

# Immunization Protocol for Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine

As of September 16, 2021, the Pfizer-BioNTech COMIRNATY® 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 9, 2020 for adults 18 years of age and older, and on May 5, 2021 for adolescents 12-17 years of age.

The change in name reflected in this protocol from Pfizer-BioNTech to Pfizer-BioNTech COMIRNATY® 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 Moderna SPIKEVAX® 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. Please also be advised that a different formulation of BioNTech COVID-19 vaccine exists for ages 5-11 with a separate protocol from the one presented here.

<b>Purpose</b>	To provide information and guidance for the COVID-19 Immunization Program in Nunavut.
<b>Objective</b>	To reduce severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
<b>Indication</b>	Active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals aged 12 years of age and older. <sup>1</sup>  Data on the efficacy of the Pfizer-BioNTech COMIRNATY® COVID-19 vaccine against emerging variants of concern is evolving. <sup>2</sup>
<b>Eligibility</b>	Individuals aged 12 years of age and older without contraindications to the vaccine.
<b>Product</b>	Pfizer BioNTech COMIRNATY® COVID-19 Vaccine (BNT162b2-mRNA SARS-CoV-2 vaccine).
<b>Vaccine type</b>	30 mcg of SARS-CoV-2 spike protein mRNA (for more information 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. <sup>2</sup>
<b>Vaccine components</b>	<i>Medicinal ingredients:</i> messenger ribonucleic acid (mRNA)  <i>Non-medicinal ingredients:</i> ALC-0315 - ((4-hydroxybutyl) azanediy)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 - 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3- phosphocholine, cholesterol, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, potassium chloride, sodium chloride, sucrose, water for injection.
<b>Formats available</b>	Multiple-dose vials (up to 6 doses) preservative-free frozen suspension. Dilution is required. <sup>1</sup>  <u>Pfizer-BioNTech COMIRNATY® COVID-19 multiple dose vials have purple caps which distinguishes them from other formulations and manufacturers.</u>  After dilution each vial contains up to 6 doses of 0.3 mL using low-dead volume syringes and/or needles; only five doses may be available if a standard syringe and

	<p>needle are used. The packaging on the vial indicates 5 doses are available but it is acceptable to withdraw 6 doses from a single vial.</p>
<b>Manufacturer</b>	<p>Pfizer-BioNTech COVID-19 Vaccine</p> <p>BioNTech Manufacturing GmbH An der Goldgrube 12 Mainz, Rhineland-Palatinate, Germany 55131</p>
<b>Thawing Prior to Dilution</b>	<p>Record the time removed from the freezer on the Pfizer <i>Mandatory Vial Tracking Form</i>.</p> <p>Prior to dilution minimize exposure to room light and avoid exposure to sunlight and ultraviolet light.</p> <p><b>Prior to Dilution:</b> The Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine multiple dose vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative.</p> <p>Vials can be stored ultra-frozen (-80°C to -60 °C) until expiry date printed on the label provided cold chain is maintained.</p> <p>Vials can be stored frozen (-25 °C to -15 °C) for 14 days.</p> <p>Thaw vial(s) of COMIRNATY® before use either by:</p> <ol style="list-style-type: none"> <li>1. Allowing vial(s) to thaw in the refrigerator (2°C to 8°C). A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month (31 days).</li> <li>2. Allowing vial(s) to sit at room temperature (up to 25°C) for 30 minutes.</li> </ol> <p>Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature.</p> <p>Before dilution, invert vaccine vial gently 10 times. Do not shake. Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if liquid is discoloured or if other particles are observed.</p>
<b>Dilution</b>	<p>Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. This diluent is not packaged with the vaccine and will be provided separately.</p> <p>Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.</p> <p>Using aseptic technique, withdraw 1.8mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe (21-gauge or narrower needle).</p> <p>Cleanse the vaccine vial stopper with a single-use antiseptic swab.</p> <p>Add 1.8mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.</p>

	<p>Equalize vial pressure before removing the needle from the vial by withdrawing 1.8mL air into the empty diluent syringe.</p> <p>Gently invert the vial containing COMIRNATY® 10 times to mix. Again, do not shake.</p> <p>Inspect the vaccine in the vial.</p> <p>Record the date and time of dilution on the vial label and on the Pfizer <i>Mandatory Vial Tracking Form</i>.</p> <p>Store between 2°C to 25°C.</p> <p>Discard any unused vaccine 6 hours after dilution.</p> <p>After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this protocol regarding the number of doses per vial after dilution supersedes the number of doses stated on the vial labels and cartons. It will often be possible to obtain 6 doses from one vial.</p>
<p><b>Preparation of Individual 0.3mL Doses/Reconstitution</b></p>	<p>Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab and withdraw 0.3mL of COMIRNATY®, preferentially using low dead-volume syringes and/or needles.</p> <p>Each dose must contain 0.3mL of vaccine.</p> <p>If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume.</p> <p>Administer immediately, and no later than 6 hours after dilution.</p>
<p><b>Administration</b></p>	<p><b>This vaccine has special storage and handling requirements. It should be transported frozen (typically ultra-frozen at -80 °C to -60 °C but in certain circumstances frozen at -25 °C to -15 °C) to remain stable. Follow the storage, thawing, and handling instructions in this protocol and from the COVID-19 Vaccine Transport Protocol in Appendix E carefully to ensure the vaccine will be effective.</b></p> <p><b><u>Do not administer the vaccine</u> if the storage and handling guidance above has not been followed.</b></p> <p><b>Please see Appendix 2 for further guidance.</b></p> <p>It is often helpful to use low-dead-volume syringes and/or needles. Irrespective of the type of syringe or needle:</p> <ul style="list-style-type: none"> <li>• Each dose must contain 0.3 mL of vaccine.</li> <li>• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.</li> <li>• Do not pool excess vaccine from multiple vials.</li> <li>• Administer immediately, and no later than 6 hours after dilution.</li> </ul> <p>Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension. During the visual inspection:</p>

	<ul style="list-style-type: none"> <li>• verify the final dosing volume of 0.3 mL.</li> <li>• confirm there are no particulates and that no discolouration is observed.</li> <li>• do not administer if vaccine is discoloured or contains particulate matter.</li> </ul> <p>Administer Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine intramuscularly in the deltoid muscle.</p> <p>Do not inject the vaccine intravascularly, subcutaneously or intradermally.</p>
<b>Dose series</b>	<p><b>Pfizer-BioNTech COMIRNATY® COVID-19 vaccine is administered intramuscularly after dilution as a series of two doses (0.3 mL each) <u>8 weeks</u> apart.</b></p> <p>The interval between dose 1 and dose 2 (8 weeks) has been revised based on emerging evidence regarding improved protection when extended beyond the currently authorized intervals. This guidance supersedes the dose interval recommended in the product monograph.</p> <p>The minimum interval is 19 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).<sup>2</sup></p> <p><b>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).<sup>2</sup></b></p>
<b>Additional dose for immunocompromised</b>	<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. 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.<sup>2</sup></p> <p>Nunavut is adopting this NACI recommendation for its COVID-19 immunization programs. An additional full dose for immunocompromised individuals should be administered a minimum of 4 weeks after the second dose is given.</p> <p>Eligibility criteria for additional dose for immunocompromised patients:</p> <ol style="list-style-type: none"> <li>1. Aged 12 years and older, having received 2 previous doses of mRNA COVID-19 vaccines.</li> </ol>

2. Meet the moderate to severely immunocompromised criteria. An individual will have one of the following (requires verification by clinicians authorized to diagnose and manage medical conditions):
  - a. Active treatment for solid tumour or hematologic malignancies;
  - b. Receipt of solid-organ transplant and taking immunosuppressive therapy;
  - c. Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (with 2 years of transplantation or taking immunosuppression therapy);
  - d. Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome);
  - 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. Please note: other jurisdictions may have a slightly different list of medical conditions to qualify an individual for an additional dose.
2. Meeting the minimal dosing interval requirement (at least 28 days) after receiving a 1 or 2-dose complete primary series.

**Booster Dose**

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.

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<sup>®</sup> or Moderna SPIKEVAX<sup>®</sup>) should be offered a minimum of 6 months after completion of the primary series. Either Pfizer-BioNTech COMIRNATY<sup>®</sup> or Moderna SPIKEVAX<sup>®</sup> can be used as a booster dose, regardless of which mRNA vaccine was used in the primary series.

**The recommended booster dose for Pfizer-BioNTech COMIRNATY<sup>®</sup> is 0.3mL for all recipients (full dose). This differs from Moderna SPIKEVAX<sup>®</sup> booster dose guidance where NACI recommends a half dose (0.25mL) for the general population.**

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.

Please reach out to your RCDC if you have any questions about this guidance.

<p><b>Vaccine interchangeability</b></p>	<p>NACI recommends that, if readily available, the <b>same</b> mRNA COVID-19 vaccine product should be offered for the subsequent dose in a primary 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 <b>should</b> be counted, and the series need not be restarted.<sup>2</sup></p> <p>For mixed COVID-19 vaccine schedules, the minimum interval between doses should be based on the minimum interval of the product used for the first dose (e.g., Pfizer-BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine).<sup>2</sup></p> <p>Please contact your RCDC with any questions regarding vaccine interchangeability.</p>
<p><b>Contraindications</b></p>	<p>Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine is only authorized for use in people aged 12 years and older.</p> <p>Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active substance or to any ingredient in the formulation or packaging of this specific vaccine.<sup>1</sup></p> <p>Rare anaphylactic reactions have been reported following immunization with mRNA COVID-19 vaccines. One Pfizer-BioNTech COMIRNATY® vaccine component that has been identified as potentially resulting in a rare allergic reaction is polyethylene glycol (PEG).<sup>2</sup></p> <p>If the patient has a history of myocarditis or pericarditis secondary to receipt of a COVID-19 vaccine, or a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine consult the Office of the Chief Public Health Officer (CPHO) for guidance before administering any subsequent dose of a COVID-19 vaccine.</p>
<p><b>Precautions and additional notes</b></p>	<p><b><u>Anaphylaxis:</u></b> 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 – <b>an extended period of observation post-vaccination of 30 minutes should be provided.</b><sup>2</sup></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 - <b>an extended period of observation post-vaccination of 30 minutes should be provided.</b><sup>2</sup></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.**<sup>2</sup>

***Myocarditis and pericarditis:*** Very rare cases of myocarditis and pericarditis following vaccination with Pfizer-BioNTech COMIRNATY® COVID-19 vaccine have been reported during post-authorization use. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the onset of symptoms has been within a few days following receipt of Pfizer-BioNTech COMIRNATY® 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 Pfizer-BioNTech COMIRNATY® 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.<sup>1</sup>

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, 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.<sup>2</sup>

***Hematologic-Bleeding:*** 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.<sup>2</sup>

Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.<sup>1</sup>

	<p><b><i>Immune:</i></b> 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 <i>Additional dose for immunocompromised</i> section of protocol.</p> <p><b><i>Syncope:</i></b> 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.</p>
<p><b>Administration of other vaccines, drugs, or biological products</b></p>	<p><b><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></b></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.<sup>2</sup></p> <p>There is a theoretical risk that Pfizer-BioNTech COMIRNATY® 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.<sup>2</sup></p> <p>However, in cases where an opportunity to perform the TST or IGRA test might be missed, <b>the testing should not be delayed since these are theoretical considerations.</b> 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.<sup>2</sup></p> <p>Please refer to additional guidance provided by the Nunavut Tuberculosis Program.</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.<sup>2</sup></p>
<p><b>Special Populations</b></p>	<p><b><i>Individuals previously infected with SARS-CoV-2:</i></b> 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.<sup>2</sup></p>

	<p><b><i>Individuals who have an autoimmune condition:</i></b> (See above section <b><i>Additional dose for immunocompromised</i></b>). People who are immunocompromised and people with autoimmune disease should be vaccinated with COVID-19 vaccines (unless otherwise contraindicated). As for all individuals, mRNA vaccines are the preferred option because of their higher efficacy and because they do not carry a risk of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT). Ideally, the COVID-19 vaccine series should be completed 2 weeks before starting immunosuppressive therapy or when immunosuppressive therapy is the lowest but can be given when needed. This ensures that COVID-19 protection is provided sooner. The immune response may be lower in those who are immunosuppressed. These individuals should continue to follow public health recommendations on preventing infection with SARS-CoV-2 (such as wearing a mask, physical distancing, and hand hygiene) even if they have been vaccinated. Vaccination of their close contacts will also help protect them.<sup>2</sup></p> <p><b><i>Individuals who are pregnant or breastfeeding:</i></b> 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.<sup>2</sup></p>
<p><b>Post-vaccination counselling</b></p>	<p>Prophylactic oral analgesics or antipyretics (e.g., acetaminophen or ibuprofen) should not be routinely used before or at the time of vaccination, but their use is not a contraindication to vaccination. Oral analgesics or antipyretics may be considered for the management of vaccine side effects (e.g., pain or fever, respectively), if they occur after vaccination.<sup>2</sup></p> <p>The After Care Sheet should be given to clients following vaccination.</p>
<p><b>Vaccine Supply and Distribution</b></p>	<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>
<p><b>Storage and transport of frozen vials prior to use</b></p>	<p>Cartons of Pfizer-BioNTech BioNTech COMIRNATY® COVID-19 Vaccine multiple dose vials are shipped from southern Canada in thermal containers with dry ice (i.e. at ultra-frozen or -80°C to -60 °C conditions).</p>

	<p>Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F) until the expiry date printed on the label. Vials may also be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. <b>Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.</b></p> <p>If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine arrives may be used as <u>temporary</u> storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.</p> <p><b><u>Transportation of Frozen Vials</u></b></p> <p>If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Once received, the vaccine should be stored at temperatures of -25°C to -15°C unless otherwise advised by pharmacy and protected from light.</p>
<p><b>Storage of refrigerated, unpunctured and undiluted vials</b></p>	<p>Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 1 month (31 days) prior to first use.</p> <p>Prior to dilution vials can be stored for no more than 2 hours at room temperature.</p> <p><b>Vials must reach room temperature before dilution. Please see guidance above.</b></p>
<p><b>Storage of Punctured and diluted vials</b></p>	<p>After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.</p> <p>Any vaccine remaining in vials must be discarded after 6 hours. After dilution, the vaccine vials can be handled in room light conditions.</p>
<p><b>Consent</b></p>	<p>Consent forms must be reviewed and signed prior to vaccination. Clients with capacity to consent (ie: 18+ and mature minors) will review and sign consent forms at time of vaccination. Clients without capacity to consent (ie: developmental delay, under 12 years of age) will require a parent or legal guardian to provide consent. (For more information: Appendix C Orientation to Obtaining Consent for Administration of COVID19 Vaccines).</p>

<p><b>Anaphylaxis</b></p>	<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: <a href="#">Anaphylaxis: Initial Management in Non-Hospital Settings</a>, in the Canadian Immunization Guide.</p> <p>NACI recommends that in individuals with a history of a severe, immediate (<math>\leq 4</math>h 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><b>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.</b></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>
<p><b>Side Effects</b></p>	<p><b><u>Injection site reactions:</u></b> pain at injection site, tenderness and swelling of the lymph nodes (underarm) in the same arm of the injection, swelling (hardness), and redness.<sup>1</sup></p> <p><b><u>Systemic side effects:</u></b> fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, diarrhea, and fever.<sup>1</sup></p> <p>Adverse reactions in adolescents 12 to 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).<sup>1</sup></p> <p>Adverse reactions in recipients aged 16 and older included pain at the injection site (84.3%), fatigue (64.7%), headache (57.1%), chills (34.7%), muscle pain (40.2%), fever (15.2%), joint pain (25.2%), injection site swelling (11.1%), injection site redness (9.9%), lymphadenopathy (0.4%), and nausea (1.2%).<sup>1</sup></p> <p>There is a remote chance that the Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine could cause a severe allergic reaction or hypersensitivity reaction (e.g., rash, pruritus, urticaria, angioedema). It is important to have each person wait for 15 minutes after receiving their immunization and know how to contact clinic staff if they feel unwell.<sup>2</sup> Please see precautions and additional notes section regarding individuals who require a longer post-immunization observation period.</p>
<p><b>Reportable Adverse Events/Side</b></p>	<p>Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to RCDC. Review section 3.5 Management and Reporting of Adverse Events in the Nunavut Immunization Manual. Appendix D</p>

<b>Effects/Administration Errors</b>	<p>Reporting an Adverse Event Following Immunization provides additional information.</p> <p><b><u>Rare reactions:</u></b> rare reactions that have been reported and confirmed after taking an mRNA vaccine are:</p> <ul style="list-style-type: none"> <li>• Myocarditis and pericarditis</li> <li>• Bell’s palsy (facial paralysis)</li> <li>• Guillain- Barré syndrome</li> <li>• Anaphylaxis</li> </ul> <p>The AEFI form is available here:  <a href="https://www.gov.nu.ca/health/information/immunization/AEFI">Report of adverse events following immunization (AEFI) (canada.ca)</a></p> <p>Section 3.5 of the Immunization Manual is available here:  <a href="https://www.gov.nu.ca/health/information/manuals-guidelines">https://www.gov.nu.ca/health/information/manuals-guidelines</a></p> <p>If an inadvertent vaccine error is found, health care providers in Nunavut should:</p> <ol style="list-style-type: none"> <li>1. Inform the client of the vaccine administration error as soon as possible. <ul style="list-style-type: none"> <li>• Explain the possibility for local or systemic reactions.</li> </ul> </li> <li>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.</li> <li>3. Complete an AEFI form and submit it to the RCDC only if the inadvertent vaccine administration error results in an AEFI.</li> </ol>
<b>Vaccine Coverage and Reporting</b>	<p>Vial tracking forms must be filled out for each vial of Pfizer-BioNTech COMIRNATY® and submitted by e-mail to the Regional Communicable Disease Coordinator and <a href="mailto:CDCLabs@gov.nu.ca">CDCLabs@gov.nu.ca</a>. Please see Appendix E.</p>
<b>Documentation</b>	<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> <p>Follow operational team guidance on processes to track and call back clients for second dose.</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 (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.<sup>1</sup></p>

<b>Vaccinations in the context of COVID-19</b>	<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. For additional information on infection prevention and control please consult: <a href="https://www.gov.nu.ca/sites/default/files/infection_prevention_and_control_resources.pdf">https://www.gov.nu.ca/sites/default/files/infection_prevention_and_control_resources.pdf</a>.</p> <p>A point of care risk assessment is the usual practice for decisions about personal protective equipment. Immunizers should wear 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>
<b>Materials and resources</b>	<p>Nunavut Immunization Manual <a href="https://gov.nu.ca/health/information/manuals-guidelines">https://gov.nu.ca/health/information/manuals-guidelines</a></p> <p>COVID-19 Vaccine Information Sheet, Consent Form, After Care Sheet</p> <p>Nunavut Communicable Disease Manual: COVID-19 Public Health Protocol <a href="https://gov.nu.ca/health/information/manuals-guidelines">https://gov.nu.ca/health/information/manuals-guidelines</a></p> <p>Protocols and materials are available on the Department of Health website (<a href="http://www.gov.nu.ca/health">www.gov.nu.ca/health</a> )</p>
<b>Appendices</b>	<p>Appendix 1 Condition specific criteria and prescribed actions</p> <p>Appendix 2 Thawing, Dilution and Preparation of Dose</p> <p>Vaccine Consent Form</p> <p>Vaccine Information Sheet</p> <p>Vaccine Aftercare Sheet (with translations)</p> <p>Appendix B Guidance for Vaccination with COVID-19 Vaccines - Home Visit</p> <p>Appendix C Orientation to Obtaining Consent for Administration of COVID-19 vaccines</p> <p>Appendix D Reporting an Adverse Event Following Immunization</p> <p>Appendix E COVID-19 Vaccine Transport Protocol</p> <p>Appendix F Vaccine Clinic Screening Questions</p> <p>Appendix G Vaccine Clinic Booking Script</p> <p>Appendix H COVID-19 Booster Vaccine Doses Fact Sheet</p>
<b>References</b>	<p>1. Pfizer-BioNTech COMIRNATY® (2021). Pfizer-BioNTech COMIRNATY® COVID-19 vaccine product monograph.</p>

[https://www.pfizer.ca/sites/default/files/202109/COMIRNATY\\_PM\\_EN\\_252736\\_16-Sep-2021.pdf](https://www.pfizer.ca/sites/default/files/202109/COMIRNATY_PM_EN_252736_16-Sep-2021.pdf) (accessed October 30<sup>th</sup>, 2021).

2. National Advisory Committee on Immunization (2021). *An advisory Committee Statement: Recommendations on the use of COVID-19 Vaccines*.  
<https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/recommendations-use-covid-19-vaccines-en.pdf> (accessed May 28<sup>th</sup>, 2021)
3. Society of Obstetricians and Gynecologists of Canada (2021). *SOGC Statement on COVID-19 Vaccination in Pregnancy. Reaffirmed May 25, 2021*.  
[https://www.sogc.org/common/Uploaded%20files/Latest%20News/SOGC\\_Statement\\_COVID-19\\_Vaccination\\_in\\_Pregnancy.pdf](https://www.sogc.org/common/Uploaded%20files/Latest%20News/SOGC_Statement_COVID-19_Vaccination_in_Pregnancy.pdf) (accessed June 6<sup>th</sup>, 2021).

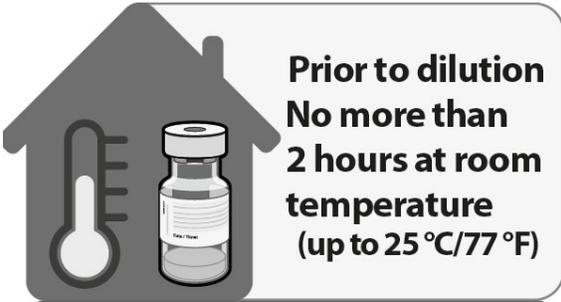
Approved by Dr. Michael Patterson, Chief Public Health Officer, on November 1, 2021. Department of Health, Government of Nunavut

## Appendix 1. Condition-specific criteria and prescribed actions.

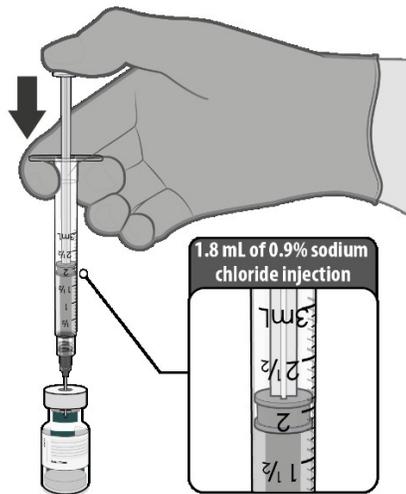
*The criteria listed below include indications, contraindications, and considerations around special populations for implementing the vaccine protocol. However, the criteria must be reviewed and further delineated according to the licensed prescriber's parameters. Additional criteria and prescribed actions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

	<b>Criteria</b>	<b>Prescribed Action</b>
Indications	Client is aged 12-17 years of age	Proceed to vaccinate if meets remaining criteria and consent obtained from individual as mature minor or from parent/guardian as required.
	Client is less than 12 years of age.	Do not vaccinate
Contraindications	Client had a systemic allergic reaction, anaphylaxis, to first dose of COVID-19 vaccine.	Do not vaccinate today and consult the Office of the CPHO/RCDC for further guidance.
	Client has an allergy to polyethylene glycol (PEG) 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 <sup>rd</sup> 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 <sup>rd</sup> dose and submit referral to community MD.

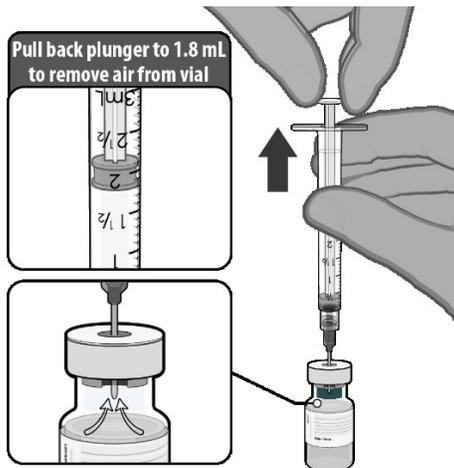
Appendix 2. Thawing, dilution and preparation of dose

<p><b>THAWING PRIOR TO DILUTION</b></p>	
 <p><b>Prior to dilution No more than 2 hours at room temperature (up to 25°C/77°F)</b></p>	<ul style="list-style-type: none"> <li>• Thaw vial(s) of Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine before use either by:               <ul style="list-style-type: none"> <li>○ Allowing vial(s) to thaw in the refrigerator (2°C to 8°C [35°F to 46°F]). A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.</li> <li>○ Allowing vial(s) to sit at room temperature (up to 25°C [77°F]) for 30 minutes.</li> </ul> </li> <li>• Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature.</li> </ul>
 <p><b>Gently x 10</b></p>	<ul style="list-style-type: none"> <li>• Before dilution, invert vaccine vial <b>gently</b> 10 times.</li> <li>• <u>Do not shake.</u></li> <li>• Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain <u>white to off-white opaque amorphous particles</u>.</li> <li>• Do not use if liquid is discoloured or if other particles are observed.</li> </ul>

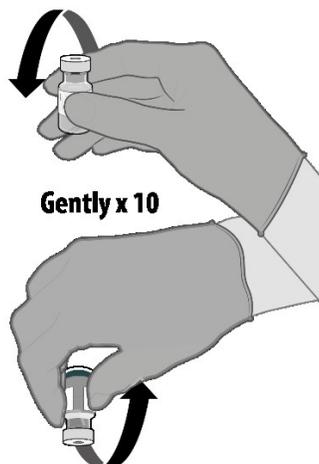
## DILUTION



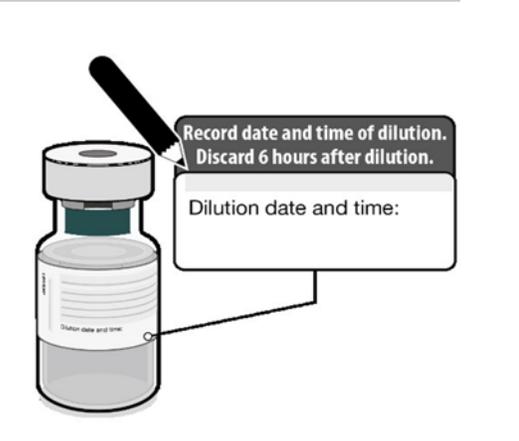
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

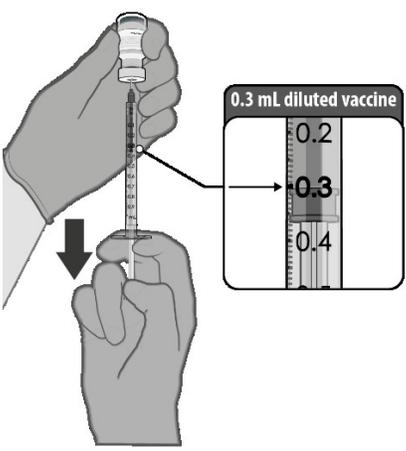


- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.



- **Gently** invert the vial containing the Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.

	<ul style="list-style-type: none"> <li>• Record the date and time of dilution on the Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine vial label.</li> <li>• Store between 2°C to 25°C (35°F to 77°F).</li> <li>• Discard any unused vaccine 6 hours after dilution.</li> </ul>
---	--

<p><b>PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COMIRNATY® COVID-19 VACCINE</b></p>	
	<ul style="list-style-type: none"> <li>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.3 mL</u> of the Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine, preferentially using low dead-volume syringes and/or needles.</li> <li>• Each dose must contain 0.3 mL of vaccine.</li> <li>• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.</li> <li>• Administer immediately, and no later than 6 hours after dilution.</li> <li>• Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction.</li> </ul>

























# Information Sheet

## COMIRNATY® Pfizer-BioNTech COVID-19 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 do not 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 COMIRNATY® Pfizer-BioNTech vaccine against COVID-19?

The COMIRNATY® Pfizer-BioNTech vaccine is free and available to all Nunavummiut over the age of 12. It is up to you whether you decide to get the vaccine for yourself or your child. **It is important to know that you cannot get COVID-19 infection from the vaccine.**

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

Studies have shown that the COMIRNATY® Pfizer-BioNTech vaccine is very effective. It is important to ensure you complete the vaccine series. The final 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 COMIRNATY® Pfizer-BioNTech 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.

### 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.**
- COMIRNATY®Pfizer-BioNTech vaccine is safe and effective for pregnant people.

### How safe is the COMIRNATY® Pfizer-BioNTech 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 COMIRNATY® Pfizer-BioNTech vaccine?

The most common side effects that people get after the COMIRNATY® Pfizer-BioNTech 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. 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.



# 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.
- 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.

## 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.

### 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 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) pittaqaqun.
- Naunaitkutit qanurilidjutini nakuuhirnikkut (allergic) ilaqaqun:
  - 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 pittaqaqun aqagunguqqat kapuqtauhimavingnirnin tammainnaqpaktullu ingmingnik atauhirmi malruungniluunniit ubluni.
  - Ulurianarniq, puvinniq aupadjangniqluunniit kapijauvingmi pillualiqpaktun hulaqutit. Niglaumajuq, qinipajuq allarun unaluunniit hiku

- puuqtauhimauuq allarutimi ikajuutijaaqun.
- Unaguhungniq, niaqurliurniq, nukiinni ulurianarniq, ipiringnirniinni ulurianarniq, mirianguniq, miriarniq, qaalin'nguhungniq kidjangniqluunniit pittaqaqun.
- Puvihimajun qinirhinat unirhukni pijaaqturlu hulaquti.
- Ihariagigungni, ulurianarnirun kidjangnirnulluunniit havautit (imaatun Tylenol unaluunniit Advil) ikajuutauttaaqun ulugiarnarnirun kidjangnirnulluunniit. Maliklugin maliqujaujun titiraani uqaqatigilugulu munarhi uqaqjijaujumaguvun havautikkut.
- Qajangnaqtut hulaqutit kinguagun kapurhirmirmin pilluajuitpiaqun - qujaginnaq ihumaaluutiqaruvin ukunani naunaitkutinik piliqtunik kinguagun kapurhirmirnin, hivajadjevan Munarhitkut uqaqjutikhanun.
- 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 kapurhurutikharnik.
- Maliqqahimmaarlugin pitqujauhimajun hiamitiqtailinikkut COVID-19 Qalagjuarnirmik ilaujullu algangnik-uaqtiarnirnik, ahiqpaniinnirniklu 2 miitanik aallanin, kikliqaqtirniq / akturuirlugillu aallat iglumiutaqatigingitatin.
- Unniutilugu inuk kapihinarhimajuq tukliqmik pingahuanikluunniit kapuutikhamik pihimavakkuvun qujaginnanik qanuqtun hulaqutinik talvanna hivulliqpaarnin kapuqtauhimavingnin.







## 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 more unstable than most other vaccines currently in use and is 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 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.



**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"/> 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 15min 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 min 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 COVID19. 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](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

*COVID-19 Mass Vaccination Clinic Materials  
V3 – November 01, 2021  
Department of Health, Government of Nunavut.  
May be adapted by other jurisdictions with attribution.*



- 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>)







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 SPIKEVAX® and Pfizer-BioNTech COMIRNATY® 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 3<sup>rd</sup> 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 SPIKEVAX® or Pfizer-BioNTech COMIRNATY® 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.





## 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). The national AEFI reporting form has been updated and can be found here: <https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html>

### 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





















### 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.











**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](mailto: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













## 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?”*

# 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.



# COVID-19 Ikayuutighaq Pingahuat Kapuut

Taiguuqulugu una kangiqhidjut titiraq taiguatiaqlugu apiripkaqlutillu apirhuutigharnik munaqhinun kapuqhiqtinatit.

## Huuq ihariagiyat ikayuutighaq kapuqhidjut?

Ublumimun, qalagyuarnirmun COVID-19 kapuutit tautungnaqtut anginirhakkut kapuqhiqhimayut ihuarutigiyat aanniaqtailinirmun aghut, aanniavingmungarnirmun, huinirmunlu qalagyuarnirmun COVID-19 tamavyaini inugiangnirni. Kihimi, naunaiyautit nuivalialiqut kapuutit ihuarnirit mihingnautiqangitut aanniarunmik mikiyuqulug qalagyuarniq COVID-19 aanniarut mighiyuuminaqtuq qakugu, tadjatamna qalagyuarnirmun COVID-19 kapuut mikiyumik ihualuangaqtuq uvanga anginirhaanun hiamitiqtup Delta variantmin (B.1.617.2).

Mighiyuumirutait ihuarnirit pidjutauniaqtut angikliyuumiqtuq hiamitirnira aanniarutit. Taimaali, ilaliutihimayut ikayuutighat kapuutit ihariagiyayut ihuaqtumik aanniaqtailidjutighat ilanginun inugiangnirmun.

## Qakugu ikayuutighakkut kapuutinik kapuqhirniaqqat?

Tautungnaqtut uuktuutini ihumagiyayut tapkua ikayuutighat kapuutit haffuminga mRNAmik kapuqhiqtughat siksini tatqiqhiutini kinguani hivulirmik kapuqhirnirmik tunihyaangini ilaliutihimayunik aanniaqtailidjutighanik qalagyuarnirmun COVID-19. Una naunaiyauta siksini tatqiqhiutini tuglirmik kapuqhirunmik haffuminga mRNA kapuutaanik.

## Hunauva aalaujuta qitqani ikayuutit kapuutit ilaliutihimayuglu kapuqhirut hivuani (imaa tapkua aannialaqitailidjutiqaqtut)?

Tamavyainun inungnun, tugliq kapuqhirut angiqtauhimayumi qalagyuarnirmun COVID-19 kapuutaa (imaa Moderna SPIKEVAX® unaluuniin Pfizer BioNTech COMIRNATY®) naamaktuq initirutaa hivuani kapuutit kapuqhirutait. Nunaquyumi tautungnaqtut ihumagiyayut tapkua aadjiliurutigiblugit inugiangnirit, atautit kitut aanniaqtailidjutiqaqtut aannialaqitaaqtut kiudjutaanun qalagyuarnirup COVID-19 kapuutaanin. Taimaali, hapkua atautit kapuqhiqpaktut pingaiqturlugit haffuminga Moderna SPIKEVAXmik® unaluuniin Pfizer BioNTech COMIRNATY®.

Pidjuta ikayuutighaq kapuut ihuaqhaidjutaayug aanniaqtailinirmun mighiyuumiqtuq qakunguraangat

aktilaanganun hakuiqpaliabluni atautinun kitut kiudjutigiyat ihuaqtumik kapuqhimayunun.

## Tadja, kitut tuniyayughat ikayuutighamik kapuunmik Nunavunmi?

Nunavunmi tadjat, tamaita kapuqhiqtaqtut atautit ukiuqaqtut avatqumayumik tualut kapuqhiqtaqtut ikayuutighanik haffuminga Moderna SPIKEVAXmik® Pfizer BioNTech COMIRNATYmikluuniin®. Uqaqatigilugit munaqhitkut quyaginaq apirhuutighaaruvin kapuqhirnikkut.

## Piyariaqaqai mRNA kapuutaanik ikayuutighamik kapuunmik?

Pitquyayug tapkua Moderna SPIKEVAXmik® Pfizer BioNTech COMIRNATYmikluuniin® kapuqhiqtaqtut ikayuutighamik, kituugaluqtilugu kapuut kapuqhirutit hivuani.

## Qalagyuarnirmun COVID-19 kapuutit ukiutigut kapuqhiqpallirniaqqat fluuqtailinikkut kapuutaanik?

Ukiut amigainiaqtut atungnirit ihumaliurutigilugit auladjutait kapuqhirnikullu qaffiuniit ihariagiyayut inirianganu hivuanin pihimalugu hivituyumik-aanniaqtailidjut. Qakugunguqqat, ilituriyauniaqtuq tapkua naituq malruk-kapuqhirutik (unaluuniin pingahuuyut aannialaqitailidjutiqaqtut) hivuani, ikayuutikkut kapuqhiutit imaa siksini tatqiqhiutini kinguani tuglirup kapuqhirutit, pidjutauniaqtuq aanniaqtailinirmun. Tautungnarnirit haffumunga aulahimaaqtut.

## Ukua ikayuutit kapuqhirutit piyariaqarniaqqat tingmitinani avaliingaaqitauhimaitumik?

Tadja, upalungaiyautiqangitug una piyariarutaanun aviktuqhimayumi maligahanun.



# Dose de rappel d'un vaccin contre la COVID-19

Veillez lire attentivement la présente fiche d'information et poser vos questions à un professionnel de la santé avant de recevoir un vaccin.

## À quoi servent les doses de rappel?

À l'heure actuelle, les vaccins contre la COVID-19 maintiennent une haute efficacité contre les infections graves, les hospitalisations et les décès associés à la maladie dans la majorité des populations. Toutefois, des données émergentes indiquent que l'efficacité vaccinale contre les infections asymptomatiques et les infections légères à la COVID-19 pourrait baisser au fil du temps, et que les vaccins actuellement autorisés pourraient offrir une protection inférieure contre le très contagieux variant Delta (B.1.617.2).

Un déclin de l'efficacité pourrait faire augmenter la transmission de la maladie. Ainsi, une dose supplémentaire ou une dose de rappel pourrait être requise pour assurer une bonne protection chez certaines populations.

## À quel moment la dose de rappel devrait-elle être administrée?

Les données d'essais cliniques indiquent que la dose de rappel d'un vaccin à ARNm devrait être administrée six mois après la série primaire afin de fournir une protection accrue contre la COVID-19. Cela signifie qu'elle devrait être administrée six mois après la réception de la deuxième dose d'un vaccin à ARNm.

## Quelle est la différence entre une dose de rappel et une dose supplémentaire dans une série primaire (administrée aux personnes immunodéprimées)?

Pour la plupart des gens, deux doses d'un vaccin autorisé contre la COVID-19 (SPIKEVAX® de Moderna ou COMIRNATY® de Pfizer-BioNTech) sont suffisantes pour compléter une série vaccinale primaire. Des données issues de la vie réelle indiquent que, comparativement à la population générale, les personnes modérément ou gravement immunodéprimées présentent une réponse immunitaire inférieure aux vaccins contre la COVID-19. Ainsi, ces personnes reçoivent une série primaire de trois doses du vaccin SPIKEVAX® de Moderna ou du vaccin COMIRNATY® de Pfizer-BioNTech.

Le but de la dose de rappel est de restaurer la protection, qui pourrait avoir baissé avec le temps jusqu'à un niveau jugé insuffisant, chez les personnes qui avaient initialement présenté une bonne réponse à la série vaccinale primaire.

## À l'heure actuelle, qui devrait recevoir une dose de rappel au Nunavut?

Présentement au Nunavut, toutes les personnes admissibles de plus de 12 ans peuvent recevoir une dose de rappel du vaccin SPIKEVAX® de Moderna ou du vaccin COMIRNATY® de Pfizer-BioNTech. Veuillez consulter un professionnel de la santé si vous avez des questions au sujet de l'admissibilité.

## Dois-je recevoir le même vaccin à ARNm pour la dose de rappel?

Selon les recommandations actuelles, les vaccins SPIKEVAX® (Moderna) et COMIRNATY® (Pfizer-BioNTech) peuvent être administrés comme doses de rappel, quel que soit le vaccin reçu à la série primaire.

## Les vaccins contre la COVID-19 seront-ils administrés chaque année comme c'est le cas pour le vaccin contre la grippe?

Des années d'utilisation post commercialisation peuvent être nécessaires pour déterminer le nombre de doses requises et les intervalles optimaux entre celles-ci pour que la série primaire procure une protection à long terme. Au fil du temps, on pourrait constater qu'une courte série primaire de deux doses (ou de trois doses pour les personnes immunodéprimées), suivie d'une dose de rappel au moins six mois après la deuxième dose, pourrait procurer une protection durable. Les connaissances sur le sujet continuent d'évoluer.

## La dose de rappel deviendra-t-elle une exigence pour voyager sans période d'isolement?

Pour l'instant, il n'est pas prévu que l'administration d'une dose de rappel fasse partie des règlements territoriaux.