[®]) should be offered a minimum of 6 months after completion of the primary series. Either Pfizer-BioNTech COMIRNATY[®] or Moderna SPIKEVAX[®] can be used as a booster dose, regardless of which mRNA vaccine was used in the primary series.</p> <p>The recommended booster dose for Moderna SPIKEVAX[®] is 0.25mL for most recipients and 0.5mL for seniors over 60 years of age living in long-term care homes or other congregate settings and Elders over 70 years of age.</p> <p>This dose should be offered at an 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.</p> <p>Please reach out to your RCDC if you have any questions about this guidance.</p> |
| <p>Vaccine interchangeability</p> | <p>NACI recommends that, if readily available, the <u>same</u> 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-</p> |

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| | BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine). ² |
| Contraindications | <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> <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</p> <p>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</p> <p>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.</p> |
| Precautions and additional notes | <p><u>Anaphylaxis:</u> Please see anaphylaxis section below for additional information on follow-up needed if anaphylaxis is suspected related to COVID-19 vaccination.</p> <p>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.</p> <p>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</p> <p>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</p> <p>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</p> <p><u>Myocarditis and pericarditis:</u> 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</p> |

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.

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| | <p><u>Syncope:</u> 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</p> |
| <p>Administration of other drugs, or biological products</p> | <p><u>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.</u></p> <p>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</p> <p>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</p> <p>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</p> <p>Please refer to additional guidance provided by the Nunavut Tuberculosis Program in Appendix F.</p> <p>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</p> |
| <p>Special Populations</p> | <p><u>Individuals previously infected with SARS-CoV-2:</u> 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</p> <p><u>Individuals who have an autoimmune condition:</u> 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</p> |

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| | <p>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</p> <p><i>Individuals who are pregnant or breastfeeding:</i> 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 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> |

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| 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 information, please refer to Appendix C <i>Orientation to Obtaining Consent for Administration of the Moderna SPIKEVAX® COVID-19 Vaccine</i>).</p> |
| Anaphylaxis | <p>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.</p> <p>NACI recommends that in individuals with a history of a severe, immediate (≤ 4h following vaccination) allergic reaction (e.g., anaphylaxis) after previous administration of an mRNA COVID-19 vaccine, administration of a subsequent dose in the series when indicated may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. The risk of a severe immediate allergic reaction after re-immunization appears to be low and no long-term morbidity has been associated with re-vaccination.</p> <p>For any further immunization after anaphylaxis to a previous dose of an mRNA COVID-19 vaccine, consultation with an allergist AND guidance and approval from the Office of the CPHO must first be obtained. Please reach out to your RCDC.</p> <p>If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis. Individuals should be observed for at least 30 minutes after re-vaccination. For example, a longer period of observation is warranted for individuals exhibiting any symptom suggestive of an evolving AEFI at the end of the 30-minute observation period.</p> |
| Side Effects | <p><u>Injection site reactions:</u> 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><u>Systemic side effects:</u> 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> |

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| | <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> |
| <p>Reportable Adverse Events/Side Effects/Administration Errors</p> | <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. 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. |
| <p>Vaccine Coverage and Reporting</p> | <p>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.</p> |
| <p>Documentation</p> | <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>Health care providers are required to document vaccine administration in Meditech and ensure the consent form is completed and stored as per health centre processes.</p> <p>Update recipient’s Personal Immunization Record and provide date of next dose of vaccine.</p> |

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| | Follow operational team guidance on processes to track and call back clients for second dose. |
| 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_resources.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) Appendix B Guidance for Vaccination with COVID-19 Vaccines During a Home Visit Appendix C Orientation to Obtaining Consent for Administration of COVID-19 Vaccines Appendix D Reporting an Adverse Event Following Immunization Appendix E COVID-19 Vaccine Transport Protocol Appendix F Nunavut Guidance on TSTs and COVID-19 Vaccines Appendix G Vaccine Clinic Screening Questions Appendix H Vaccine Clinic Booking Script Appendix I Vaccine Aftercare Sheet (with translations) Appendix J Vaccine Consent Form Appendix K Vaccine Information Sheet (with translations) Appendix L COVID-19 Booster Vaccine Doses Fact Sheet</p> |
| References | <ol style="list-style-type: none"> 1. Moderna (2021). <i>SPIKEVAX® (elasomeroan mRNA vaccine)</i>. Moderna: 2021. Available: covid-19-vaccine-moderna-pm-en.pdf (canada.ca) (accessed September 20, 2021). 2. National Advisory Committee on Immunization (2021). <i>An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): Recommendations on the use of COVID-19 Vaccines</i>. 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](https://naci/recommendations-use-covid-19-vaccines.html) (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](https://naci/recommendations-use-covid-19-vaccines.html) (accessed October 01, 2021).
5. National Advisory Committee on Immunization (2021). *National Advisory Committee on Immunization (NACI) rapid response: Interim guidance on booster COVID-19 vaccine doses in Canada 01 November, 2021*. Public Health Agency of Canada: 2021. Available: [- \(canada.ca\)](https://naci/recommendations-use-covid-19-vaccines.html) (accessed November 01, 2021).

Approved by the Chief Public Health Officer on November 01, 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 has had a systemic allergic reaction, anaphylaxis, to first dose of COVID-19 vaccine. | Do not vaccinate today and consult the Office of the CPHO/RCDC for further guidance. |
| | Client was diagnosed with myocarditis or pericarditis following a previous COVID-19 vaccine. | Do not vaccinate today and consult the Office of the CPHO/RCDC 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 today and consult the Office of the CPHO/RCDC 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. Advise client of potential for 3 rd dose and submit referral to community MD. |
| | Patient has an auto-immune disorder. | Proceed to vaccinate if meets remaining criteria. Advise client of potential for 3 rd dose and submit referral to community MD. |



Appendix B COVID-19 Vaccine Protocol

Guidance for Vaccination with COVID-19 Vaccines During a Home Visit

Background:

There are several reasons a small number of individuals may not be able to come to the health centre or clinic to be vaccinated and may need to receive the COVID-19 vaccine at home. While every effort should be made for clients to travel to the clinic for their immunization, there will be circumstances where this is just not feasible. The purpose of this document is to outline a procedure to bring the vaccine to these clients in a home visit in a way which ensures:

- The vaccine is transported in a way which maintains its effectiveness when administered.
- Wastage of the vaccine resulting from the home visit is as limited as possible.

Note that COVID-19 vaccines are more unstable than most other vaccines currently in use and there is concern that jarring or shaking the vaccine would make the vaccine less effective or ineffective. Frozen transport is preferred to any liquid/thawed transport. **Do not transport pre-filled syringes or punctured/diluted vials.**

Preparing for a home visit:

Please note that COVID-19 vaccines are less stable than most other vaccines currently in use and they are recommended to be transported in a frozen state and then thawed (please see appropriate thawing guidance in the SPIKEVAX® and COMIRNATY® COVID-19 immunization protocols as they are unique for both vaccines).

The risk of transporting the vaccine in a liquid, thawed state is that any jarring or shaking, even from going over a gravel road in a car, would render the vaccine ineffective and not protect the vaccinated client from COVID-19 infection so frozen is the preferred option.

The following steps should take place at least a day before the home visit is planned:

Identifying Health Care Providers:

- Two healthcare staff are to attend the home visit, including an interpreter if required. If only one nurse is available to attend, a second attendant must accompany in case any urgent situations arise.



Identifying clients:

- Home care clients should be carefully screened to identify individuals who cannot access the clinic. All options to assist the client to attend the clinic should be explored before making plans for a home visit. This could include doing a radio call out for volunteers to drive clients who require assistance to the clinic.
- Once a client has been identified for home visit - explore with the client and family if anyone else in the house is eligible to receive the vaccine. Consideration should be given to vaccinating anyone in the household who is eligible to reduce wastage of vaccine by using all doses in the vial. Please review eligibility requirements in the appropriate COVID-19 immunization protocol.
- If the community has an Elder's apartment complex (these are self-contained / separate apartments) and there is one Elder who cannot reasonably travel to the clinic, consider offering vaccination to all Elders living in those apartments at the same time to minimize wastage / doses discarded.

Obtaining consent:

- When clients are identified, make arrangements to conduct a home visit, with an interpreter if required, to obtain their informed consent for the vaccine. You will need to take both the consent forms and information sheets to this visit. The consent forms are brought back to the health centre and the information sheet left with the client.
- If possible, obtain consent, in advance, from other eligible family members, other household contacts or others in the apartment building at the same time. This helps to confirm there will be 10 people willing to be vaccinated during the same visit. While this is a time-consuming process, it will reduce vaccine wastage.
- Note that this step may be combined with the visit itself in some circumstances. At minimum, verbal consent should be obtained prior to the home visit.

Making appointments:

- At the visit to obtain consent, provide an appointment card. Alternatively, advise the client that they will be contacted by the health centre to confirm the appointment date and time.
- Inform the client and family in advance that the healthcare team may be at the home for longer than one hour, to allow required thawing time. Reminder: thawed vials cannot be moved between households.

Securing vaccine:

- Notify the person in charge of ordering the vaccine that a vial will be required for vaccinations during a home visit so that a vial will be available on that day.



- Refrigeration packs for transporting the vaccine are to be assembled with the cooling packs placed in the freezer or fridge. For any inquiries related to vaccine transport, please contact your regional pharmacy or the COVID-19 Special Operations Division.

On the day of the home visit:

- The morning of the home visit, the clerk is to contact the client to:
 - Confirm the time for the home visit.
 - Confirm that the client and household members are still wanting to receive vaccine.
 - Screen for any symptoms of acute or febrile illness using the COVID-19 Vaccine Clinic Screening Questionnaire.
 - Confirm all individuals eligible for the vaccine are booked and registered on Meditech.
- The clerk should notify the nurse of any concerns prior to the visit.
- Gather supplies (see list below) and assemble the transportation refrigeration pack (see Appendix A for details on assembling pack).
- The frozen or fridge temperature vial will be signed out to indicate it is being used for a home visit. A Vaccine Vial Tracking Log will need to accompany the vaccine. The vial should not be taken out of the freezer or fridge and put into the refrigeration pack until the health care team are ready to leave the health centre. **Do not transport pre-filled syringes or punctured/diluted vials.**
- **The refrigeration cooler with the vial should be held in the hands or on the lap of one of the immunizers during transport. The cooler is not to be put on the floor or in the trunk of a car. Every attempt should be made to carry the cooler without jostling.**
- The vial is transported back to the clinic in the cooler to be discarded; any wastage is recorded on the Vaccine Vial Tracking Log. NOTE: Any remaining doses in a punctured vial should not be used after transport.

Documentation:

- Once the team returns from the home visit, it is the nurse's responsibility to document the encounter on Meditech including the time and date of administration, quantity of administered dose, anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.



Materials Needed to Administer the Vaccine (non-outbreak community):

Patient’s file and immunization record cannot leave the health centre but should be reviewed prior to the home visit.

| | |
|---|--|
| <input type="checkbox"/> Cell phone | <input type="checkbox"/> Vaccination record wallet card |
| <input type="checkbox"/> Anaphylaxis kit – (Appendix B) | <input type="checkbox"/> Completed Consent Forms |
| <input type="checkbox"/> Cooler with frozen packs and vaccine (Appendix A). | <input type="checkbox"/> Spare Consent Forms and Information Sheets in appropriate languages |
| <input type="checkbox"/> Surgical masks (for providers, client and household members) | <input type="checkbox"/> 10 - After Care sheets in appropriate languages |
| <input type="checkbox"/> Disposable face shield or goggles | <input type="checkbox"/> Reporting Adverse Event Forms |
| <input type="checkbox"/> Hand sanitizer | <input type="checkbox"/> Vaccine Log |
| <input type="checkbox"/> Cotton balls or gauze pads | <input type="checkbox"/> Blue pad |
| <input type="checkbox"/> Sterile syringes and needles | <input type="checkbox"/> Sharps container |
| <input type="checkbox"/> Antiseptic swabs | <input type="checkbox"/> Bag(s) for used materials |

Materials Needed to Administer the Vaccine (outbreak community):

- In addition to above materials, the following additional PPE is required:
 - Disposable gown, gloves, booties.



During the home visit (non-outbreak community):

1. Just before leaving the clinic, the clerk to call the client and notify them the team is en-route.
2. Don mask before leaving the car; bring masks for household members.
3. Remove outerwear and don face shield (or goggles) immediately upon entering the home.
4. Ask the clients and others in the home to also don a mask.
5. Sanitize hands, put a blue pad down on a surface to create a clean field and remove the frozen vial from the refrigerated container, marking the time the vaccine is removed on the Vaccine Vial Tracking Log. Record the time the vaccine will be thawed (1 hour later), diluted (if applicable) and when it should be discarded. For patient comfort, the vaccine can be left at room temperature for a further 15 minutes to ensure room temperature and minimize discomfort.
6. While vaccine is thawing, review informed consent a final time in case client has any questions. At this time, also review consents of other household members receiving the vaccine.
7. Place remaining vaccine administration supplies on the clean field. The sharps container and anaphylaxis kit placed nearby and easily accessible.
8. Prepare and administer as per the appropriate COVID-19 Immunization Protocol.
9. Put syringe directly into the sharps container and document vaccine administration on the back of the consent form. Give client the After Care sheet.
10. Stay with the client for at least 15 minutes to ensure there are no adverse reactions; 30 minutes if there are concerns about allergies. Ensure client has a means to contact health centre if having a reaction beyond the 15 minute wait.
11. Give client their vaccination record wallet card as well as an Appointment Card with a date for the second dose according to the appropriate vaccine protocol. Inform the client the health centre will contact them prior to the next appointment.
12. Collect used materials and take with you in a bag.
13. Perform hand hygiene with hand sanitizer.



During the home visit (outbreak community):

- As above with additional measures to prevent transmission of infection - droplet and contact precautions when visiting the home of a client with suspected COVID-19. This includes gown, gloves, booties, surgical mask and face shield.
- Additional resources are available in the Infection Prevention and Control Manual and Housekeeping Manual including posters on donning and doffing PPE.
- In an outbreak community it would be safer to vaccinate household contacts rather than those who live in other households in the same building to reduce the spread of infection. This may mean some vaccine wastage occurs.

Additional Infection Prevention and Control Strategies:

1. Explain to client that you will be using disposable PPE and ask if your disposable PPE can be left in the home for the client to discard. Explain to client that they should maintain at least 2 metres physical distancing while removing PPE.
2. Only carry supplies required to administer vaccine and disposable PPE. Avoid using your cell phone or accessing anything that may be in your pockets.
3. Bring vaccine supplies into the house as described above – in outbreak communities, may wish to wait outside of home for part of the time while vaccine is thawing.

References

Ontario Ministry of Health. (2020). Novel Coronavirus (COVID-19) Guidance for Home and Community Care Providers Retrieved from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_home_community_care_guidance.pdf

Government of Nunavut, Department of Health. Immunization Manual. Retrieved from: <https://www.gov.nu.ca/health/information/manuals-guidelines>



Appendix A: 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: 3.7.6 Anaphylaxis Management in the Community

[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.]

This section is intended as a guide for the initial management of patients in a mass immunization clinic, public health clinic, or similar non-emergency setting. For severe life-threatening anaphylaxis, advanced care should be managed in the health centre or hospital setting following the protocol outlined in Section D-09 and D-10 of the Government of Nunavut Drug Formulary.

Action of Epinephrine

IM is the preferred route for the administration of epinephrine and the thigh is the preferred site for its administration.

When epinephrine is administered intramuscularly, it acts on beta adrenergic receptors found in the skeletal muscle vasculature causing vasodilation. Thus, when IM immunization is given and epinephrine is indicated, it should not be administered into the same muscle mass as the vaccine was administered. The epinephrine will produce vasodilation locally at the site, increase vascular permeability, and may increase absorption of the offending antigen.

Side effects of excessive doses of epinephrine pose little danger but can add to the person's distress by causing palpitations, tachycardia, flushing, and headache. Cardiac dysrhythmias can occur in older adults but are rare in otherwise healthy children.

Administration of Epinephrine

Call emergency response as per community guidelines.

Administer epinephrine IM immediately. The most important step in the management of anaphylaxis is the immediate administration of aqueous epinephrine 1:1,000. Failure to use epinephrine promptly is more dangerous than its improper use. Use the epinephrine dosing chart outlined in "Anaphylaxis: Initial Management in Non-hospital Setting" in Section 3.7.10.

IM injection of epinephrine into the thigh is the preferred route for administration.

DO NOT inject epinephrine into the same muscle mass (e.g., thigh) as the vaccine was administered.



If the thigh cannot be used in a child \geq 12 months of age or an adult (e.g., client has received IM injections in both thighs), give epinephrine IM into the deltoid muscle(s).

If both arms and both legs have been used for IM immunizations, administer epinephrine SC into the upper outer triceps area of the arm(s), or into the fatty area of the anterolateral thigh.

Injection of epinephrine can be made through clothing, if necessary. Repeat epinephrine at 5-minute intervals twice as needed (i.e., if breathing becomes more laboured or level of consciousness decreases). Note: Administer a maximum of three doses of epinephrine.

Alternate between right and left thigh or arm sites for repeat doses of epinephrine (to maximize absorption of epinephrine).

Note: An epinephrine self-injector (Epipen or Twinject) can also be used in the situation when the immunization provider is not present and if the layperson who administers the self-injector is knowledgeable about proper use. The regular preparations contain 0.3 mL of epinephrine 1:1000 and can be used for individuals over 6 years of age. If a vaccinee or their parent/guardian refuses the administration of epinephrine when it is indicated, inform them of the risk and immediately call for help to arrange for transfer to an acute care facility. The administration of diphenhydramine hydrochloride (Benadryl) is not appropriate in this situation. Diphenhydramine hydrochloride is considered second-line therapy to epinephrine and should never be administered alone in the treatment of anaphylaxis.

Diphenhydramine Hydrochloride (Benadryl)

Give one dose of diphenhydramine hydrochloride (Benadryl) IM as an adjunct to epinephrine when the person is not responding well to epinephrine, or to maintain symptom control in those who have responded (as epinephrine is a short-acting agent). Its use is recommended when transfer to an acute care facility cannot be done within 30 minutes. Its use is considered second-line therapy to epinephrine and should never be administered alone in the treatment of anaphylaxis.

The approximate doses for injection (50 mg/ml solution) are outlined in “Anaphylaxis: Initial Management in Non-hospital Setting” in 3.7.10. NOTE: BENADRYL IS PAINFUL WHEN GIVEN IM.

When administering diphenhydramine hydrochloride IM, preferably administer at a different site to that in which epinephrine was given. However, if necessary, give diphenhydramine hydrochloride in the same thigh as that in which epinephrine was given.

Diphenhydramine hydrochloride can be given into the same muscle mass as the vaccine was given.



Diphenhydramine hydrochloride can be given at any time interval either after the initial or repeat doses of epinephrine, as indicated by the person's condition.

3.7.7 Other Considerations

Position client in the recumbent position and elevate legs, as tolerated symptomatically. This slows progression of circulatory compromise, if present, by preventing orthostatic hypotension and helping to shunt effective circulation from the periphery to the head, heart, and kidneys.

Monitor pulse, respiratory effort, and level of consciousness to guide medication use: • If person experiences respiratory difficulty: elevate head and chest slightly.

- If airway is impaired: improve position by using head tilt, chin lift, or jaw thrust.
- If vomiting is likely, turn person to side lying position.

Arrange for rapid transport by vehicle to the health center or emergency room (depending on community). Since 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2 – 9 hour asymptomatic period, hospitalization or a long period of observation is recommended for monitoring.

3.7.8 Recording of the Anaphylactic Event

Administration of epinephrine and diphenhydramine hydrochloride may be recorded on the "Anaphylaxis Assessment Guide and Record" found in section 3.7.11.

Report the case of anaphylaxis using the Adverse Events Following Immunization (AEFI) form found in Section 3.5.

Document the vaccine reaction on Immunization Record under the comments section.

Await the CPHO review and recommendation regarding subsequent immunization with the associated biological product(s).

If the reaction is deemed to have been anaphylactic, the associated biological product(s) cannot be administered in the future. Except in the case of rabies post-exposure vaccine, the history of anaphylaxis is a contraindication to the administration of the associated biological product(s).

Record this contraindication in the client's personal and electronic immunization record. Discuss with the client/guardian the CPHO recommendation regarding subsequent immunization.



References

- British Columbia Centre for Disease Control Section V –Management of Anaphylaxis in a Non-clinical Setting, by the British Columbia Centre for Disease Control. The materials in this section were adapted and are being used with permission of British Columbia Centre for Disease Control.
- Government of Nunavut, Department of Health. Immunization Manual. Retrieved from: The Immunization Manual (<https://gov.nu.ca/health/information/manuals-guidelines>)



Appendix D: Reporting an Adverse Event Following Immunization with COVID-19 Vaccines

Refer to Government of Nunavut's [Immunization Manual](#) for more information

The [Practice Guidelines](#) in the Immunization Manual provide a comprehensive description of reporting an adverse event following immunization (AEFI).

Definition of an adverse event following immunization:

An AEFI is any untoward medical occurrence in a vaccinee that follows immunization and may or may not have a causal relationship with the vaccine or the immunization process.

Temporal association alone (onset of event following receipt of vaccine) is not proof of causation.

Recommendations following an adverse event:

A health professional who is aware of an adverse event following immunization occurring must complete an [AEFI Report Form](#). Completed forms should be faxed or emailed to the Regional Communicable Disease Coordinator (RCDC) as soon as possible after the event. A Public Health Officer (PHO), or delegate, will review and work with the team to provide recommendations back to the provider. The Office of the CPHO will ensure all AEFIs are reported to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS).

Recommendations following adverse event review should be discussed with the client, provided to the client's primary health care provider and documented on the client's chart.

Examples of when to complete an AEFI Report Form (more detail in Practice Guidelines):

| Example | AEFI Report Form |
|--|---|
| Events which the client's health care provider considers may be a reason to postpone a future immunization with the same vaccine. | Fill out and send AEFI Report Form to RCDC |
| Any unexpected events that are not considered usual side effects of the vaccine. | Fill out and send AEFI Report Form to RCDC |
| All events managed as anaphylaxis and any allergic events. | Fill out and send AEFI Report Form to RCDC |
| All neurological events including febrile and afebrile convulsions. | Fill out and send AEFI Report Form to RCDC |
| All serious events: life threatening or resulting in death; requiring medical treatment or hospitalization; or resulting in a residual disability. | Fill out and send AEFI Report Form to RCDC <i>Note: For COVID-19 vaccines, send report if death occurs up to 30 days after vaccination, regardless of cause.</i> |
| Local injection site reactions and non-specific systemic reactions (e.g., headache, myalgia) (side effects from the vaccine are found in the COVID-19 Vaccine Information Sheet) | No AEFI Report Form required unless reactions are much more severe than anticipated or last much longer than typically expected. |
| Vasovagal syncope (fainting). | No AEFI Report Form required |
| Events which have another obvious cause (e.g., co-existing conditions). | No AEFI Report Form required |

Appendix E - Transporting and Tracking Vials of Moderna SPIKEVAX® and Pfizer BioNTech COMIRNATY® COVID-19 Vaccines from Regional Distribution Hubs to Vaccination Clinic Sites

Last updated: October 04, 2021

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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 between sites. In addition:

- Vials should never be transported at room temperature between sites.
- Punctured vials should never be transported between sites.
- Liquid (thawed or refrigerator temperature vials) should not be transported by air.
- COVID-19 vaccine will be transported to the Regional Hubs in Iqaluit, Rankin Inlet and Cambridge Bay. These communities will act as regional distribution sites. The vaccines will be further transported to the communities and from the health centre to the vaccination clinic site. At each stage 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*.

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.
- Do not use dry ice.

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 A):

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 A](#).

COVID19 Vaccine Vial Inventory for Community Freezers or Vaccine Fridges Log (Appendix B):

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 B**.

COVID19 Vaccine Vial Tracking Log (Appendix C):

This log is designed to capture information on each vial at a vaccination clinic site including: who signed out each vial from the health centre, who the vial was assigned to at the clinic; and the number of doses given as well as the total wastage per vial. Guidance on using Moderna SPIKEVAX® and Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine(s) Vial Tracking Log is provided in **Appendix C**.

Transport into Territory:

Vaccine will be shipped as per the Federal, Provincial, and Territorial processes to either 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:

Vaccine vials must be maintained at a temperature of **-25°C to -15°C** during transport directly from Regional Hubs to the health centre in a community. This can be achieved by transporting the vials in a portable freezer or in a Crêdo Cube. The Cube(s) is returned to the Regional Pharmacy after the vaccine is placed in the freezer or vaccine fridge in the first community and is never used to transport vials to a subsequent community. Pharmacy technicians pack the vaccine in the freezer or Crêdo Cube for transport to communities.

Planning for transport:

- Review the weekly distribution plan to identify the number of vials to be sent to each of the communities so an appropriate number is sent.
- Ensure each health centre has the appropriate storage equipment, ability, and capacity to store vaccine at the necessary temperature at time of transport.
- Communicate clearly with receiving site on exact time of vaccine delivery to ensure their readiness.
- Plug the portable freezer into a power source to bring to appropriate temperature. Freezer Protocol is provided in **Appendix D**.
- If a Crêdo Cube is being used, the pharmacy technician at the regional pharmacy hub will ensure the cool packs are placed into the freezer the night before transport.
- Place the packing materials such as packing peanuts, bubble wrap, blue pads or other materials in the freezer (-25°C to -15°C) the night before for conditioning prior to placing in container around vials.
- Initiate the COVID-19 Vaccine Vial Shipping Log to document transport of vaccine vials.

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**.
- **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 one Community to Another

In some circumstances, vials of vaccine will be transported from a Regional Hub to a community, and then on to another community. Only frozen vaccine can be transported by air; this means that if the first community does not have a freezer to store the vaccine, contact the pharmacy team.

A cooler can only be used to transport vaccine to another community when the vials have been stored in the frozen state in the first community; i.e. at a temperature of **-25°C to -15°C** and are placed into the cooler frozen. **Frozen vaccine transport by air in a cooler is assumed to be thawing upon arrival and should be placed in a vaccine fridge and used within 31 days.**

Planning for transport:

- Pharmacy will review the weekly distribution plan to identify the number of vials to be sent to each of the communities so an appropriate number is sent.
- Pharmacy will work with and oversee Health centre staff to ensure they have the appropriate storage equipment, ability, and capacity to store vaccine at the necessary temperature at time of transport. Pharmacy will communicate clearly with receiving site on exact time of vaccine delivery to ensure their readiness.
- In very rare circumstances a cooler may be used to ship vaccine onwards from a community, but plans are being made to minimize the use of coolers as it is preferable to maintain a temperature of **-25°C to -15°C** throughout transport.
- Prior approval from the pharmacy team to ship the vaccines in a cooler is required.
- If a cooler is being used place the cool packs into the freezer the night before transport.



Additional notes on home visiting guidance:

In some situations, vaccination is provided during a home visit. Please see Appendix B (*Guidance for Vaccination with COVID-19 Vaccines during a Home Visit*) in the SPIKEVAX® Protocol.

For consideration for future revisions to this guidance (evolving evidence and other guidance from other jurisdictions to be monitored):

- Use of portable freezers in community-to-community vaccine transport.
- Situations in which return of thawed vaccine from an administration site to the health centre might be possible
- The use of TempTale or cold chain markers in cooler at vaccination site.



Appendix B: 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 |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |



NU COVID-19 VACCINATION - MANDATORY VACCINE VIAL TRACKING - PFIZER COMIRNATY®

| | |
|--|--|
| Date: | |
| Community: | |
| Mass vaccination clinic Y/N | |
| Date Vaccine arrived in the Community | |
| Freezer available in community Y/N | |
| Freezer Accompanying Vaccinators Y / N | |
| (Held at -15 to -25 degrees until ready for use) | |

Please scan in batches and email form as soon as feasible to RCDC, copying cdclabs@gov.nu.ca, every few hours (no later than same day). More detail on roles noted below. Date sent to RCDC and CDCLabs@gov.nu.ca: _____

Emails
 For Kitikmeot region: fdigout@gov.nu.ca
 For Kivalliq region: kivalliq_covid19@gov.nu.ca
 For Qikiqtaaluk region: covid19_qikiqtaalukrcdc@gov.nu.ca

| | | | | | | | | | |
|--|--|-------------------------------|--|--|--|--|--|--|--|
| LOT# | | ASSIGNED VIAL # | | | | | | | |
| EXPIRY | | Name of Person Signed out to: | | | | | | | |
| | | Name of Person Assigned to**: | | | | | | | |
| Removed from Freezer: | | time (24hr) | | | | | | | |
| Thawed in refrigerator (+2°C to +8°C) (Takes ~3 hours to thaw) Stable for 31 days undiluted | | Y / N | | | | | | | |
| | | start time | | | | | | | |
| | | end time | | | | | | | |
| | | date to discard by (31 days) | | | | | | | |
| Thawed at Room Temperature (+8°C to +25°C) (Takes 30 minutes to thaw) Stable for 2 hours undiluted | | Y / N | | | | | | | |
| | | start time | | | | | | | |
| | | end time | | | | | | | |
| | | time to puncture by (2 hours) | | | | | | | |
| Vial Punctured (Vaccine stable for 6 hours ONLY) | | Y / N | | | | | | | |
| | | start time | | | | | | | |
| | | end time (must discard) | | | | | | | |
| Initials of clients given dose from vial (optional) | | 1 | | | | | | | |
| | | 2 | | | | | | | |
| | | 3 | | | | | | | |
| | | 4 | | | | | | | |
| | | 5 | | | | | | | |
| | | 6 | | | | | | | |
| | | 7 | | | | | | | |
| Doses Used from Vial: (usual 6 per vial) | | Administered | | | | | | | |
| | | Wasted* | | | | | | | |
| | | Wastage code | | | | | | | |
| | | Waste/use comments | | | | | | | |
| Vial used for home visiting | | Y / N | | | | | | | |
| Signature of vaccine floater or clinical lead | | | | | | | | | |

*Note: wasted or discarded refers to all unused doses (timed out, no one left to vaccinate without transporting vial). Important to capture
 ** If same person assigned to for all vials, can draw a line through to the end to indicate this
 Please follow green and red sticker process as outlined by pharmacy team.
 Empty vials-keep and store. Send count of empty vials at end of day. Vials can be discarded when this tracking sheet matched, signed off, and sent to RCDC and CDCLbas@gov.nu.ca

Roles: RCDC to review forms, flag any concerns, and follow up with clinic as appropriate
 Person monitoring CDCLabs will store a copy in a secured folder on shared drive

| Wastage Codes | |
|---------------|----------------------------------|
| AA | Damaged vial/vaccine |
| BB | Refrigerated > 31 days |
| CC | Room Temp > 2 hours |
| DD | Punctured > 6 hours (Cumulative) |
| EE | Not enough in Vial |

Additional Notes / Comments / Observations on storage/transport/use:

Nunavut COVID-19 Mass Immunization Clinic Materials
 Last updated: October 29, 2021

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>.

Age of Consent:

Both the Moderna SPIKEVAX[®] COVID-19 vaccine and the Pfizer-BioNTech COMIRNATY[®] vaccine is authorized for use in those 12 years of age and over. In Nunavut the age of majority, the age at which someone can consent for themselves, is 19 years. Mature minors have the necessary capacity to understand the risks and benefits of immunization. *Mature minor status is always decided on a case-by-case basis and requires a judgment call by the immunization provider. A mature minor can override the medical decisions made by his/her parents and can either give consent or refuse immunizations. (NU Immunization Manual Section 3.2.3).* Please refer to the Immunization Manual for further information regarding considerations around informed consent for mature minors.

Documentation:

The COVID-19 Vaccine Consent Form includes information identifying the client on the front and back of the form. Please ensure that this information is completed on both sides of the form when you are obtaining consent from the client or the parent/guardian. The immunizer documents administration of the vaccine on the back of the form and it is important to have the client's contact information on the same side of the sheet as their signature.

Overview of COVID-19 Infection:

COVID-19 is most commonly spread by an infected person to others through coughing, sneezing, talking, singing or breathing. Someone with COVID-19 may not have any symptoms and not know they have COVID-19, but still be able to infect others.

For most people, symptoms of COVID-19 are similar to other respiratory illnesses like the flu or common cold. A smaller number of people with COVID-19 can develop much more severe symptoms requiring hospitalization and it may result in long term side effects or even death.

Risks and Benefits of Receiving the Vaccine:

Benefits:

The benefit of receiving the vaccine is protection against infection by COVID-19. The Moderna SPIKEVAX[®] and Pfizer-BioNTech COMIRNATY[®] vaccines have been evaluated as being both safe and effective in large studies and has been authorized for use by Health Canada following careful review.

- While there is some protection 14 days after the first dose it is not known how long immunity will last after only one dose which means it is important to come back for the second dose.

Risks:

Risks of receiving the vaccine relate to both common side effects and very rare allergic reactions. As indicated in the information sheet:

The most common reactions that people get after the Moderna and Pfizer-BioNTech vaccines are minor and include:

has improved. Please note, it would be rare for someone who is this sick to be at the vaccination clinic.

Have you had COVID-19? (If yes please indicate when symptoms started below)

You can still receive the vaccine if you've had or think you've had COVID-19 before.

If someone has had COVID-19 it is important to ask when their symptoms started to make sure they are not still infectious. They are no longer infectious 10 days after their symptoms start at which time they can be vaccinated. Vaccination provides additional protection even if someone has had COVID-19.

Are you, or could you be pregnant? (*You will still be offered the vaccine.*)

If someone is, or could be pregnant, they need to know that pregnant people were not included in the initial studies on the Moderna and Pfizer-BioNTech vaccines but there is now international real world data to show that COVID-19 vaccines are safe and effective in pregnancy. These clients should be offered the opportunity to discuss vaccination with a nurse or doctor.

If this is your second or third dose, did you have any side effects after a previous dose? (*If yes, please provide details below.*)

If the client had an anaphylactic reaction to the first dose of the Moderna SPIKEVAX[®] or Pfizer-BioNTech COMIRNATY[®] vaccine they will need to discuss it with the nurse or doctor at the clinic and they should not be offered any additional doses without further consultation from the Office of the Chief Public Health Officer.

Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy)? (*If yes, please provide details below.*)

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. Nunavut currently recommends a 3rd dose be given to individuals with moderate to severe immunosuppression. Please refer to the relevant COVID-19 immunization protocol for inclusion criteria and further guidance.

Have you received a TB test (TST or IGRA) in the past 4 weeks? (*If yes, when was the TB test: Day / Month / Year.*)

A TST or IGRA should not be administered within 28 days of an mRNA COVID-19 vaccine.

There is a theoretical risk that the Moderna 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 (including reading) have been completed.

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.

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

Appendix G COVID-19 Vaccine Protocol

COVID-19 Mass Vaccination Clinic Booking Script

1. *“Hello. I’m calling to offer you (or your child) the COVID-19 vaccine.”*

2. Book appointment as per health centre or mass vaccination clinic processes.
 - Please ensure you have checked both name and date of birth and review spelling on Meditech.
 - Appointments should be booked in Meditech whenever possible.

3. Ask *“Is there anybody else we should book an appointment for right now who also wants to have the vaccine, such as others in your household?”*

4. Book those appointments as per health centre or mass vaccination clinic processes, same as above.

5. Book appointment. Tell the caller ***“I have some information for you about your vaccine”***:
 - ✓ *Your (or your child’s) appointment is on (DATE: _____) at (Time: _____)*
 - ✓ *The vaccination clinic will be located at: (PLACE: _____)*
 - ✓ *Masks are required at the COVID-19 vaccination clinic.*
 - ✓ *If you can, try to only bring people who have an appointment to get a vaccination to the clinic. We are trying to not have crowds at the place of the immunizations.*
 - ✓ *If you have symptoms of COVID-19 (e.g. cough, fever, difficulty breathing) please do not come to the immunization clinic. Call the Health Centre and talk with a nurse.*
 - ✓ *People should wear T-shirts or sleeveless shirts to make it easy to get their vaccine.*

IF PERSON SAYS NO TO VACCINE, YOU COULD SAY: *“We are recommending that all adults and children over 12 get the COVID-19 vaccine. The vaccine is the best protection we have against getting sick from COVID-19. Would you like to talk with a nurse about your concerns with the vaccine?”*

Appendix H COVID-19 Vaccine Protocol

COVID-19 Mass Vaccination Clinic Booking Script

1. *“Hello. I’m calling to offer you (or your child) the COVID-19 vaccine.”*

2. Book appointment as per health centre or mass vaccination clinic processes.
 - Please ensure you have checked **both** name and date of birth and review spelling on Meditech.
 - Appointments should be booked in Meditech whenever possible.

3. Ask *“Is there anybody else we should book an appointment for right now who also wants to have the vaccine, such as others in your household?”*

4. Book those appointments as per health centre or mass vaccination clinic processes, same as above.

5. Confirm that the client will be in the community for both the first and second dose. The second dose happens after 21 days for Pfizer and 28 days for Moderna. Say: **“Will you be in the community in 21 (Pfizer) or 28 (Moderna) days to receive the second dose of the vaccine?”**
 - If yes, proceed to book.
 - If no, then do not book the client for the current clinic. They can be put on a list of clients to be contacted for vaccination at a later date.

6. Book appointment. Tell the caller **“I have some information for you about your vaccine”**:
 - ✓ *Your (or your child’s) appointment is on (DATE: _____) at (Time: _____)*
 - ✓ *The vaccination clinic will be located at: (PLACE: _____)*
 - ✓ *Masks are required at the COVID-19 vaccination clinic.*
 - ✓ *If you can, try to only bring people who have an appointment to get a vaccination to the clinic. We are trying to not have crowds at the place of the immunizations.*
 - ✓ *If you have symptoms of COVID-19 (e.g. cough, fever, difficulty breathing) please do not come to the immunization clinic. Call the Health Centre and talk with a nurse.*
 - ✓ *People should wear T-shirts or sleeveless shirts to make it easy to get their vaccine.*

IF PERSON SAYS NO TO VACCINE, YOU COULD SAY: *“We are recommending that all adults and children over 12 get the COVID-19 vaccine. The vaccine is the best protection we have against getting sick from COVID-19. Would you like to talk with a nurse about your concerns with the vaccine?”*

COVID-19 Vaccine After Care Sheet

What should I do right after receiving the COVID-19 vaccine?

- **Everyone must wait for at least 15 minutes** in the clinic after receiving their vaccine.
- Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy.
- Although they are uncommon, allergic reactions may occur.
- Symptoms of an allergic reaction include:
 - Rash or bumps on the skin that are often very itchy (also called hives);
 - Swelling of the face, tongue or throat;
 - Difficulty breathing.
- Let one of the staff at the clinic know if you or your child feel unwell while waiting.
- If you or your child feel unwell, please do not leave the building.

What should I expect in the next few days?

- Side effects may develop the day after you receive the vaccine and will usually go away on their own a day or two later.
 - Pain, swelling or redness where the needle was given are the most common side effects. A cool, damp cloth or ice pack wrapped in cloth may help.
 - Tiredness, headache, muscle pain, joint pain, nausea, vomiting, chills or fever may occur.
 - Swollen glands in your underarm are another possible side effect.
- If needed, pain or fever medication (such as Tylenol or Advil) may help with pain or fever. Make sure to follow the instructions on the

label and check with your health care provider if you need advice about medication.

- Serious side effects after receiving the vaccine are extremely rare - if you have any concerns about the symptoms you develop after receiving the vaccine, contact the health centre for advice.
- If you develop symptoms including chest pain, chest tightness, or heart palpitations contact your healthcare provider immediately.

Things to remember:

- The COVID-19 vaccines used in Nunavut are 2 or 3-dose vaccines. Ask your healthcare provider when you should return for your second or third dose.
- Continue to follow recommendations to prevent the spread of COVID-19 including careful handwashing, staying at least 2 metres from others, and limiting / avoiding contact with others outside of your household.
- Tell the person providing the second or third dose if you had any side effects with your first dose.

Vaccin contre la COVID – Fiche de suivi

Que dois-je faire juste après avoir reçu le vaccin contre la COVID-19?

- **Tout le monde doit attendre au moins 15 minutes** dans la clinique après avoir reçu son vaccin.
- Des temps d'attente plus longs, de 30 minutes, peuvent être recommandés si l'on craint une éventuelle allergie au vaccin.
- Bien qu'elles soient peu fréquentes, des réactions allergiques peuvent se produire.
- Les symptômes d'une réaction allergique sont les suivants :
 - Éruption ou bosses sur la peau qui provoquent souvent de fortes démangeaisons (également appelées urticaire);
 - Gonflement du visage, de la langue ou de la gorge;
 - Difficulté à respirer.
- Faites savoir à l'un des membres du personnel de la clinique si vous ou votre enfant ne vous sentez pas bien pendant l'attente.
- Si vous ou votre enfant ne vous sentez pas bien, veuillez ne pas quitter le bâtiment.

À quoi dois-je m'attendre dans les prochains jours?

- Les effets secondaires peuvent apparaître le lendemain de la vaccination et disparaissent généralement d'eux-mêmes un jour ou deux plus tard.

○

- Des douleurs, des gonflements ou des rougeurs à l'endroit où l'aiguille a été administrée sont les effets secondaires les plus fréquents. Un chiffon frais et humide ou une poche de glace enveloppée dans un tissu peut aider.
- De la fatigue, des maux de tête, des douleurs musculaires, des douleurs articulaires, des nausées, des vomissements, des frissons ou de la fièvre peuvent survenir.
- Le gonflement des glandes sous les aisselles est un autre effet secondaire possible.
- Si nécessaire, des médicaments contre la douleur ou la fièvre (tels que Tylenol ou Advil) peuvent aider à soulager la douleur ou la fièvre. Veillez à suivre les instructions figurant sur l'étiquette et consultez votre prestataire de soins de santé si vous avez besoin de conseils sur les médicaments.
- Des effets secondaires graves après avoir reçu le vaccin sont extrêmement rares. Si vous avez des inquiétudes concernant les symptômes que vous présentez après avoir reçu le vaccin, contactez le centre de santé pour obtenir des conseils.
- Si vous présentez des symptômes comme des douleurs thoraciques, une oppression thoracique ou des palpitations cardiaques, communiquez immédiatement avec votre fournisseur de soins de santé.

Vaccin contre la COVID – Fiche de suivi

Ce qu'il faut retenir :

- Les vaccins contre la COVID-19 utilisés au Nunavut sont des vaccins à deux ou trois doses. Renseignez-vous auprès de votre prestataire de soins pour connaître la date à laquelle vous devez revenir pour recevoir votre deuxième ou troisième dose.
- Continuez à suivre les recommandations visant à prévenir la propagation de la COVID-19, notamment en vous lavant soigneusement les mains, en vous tenant à au moins 2 mètres des autres et en limitant/évitant tout contact avec des personnes extérieures à votre foyer.
- Informez la personne qui vous a administré la deuxième ou troisième dose si vous avez eu des effets secondaires lors de la première dose.

COVID-19 Qalagjuarnikkut Kapuutimin –

Hulijukhauvinga kapurhiqtauhiruma uuminnga COVID-19 qalagjuarnikkut kapuutimik?

- **Tamaita utaqqijukhat ikinikhaanun 15nik minitsinik** munarhitkunni kapurhiruirumik.
- Takitqijat utaqqivighat imaatun 30nik minitsinik pitqujauttaaqun ihumaaluutiqaqqat piniaqtaarungnarhijunik kapuutimin nakuuhirutinik (allergy) kinamun.
- Piqattajuitkaluarhutik, kapuutimin nakuuhirutit qanurilidjutit (allergic) pitaaqtun.
- Naunaitkutit qanurilidjutini nakuuhirnikkut (allergic) ilaaqtun:
 - Aupadjangniq puvinniilluunniit uviningmi kukulaqiqpiarhimajun (tajjauvaktullu hives-nik)
 - Puvinniq akuliami, uqarmi iggiarmiluunniit;
 - Ajurhaliruvit anirhaaktariami.
- Ilitturipkarlugin havaktiit munarhitkunni nakuuhiruvun nutaralluunniit utaqqitillutin.
- Nakuuhiruvun nutaralluunniit, qimaktailugu munarhitkut.

Hunat niriuktakhatka tikittukhani ikittuni ubluni?

- Kapuutimin hulaqutit pitaaqtun aqagunguqqat kapuqtauhimavingnirnin tammainnaqpaktullu ingmingnik atauhirmi malruungniluunniit ubluni.
 - Ulurianarniq, puvinniq aupadjangniqluunniit kapijauvingmi pillualiqpaktun hulaqutit. Niglaumajuq, qinipajuq allarun unaluunniit hiku

puuqtauhimauuq allarutimi ikajuutijaaqtun.

- Unaguhungniq, niaqurliurniq, nukiinni ulurianarniq, ipiringnirniinni ulurianarniq, mirianguniq, miriarniq, qaalin'nguhungniq kidjangniqluunniit pitaaqtun.
- Puvihimajun qinirhinat unirhukni pijaaqturlu hulaquti.
- Ihariagigungni, ulurianarnirun kidjangnirnulluunniit havautit (imaatun Tylenol unaluunniit Advil) ikajuutauttaaqun ulugiarnarnirun kidjangnarnulluunniit. Maliklugin maliqujaujun titiraani uqaqatigilugulu munarhi uqaujijaujumaguvun havautikkut.
- Qajangnaqtut hulaqutit kinguagun kapurhirmirmin pilluajuitpiaqtun - qujaginnaq ihumaaluutiqaruvin ukunani naunaitkutinik piliqtunik kinguagun kapurhirmirnin, hivajadjevan Munarhitkut uqaudjutikhanun.
- Piqarluuvun naunaitkutinik ilaujullu hatqarmi uluhianarhijumik, hatqarmi hukahimalnirmik, uummatilluunniit hajulaqikpat uqaqatigijakhat munarhitkut qilamik.

COVID-19 Qalagjuarnikkut Kapuutimin –

Hunat itqaumajakhat:

- Ukuat COVID-19 qalagjuarnirmun kapurutit atuqtaujun Nunavunmi hapkuangujun malruuk (2) pingahulluunniit-havauhikkut (3) kapurutit. Apirilugu munarhigijat qakugu utiqtukhauguvin pijaami tuklirnik pingahuanikluunniit kapurhirutikharnik.
- Maliqqahimmaarlugin pitqujauhijun hiamitiqtailinikkut COVID-19 Qalagjuarnirmik ilaujullu algangnik-uaqtiarnirnik, ahiqpaniinnirniklu 2 miitanik aallanin, kikliqaqtirniq / akturuirugillu aallat iglumiutaqatigingitatin.
- Unniutilugu inuk kapihinarhimajuq tukliqmik pingahuanikluunniit kapuutikhamik pihimavakkuvun qujaginnanik qanuqtun hulaqutinik talvanna hivulliqpaarnin kapuqtauhimavingnin.



Moderna SPIKEVAX[®] COVID-19 Vaccine Consent Form

Please fill in or put label:

Last Name _____

First Name _____

Community _____

DOB (dd/mm/yyyy) _____

Please ensure name, community, and date of birth are completed above.

Health card number (if known): _____ House number (optional): _____

Phone number: _____ Email address (optional): _____

Gender: Man Woman Prefer to self-describe _____ Age: _____

Parent/guardian information

Name: _____ Phone: _____

For the person receiving the vaccine, please answer:

Is this your first, second or third dose of the Moderna vaccine? 1st 2nd 3rd Booster
 ***3rd dose only available for individuals with moderate - severe immunocompromise. For eligibility criteria, please see Nunavut Moderna SPIKEVAX[®] protocol.

If second, third or booster dose, what date was your previous? _____ *dd / Month / yyyy*

| | Yes | No |
|---|--------------------------|--------------------------|
| 1. Do you feel sick with a fever today? (If yes, please provide details below) | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Have you or your child had COVID-19? (If yes, please indicate when symptoms started below) <i>You can still receive the vaccine if you've had or think you've had COVID-19 before.</i> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Are you, or could you be pregnant? (You will still be offered the vaccine.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. If this is your second, third or booster dose, did you have any side effects after any previous doses? (If yes, please provide details below.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Do you have any problems with your immune system or are you taking any medications that can affect your immune system (e.g., high dose steroids, chemotherapy)? (If yes, please provide details below.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Do you have a bleeding disorder or are you taking any medications that could affect blood clotting? (If yes, please provide details below.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Have you have had a serious reaction to a vaccine in the past? (If yes, please provide details below.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are you allergic to polyethylene glycol (PEG)** which is an ingredient in the vaccine? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Have you ever had a severe allergic reaction for which you were prescribed an EpiPen? (If yes, please provide details below.) | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Have you ever been diagnosed with myocarditis or pericarditis**** following administration of a COVID-19 vaccine? (If yes, please do not proceed with vaccination today). | <input type="checkbox"/> | <input type="checkbox"/> |

** Polyethylene glycol (PEG) can rarely cause allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution.

**** Very rare cases of myocarditis and pericarditis following vaccination with mRNA vaccines have been reported. Short-term data suggest that it is self-resolving in patients and the decision to continue a COVID-19 vaccine with history of myocarditis or pericarditis should be made by the office of the Chief Public Health Officer.



**Moderna
SPIKEVAX®
COVID-19 Vaccine
Consent Form**

Please fill in or put label:
Last Name _____
First Name _____
Community _____
DOB (dd/mm/yyyy) _____

Comments from questions above:

CONSENT FOR Moderna COVID-19 Vaccine:

For additional information about mature minors please refer to Appendix C and Section 3.2.3 of the Nunavut Immunization Manual.

- I understand the information in the Information Sheet on the Moderna COVID-19 Vaccine.
- I understand the benefits and possible reactions for the Moderna COVID-19 Vaccine and the risk of not getting immunized.
- I have had the opportunity to ask questions and to have them answered to my satisfaction.
- I consent to Moderna being given to: My Child, My Ward or Myself

Print Name

Signature of Client or Parent/Legal Guardian **Date (dd/mm/yyyy)**

Additional questions to help understand the populations receiving the vaccine

| Risk Group <i>Tick all that apply</i> | Yes | No |
|---|--------------------------|--------------------------|
| Living in an Elders' facility | <input type="checkbox"/> | <input type="checkbox"/> |
| Working in an Elders' facility | <input type="checkbox"/> | <input type="checkbox"/> |
| Healthcare worker | <input type="checkbox"/> | <input type="checkbox"/> |
| Living in a shelter | <input type="checkbox"/> | <input type="checkbox"/> |
| Living in a correctional facility | <input type="checkbox"/> | <input type="checkbox"/> |
| Working in a shelter or correctional facility | <input type="checkbox"/> | <input type="checkbox"/> |
| 55 years of age or older | <input type="checkbox"/> | <input type="checkbox"/> |
| Resident of Nunavut who is a rotational worker (e.g. in mines) | <input type="checkbox"/> | <input type="checkbox"/> |
| Underlying medical condition <i>If yes, circle all those that apply in the list the below</i> | | |
| heart disease lung disease cancer | <input type="checkbox"/> | <input type="checkbox"/> |
| high blood pressure diabetes problems with your immune system | | |
| kidney disease liver disease taking medication that affects immune system | | |

Information Sheet

SPIKEVAX® COVID-19 Vaccine (mRNA-1273 SARS-CoV-2 vaccine)

Please read this information sheet carefully and ensure you have a chance to ask a healthcare provider your questions before receiving the vaccine.

If you have symptoms of COVID-19, please don't come into the clinic and call the hotline (1-888-975-8601) to see if you need testing

What is COVID 19?

COVID-19 is an illness caused by a coronavirus, a type of virus. COVID-19 was first identified in late 2019 and declared a global pandemic in early 2020.

COVID-19 is most commonly spread by an infected person to others through coughing, sneezing, talking, singing or breathing. Someone with COVID-19 may not have any symptoms and not know they have COVID-19, but still be able to infect others.

For most people, symptoms of COVID-19 are similar to other respiratory illnesses like the flu or common cold. A smaller number of people with COVID-19 can develop much more severe symptoms requiring hospitalization and it may result in long term side effects or even death.

Who should get the Moderna SPIKEVAX® vaccine against COVID 19?

The Moderna SPIKEVAX® vaccine is free and available to all Nunavummiut age 12 and over. It is up to you whether you decide to get the vaccine. **It is important to know that you cannot get COVID-19 infection from the vaccine.**

The Moderna SPIKEVAX® vaccine causes our body to produce protection against infection from COVID-19. It is a new type of vaccine that uses messenger RNA (mRNA) to help our body make protective antibodies against the virus.

Studies have shown that 14 days after the second dose of the vaccine 94% of adults developed protection against COVID-19. While there is good protection 14 days after the first dose, the second dose assures long term protection. Even adults who had, or think they might have had, COVID-19 will be offered the vaccine as it will provide additional protection.

Can children be vaccinated?

The Moderna SPIKEVAX® vaccine is only authorized for use in people aged 12 years and older. Younger age groups are likely to have vaccines available in the near future.

You might not be vaccinated today if:

- You have been told you are allergic to one of the components of the vaccine
- You had a serious allergic reaction to your first dose of COVID-19 vaccine (including an instance of myocarditis).

If you are pregnant:

- You will have the opportunity to discuss vaccination with a nurse or doctor. **It is up to you whether or not you are vaccinated.**
- Moderna SPIKEVAX® vaccine is safe and effective for pregnant people.

How safe is the Moderna vaccine?

Canada has one of the most rigorous vaccine approval systems in the world. During vaccine development, studies provide information on the safety of a vaccine as well as how effective it is in developing immunity.

What are the side effects of the Moderna SPIKEVAX® vaccine?

The most common side effects that people get after the Moderna SPIKEVAX® vaccine are minor and include:

- Pain, redness or swelling where the needle was given
- Fatigue, headache, muscle pain, joint pain, nausea/vomiting, fever and chills
- Swelling and tenderness in the underarm of the vaccinated arm

All of these side effects usually disappear within 1-3 days without treatment. If they do not go away, call the health centre.

Serious side effects such as an extreme allergic reaction are very rare. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. The clinic staff are prepared to manage an allergic reaction should it occur and will provide immediate medical care if you develop any of these symptoms.

Fiche d'information

Vaccin SPIKEVAX® contre la COVID-19 (vaccin ARNm-1273 contre le SRAS-CoV-2)

Veillez lire attentivement cette fiche d'information et vous assurer de pouvoir poser vos questions à un professionnel de la santé avant de recevoir le vaccin.

Qu'est-ce que la COVID-19?

La COVID-19 est une maladie causée par un coronavirus, un type de virus. La COVID-19 a été détectée pour la première fois à la fin de 2019 et déclarée une pandémie mondiale au début de 2020.

La COVID-19 se transmet le plus souvent par une personne infectée à d'autres personnes en toussant, en éternuant, en parlant, en chantant ou en respirant. Une personne atteinte de la COVID-19 peut ne présenter aucun symptôme et ne pas savoir qu'elle en est atteinte, mais être tout de même capable d'infecter d'autres personnes.

Pour la plupart des gens, les symptômes associés à la COVID-19 sont similaires à ceux d'autres maladies respiratoires comme la grippe ou le rhume. Un plus petit nombre de personnes atteintes de la COVID-19 peut développer des symptômes beaucoup plus graves nécessitant une hospitalisation et cela peut entraîner des effets secondaires à long terme, voire la mort.

Qui devrait recevoir le vaccin Moderna SPIKEVAX® contre la COVID 19?

Le vaccin de Moderna SPIKEVAX® est gratuit et disponible pour tous les Nunavummiit âgés de 12 ans et plus. C'est à vous de décider si vous voulez vous faire vacciner. **Il est important de savoir que vous ne pouvez pas être infecté par la COVID-19 à cause du vaccin.**

Le vaccin de Moderna SPIKEVAX® incite notre corps à produire une protection contre l'infection par la COVID-19. Il s'agit d'un nouveau type de vaccin qui utilise l'ARN messenger (ARNm) pour aider notre corps à fabriquer des anticorps protecteurs contre le virus.

Des études ont démontré que 14 jours après la deuxième dose du vaccin, 94 % des adultes ont développé une protection contre la COVID-19. Bien que la protection soit bonne 14 jours après la première dose, la deuxième dose assure une protection à long terme. Même les adultes qui ont eu, ou pensent avoir eu, la COVID-19 se verront offrir le vaccin, car il leur apportera une protection supplémentaire.

Si vous présentez des symptômes de COVID-19, ne vous présentez pas à la clinique. Appelez la ligne d'assistance téléphonique (1-888-975-8601) pour savoir si vous devez subir un test.

Les enfants peuvent-ils être vaccinés?

Le vaccin de Moderna SPIKEVAX® n'est autorisé que pour les personnes âgées de 12 ans et plus. Il est probable que des vaccins soient bientôt offerts aux tranches d'âge plus jeunes.

Vous pourriez ne pas être vacciné aujourd'hui si :

- On vous a informé que vous êtes allergique à l'un des composants du vaccin
- Vous avez eu une réaction allergique grave à votre première dose de vaccin contre la COVID-19 (y compris un cas de myocardite).

Si vous êtes enceinte :

- Vous aurez l'occasion de discuter de la vaccination avec une infirmière ou un médecin. **C'est à vous de décider si vous voulez être vaccinée ou non.**
- Le vaccin Moderna SPIKEVAX® est sûr et efficace pour les femmes enceintes.

Le vaccin de Moderna est-il sûr?

Le Canada possède l'un des systèmes d'approbation des vaccins les plus rigoureux au monde. Lors du développement d'un vaccin, les études fournissent des informations sur la sécurité d'un vaccin, ainsi que sur son efficacité à créer une immunité.

Quels sont les effets secondaires du vaccin de Moderna SPIKEVAX®?

Les effets secondaires les plus courants observés après l'administration du vaccin Moderna SPIKEVAX® sont mineurs et incluent notamment les suivants :

- Douleur, rougeur ou gonflement à l'endroit où l'aiguille a été administrée
- Fatigue, maux de tête, douleurs musculaires, douleurs articulaires, nausées/vomissements, fièvre et frissons
- Gonflement et sensibilité à l'aisselle du bras vacciné

Fiche d'information

Tous ces effets secondaires disparaissent généralement en 1 à 3 jours sans traitement. S'ils ne disparaissent pas, appelez le centre de santé.

Les effets secondaires graves tels qu'une réaction allergique extrême sont très rares. Les symptômes d'une réaction allergique comprennent l'urticaire (bosses sur la peau qui provoquent souvent de fortes démangeaisons), le gonflement du visage, de la langue ou de la gorge, ou des difficultés à respirer. Le personnel de la clinique est préparé à gérer une réaction allergique si elle se produit et vous fournira des soins médicaux immédiats si vous développez l'un de ces symptômes.

Ilitturipkaidjuti Titiraq

SPIKEVAX® COVID-19 Kapurhiruti (mRNA-1273 SARS-CoV-2 vaccine)

Taiguttiarlugu una ilitturipkaidjutikkut titiraq pilutillu apirhugiami munarhimik apirhuutingnik hivuagun kapurhiqtautinnatin.

Hunauva COVID-19 qalagjuarniq?

COVID-19 Qalagjuarniq aannialaqtuujug uumanga coronavirus-min, qanurittuq aannialaqidjuti. COVID-19 Qalagjuarniq hivulliqpaakkut ilitturijaujuq nunguligtumi 2019 uqaqtajuq nunarjuami aannialaqidjutiujug atulihaaliqtumi 2020.

COVID-19 Qalagjuarniq hiamiinnaqtuq aannialaqihimajumin inungmin aallanun qalakhurnikkut, tagjurnikkut, uqarnikkut, huqullaarnikkut anirhaaktarnikkulluunniit. Kinali piquaqtuq COVID-19 Qalagjuarnirmik ilaani piqalimaittuq nauniatkutitik ilihimangillutiklu COVID-19 Qalagjuarnirmik pihimajun, huli kihimi aannialaqipkaijaqtun aallanik.

Amigaitqijaujunun inungnun, naunaitkutit COVID-19 Qalagjuarnirmik aajjikkiiqnaqtun aallanun anirhaaktarnikkut aannialaqidjutinun imaqtun qalangnirmun (flu) qalalaqinirmulluunniit. Ikitqijaujun amigainninginnik inungni pihimajun COVID-19 Qalagjuarnirmik pijaaqtun ingattaumajunik qajangnaqtunik naunaitkutitik aanniarvingmungaqtitaqutituklu pidjutittaqtuq hivituniquaqtumik hulaqtunik imaaluunniit tuqudjutitikkut.

Kitkut pijakhaa una Moderna SPIKEVAX® kapuuti ikajuutikhamik COVID 19 qalagjuarnirmik?

Una Moderna SPIKEVAX® akiittuq hailihimajuq tamainnun Nunavunmiunnun ukiulgit 12nik avatqumajuniklu. Ilvin ihumangnik kapurhiqtaujumaguvin. **Anginiquaqtuq ilihimalutin pilimaittutin COVID-19 Qalagjuarnirmik kapuutimin.**

Una Moderna SPIKEVAX® kapuuti pipkaqtivaktaa timikput piliuqtipkarhugu hapummidjutikhanik aanniaqarnaittuliqinirmut COVID-19 Qalagjuarnirmik. Nutaangujuq kapuutikhaq atuqpaqtuq naunaipkaidjutitik RNA (mRNA) ikajuqhugu timikput piliurnikkut hapummidjutikkut aannialaqingidjutikhanik (antibodies) aannialaqidjutimin.

Qaujiharutit ilitturipkaijun taimaatun 14 ubluit qaangirutainni kinguagun tukliup kapuqtauninganin 94% inirniit piliurhimajun hapummidjutikhanik COVID-19 Qalagjuarnirmun. Piqaraluaqtillu nakuujunik

Piqaruvin naunaitkutitik COVID-19 Qalagjuarnikkut, munarhiliaruiqlutin hivajadjevan akiittuq-hivajauti (1-888-975-8601) naunaijariami ihivriutaqtaulitukhauguvin

hapummidjutikhanik 14ni ubluni kinguagun hivulliqpaamin kapurhirmirmin, tukliq kapurhirmiq

pipkaijuq aturaakpaktakhami hapummidjutitik. Taapkuallu inirniit pihimavaktun, ihumagijulluunniit pihimavagunarnarhijun, COVID-19 Qalagjuarnirmik apirijauniaqtun pijumajaamingnik kapuutimik taimaatun tunijaamana ikajuutikhanik aannialaqitaidjutikhanik.

Nutaqqat havauhiqtuutikkut kapurhiqtautaaqqat?

Una Moderna SPIKEVAX® kapuuti angiqtauhimajuq taapkunungainnarnun aturiami inungnun ukiulgit 12nik avatqumajuniklu. Ukiuqqukitqiat pighaqarniarungnarhijun kapuutikhanik hailihimajunik qakugunnuaq hivunikhani.

Kapurhiqtaulimaittungnarhivutin ublumi taimaatun:

- Unniutijauhijutit nakuuhuiqpatutin (allergic) atauhirmun ilagijaujunun kapuutimi
- Pivaktutin qajangnaqtumik nakuuhirnimik qanuriliplutin talvunga hivulliqpaami havauhiqtuutikkut COVID-19 Qalagjuarnikkut kapuutimin (ilaujuq pidjutaanik puvinnirmi uumatimi (myocarditis)).

Hingaihimaguvin:

- Uqautiqatiginiaqtun kapuutikhakkut munarhimun taaktimulluunniit. **Ilvin ihumangnun kapurhiqtaujumaguvin kapurhiqtaungitkuvilluunniit.**
- Moderna SPIKEVAX® kapuuti qajangnaittuq nakuujuq hingaun.

Qanuraaluktun qajangnaitpa Moderna kapuuti?

Kanada pihimajuq naunaijaqparhimajunik havauhiqtuutikkut kapuutikhanik angirutikhanik qanuriliurutinun nunarjuarmi. Talvani kapuutikhakkut pivallialurutin, qaujiharutin tunijun ilitturipkaidjutitik qajangnaitjutaani kapuutikhanik taimaalu qanuqtun nakuudjutiganun piliurnikkut aannialaqitaidjutikhakkut.



Ilitturipkaidjuti Titiraq

Hunauvan hulaqutit uumani Moderna SPIKEVAX® kapuutimi?

Pilluaqtauvaktun hulaqutit inuit pivaktait kinguagun Moderna SPIKEVAX® kapurhirmimi mikijun ilaujullu:

- Uluriahungniq, aupadjangniq puvinnirluunniit kapuqtaunirmi
- Unaguhungniq, niaqurliurniq, nukiinni ulurianarniq, ipiringnirmiinni ulurianarniq, mirianguniq/miriarniq, kidjangniq qaaliruhungniqlu
- Puvinniq ulurianarniqlu unitquqmi kapijauhijumajumi talirmi

Tamaita hapkuat hulaqutit tammaqpaktun iluani 1-3 ubluni havautituqhimaittumik. Tammalimaiqqata, hivajadjavatin munarhitkut.

Qajangnaqtun hulaqutit imaatun ingattaqpiarhimajunik nakuuhuirmimik qanuriliplutin pilluajuttun.

Naunaitkutin nakuuhuirmikkut qanuriliplutin ilaqaqtun hives-nik (puviniit uviningmi kukulaqihimajun), puvinniq akuliangni, uqarni iggiarniluunniit, ajurnarhijuqluunniit anirhaaktariami. Munarhitkunni havaktiit upalungaiqhimajun havagutigijaamik nakuuhuirmikkut qanurilidjutin timimun ihuirutinut pikpat tuniniaqtullu tadjainnaq havauhiqtuutikkut ikajuutikhanik piqaliruvinniq qujaginnamik hapkuninnga naunaitkutininik.

COVID-19 Booster Vaccine Doses

Please read this information sheet carefully and ensure you have a chance to ask a health care provider your questions before receiving the vaccine.

Why the need for booster doses?

To date, COVID-19 vaccines have been shown to maintain high vaccine effectiveness against serious illness, hospitalization, and death from COVID-19 in most populations. However, evidence is emerging that vaccine effectiveness against asymptomatic infection and mild COVID-19 disease may decrease with time, and that currently authorized COVID-19 vaccines may be less effective against the highly transmissible Delta variant (B.1.617.2).

A decrease in effectiveness could contribute to increased spread of infection. Therefore, an additional or booster dose may be needed to ensure adequate protection in some populations.

When should a booster dose be given?

Evidence from clinical trials suggests that booster doses of mRNA vaccines should be given six months after the primary series to provide additional protection from COVID-19. This means six months from your second dose of an mRNA vaccine.

What is the difference between a booster dose and an additional dose in a primary series (i.e. for those immunocompromised)?

For most people, 2 doses of an authorized COVID-19 vaccine (i.e. Moderna SPIKEVAX® or Pfizer BioNTech COMIRNATY®) is sufficient to complete a primary vaccine series. Real world evidence suggests that compared to the general population, individuals who are moderately to severely immunocompromised have lower immune responses to COVID-19 vaccines. Therefore, these individuals are immunized with a primary series of three doses of either Moderna SPIKEVAX® or Pfizer BioNTech COMIRNATY®.

The purpose of a booster dose is to restore protection that may have decreased over time to a level that is no longer deemed sufficient in individuals who initially responded adequately to a complete primary vaccine series.

At present time, who should be offered booster doses in Nunavut?

In Nunavut at present time, all eligible individuals over the age of 12 can receive a booster dose of either Moderna SPIKEVAX® or Pfizer BioNTech COMIRNATY®. Please talk to your health care provider if you have any questions about eligibility.

Do I need to receive the same mRNA vaccine as my booster dose?

It has been recommended that either Moderna SPIKEVAX® or Pfizer BioNTech COMIRNATY® can be offered as a booster dose, regardless of which vaccine was given in the primary series.

Will COVID-19 vaccines become an annual immunization similarly to influenza vaccine?

It can take years of post-market use to determine the optimal intervals and dose number needed for a complete primary series to sustain long-term protection. Over time, it may be learned that a short 2-dose (or 3-dose for immunocompromised) primary series, with a booster of at least 6 months after the second dose, can result in durable protection. Evidence on this subject is evolving.

Will the booster dose become a requirement to travel without isolating?

At this time, there are no plans to make this a requirement for territorial rules.