Immunization Protocol for Pfizer-BioNTech COMIRNATY® Monovalent COVID-19 Vaccine (Grey Cap Formulation)

As of September 16, 2021, the Pfizer-BioNTech COMIRNATY® vaccine transitioned to an authorization under the *Food and Drug Regulations*.

NOTE: Please be advised that different formulations of Pfizer-BioNTech COMIRNATY® COVID-19 vaccine exist with separate protocols from the one presented here.

Purpose	To provide information and guidance for the COVID-19 Immunization Program in Nunavut.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals aged 12 years of age and older.[1] Data on the efficacy of the Pfizer-BioNTech COMIRNATY® COVID-19 vaccine against emerging variants of concern is evolving.[2]
Eligibility	Individuals aged 12 years of age and older without contraindications to the vaccine. Refer to the *Contraindications* section of this protocol for more information. **Please Note: Pfizer-BioNTech COMIRNATY® Monovalent COVID-19 vaccine should only be used as a booster dose in individuals aged 16 and older**.
Product	Pfizer BioNTech COMIRNATY®COVID-19 Vaccine, mRNA
Vaccine type	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.[2]
Vaccine components	*Medicinal ingre*dients: messenger ribonucleic acid (mRNA) *Non-medicinal ingredients*: ALC-0315 – ((4-hydroxybutyl) azanediyl)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, sodium chloride, sucrose, tromethamine, tromethamine hydrochloride, water for injection
Formats available	Multiple-dose vials (up to 6 doses) preservative-free suspension. **Dilution is NOT required**.[1] Pfizer-BioNTech COMIRNATY® COVID-19 multiple dose vials have grey caps and grey label borders which distinguish them from other formulations and manufacturers. 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 needle are used.
Manufacturer	Pfizer-BioNTech COVID-19 Vaccine BioNTech Manufacturing GmbH An der Goldgrube 12 Mainz, Rhineland-Palatinate, Germany 55131

Storage and transport of unpunctured vials prior to use	• **Vials will be received at the health centre at 2°C to 8°C and must be kept refrigerated and protected from light, in the original cartons, until ready to use. DO NOT FREEZE.** • **Total time the vials are stored at 2°C to 8°C (35°F to 46°F) should be tracked and should not exceed 10 weeks within the 12-month shelf life.** ***Transportation of Vials*** • If local redistribution is needed, full cartons containing unpunctured vials may be transported at 2°C to 8°C (35°F to 46°F).
Dose Preparation	• **DO NOT DILUTE** • Vials must be kept in the refrigerator (2°C to 8°C [35°F to 46°F]) prior to first puncture. • Verify that the vial has a grey cap and a grey label border. • The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 12 months from the date of manufacture printed on the vial and carton. • Verify that the vial has not surpassed the 10-week fridge temperature expiry date indicated by pharmacy. • Visually inspect the vial. Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles. • Before use, mix by inverting vaccine vial gently 10 times. • Do not shake. • After mixing, the vaccine should appear as a white to off-white suspension with no visible particles. **Please see Appendix A – *Preparation of Dose* for further guidance. <u>The vaccine should be used within 12 hours of first puncture and may be handled in room light conditions.</u>**
Storage of punctured vials	After first puncture, store vials in the fridge or at room temperature between 2°C and 25°C (35°F to 77°F). Use within 12 hours from the time of first puncture. Any vaccine remaining in vials must be discarded after 12 hours.
Consent	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.
Administration	**Follow the storage and handling instructions in this protocol to ensure the vaccine will be effective.** **<u>Do not administer the vaccine</u> if the storage and handling guidance has not been followed.** It is helpful to use low-dead-volume syringes and/or needles. Irrespective of the type of syringe or needle: • Each dose must contain 0.3 mL of vaccine. • 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. • Do not pool excess vaccine from multiple vials.

- Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension. During the visual inspection:
- Verify the final dosing volume of 0.3 mL.
- Confirm there are no particulates and that no discolouration is observed.
- Do not administer if vaccine is discoloured or contains particulate matter.

Administer Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine intramuscularly in the deltoid muscle.

Do not inject the vaccine intravascularly, subcutaneously or intradermally.

Dose series (Primary)

Pfizer-BioNTech COMIRNATY® COVID-19 vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 8 weeks apart. For immunocompromised individuals 12 years of age and older the primary series is a three-dose regimen administered 4 to 8 weeks apart.

The interval between dose 1 and dose 2 (8 weeks) is based on evidence regarding improved protection when extended beyond the manufacturer's recommended intervals. This guidance supersedes the dose interval recommended in the product monograph.

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.

Age indication	Minimum interval between doses in primary series	Recommended interval between doses in primary series
Pfizer-BioNTech COMIRNATY® (when used in immunocompetent individuals age 12+)	19 days	8 weeks
Pfizer-BioNTech COMIRNATY® (when used for immunocompromised individuals)	19 days	4 to 8 weeks

Canada's National Advisory Committee on Immunizations (NACI) has suggested intervals between previous COVID-19 infection and COVID-19 vaccination. Please inquire about an individual's COVID-19 infection history prior to administration of a COVID-19 vaccine.

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

Additional dose for immunocompromised

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

As immunocompromised individuals may have a reduced immune response to COVID-19 vaccines, an additional dose provides another opportunity for these individuals to develop a better immune response, completing their primary series.[2]

Eligibility criteria for additional dose for immunocompromised patients:

1. Aged 6 months and older, having received 2 previous doses of mRNA COVID-19 vaccines.
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. A vaccine series should ideally be completed at least 2 weeks before initiation of immunosuppressive therapies where possible. Please reach out to your Regional Communicable Disease Coordinators (RCDCs) if you have any questions about additional dose(s) for immunocompromised individuals.
Booster Dose	**Pfizer-BioNTech COMIRNATY® Monovalent COVID-19 vaccine should only be used as a booster dose in individuals aged 16 and older**. All doses of COVID-19 vaccines after the primary series, are described as booster doses. Note that for moderately to severely immunocompromised individuals, the primary series included one additional dose that is not referred to as a booster dose. Bivalent vaccines are the preferred vaccine for booster doses among individuals in the authorized age groups, as they contain Omicron, which is the most antigenically-distinct variant from the original SARS-CoV-2 strain. However, either Pfizer-BioNTech COMIRNATY® original or bivalent preparation or Moderna SPIKEVAX® original or bivalent preparation can be used as a booster dose, regardless of which mRNA vaccine was used in the primary series. For Nunavummiut ages 5 years of age and older who have received a primary COVID-19 vaccine series, COVID-19 booster doses of an appropriate vaccine product and formulation may be offered at an interval of 6 months after a previous COVID-19 vaccine dose or SARS-CoV-2 infection. However, a shorter interval of at least 3 months may be warranted in the context of heightened epidemiologic risk, as well as operational considerations for the efficient deployment of the vaccine program. **The recommended booster dose for Pfizer-BioNTech COMIRNATY ® is 0.3mL (full dose) for all recipients in the eligible age group for this vaccine preparation (16 years and older). This differs from Moderna SPIKEVAX® booster dose guidance where NACI recommends a half dose (0.25mL) for the general population.**

COVID-19 infection timing relative to COVID-19 vaccination	Population	Suggested interval between COVID-19 infection and vaccination
Infection after primary series but before booster dose(s) (if eligible for booster dose)	Individuals 5 years of age and older currently eligible for a booster dose	6 months since previous infection unless a shorter interval of 3 to <6 months is warranted in the context of heightened epidemiological risk

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

Special Populations

Pregnancy and Breastfeeding

It is recommended that a complete vaccine series with an mRNA COVID-19 vaccine should be offered to individuals in the authorized age group who are pregnant or breastfeeding. Adolescents and adults who are pregnant or breastfeeding are included among those recommended to receive a booster dose.[2]

Individuals previously infected with SARS-CoV-2

mRNA COVID-19 vaccines should also be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine.[2]

Please see *Dose Series (Primary)* and *Booster Dose* sections for more information on suggested intervals between previous infection and COVID-19 vaccination prior to and after completion of the primary series.[2]

Persons with an Autoimmune Condition

It is recommended that an mRNA COVID-19 vaccine be offered to individuals in the authorized age group with an autoimmune condition.

Persons new to Canada

It is recommended that people who are planning to live, work or study in Canada who have had only a complete or incomplete series of non-Health Canada authorized vaccines be offered an additional dose of an mRNA vaccine, unless they have already received 3 doses of a COVID-19 vaccine.[2]

Vaccine interchangeability

NACI recommends that, if readily available, the **same** mRNA COVID-19 vaccine product 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 **should** be counted, and the series need not be restarted. [2]

For mixed COVID-19 vaccine schedules, the minimum interval between doses should be based on the minimum interval of the product used for the first dose (e.g., Pfizer-BioNTech COVID-19 vaccine should be offered a minimum of 28 days after AstraZeneca COVID-19 vaccine).[2]

	For individuals age 5+, COVID-19 vaccines may be given at the same time as, or any time before or after, live or non-live vaccines. **There are currently no data on the use of bivalent Omicron-containing mRNA COVID-19 vaccines as part of a primary series. A primary series with an original mRNA vaccine is recommended in all authorized age groups** Please contact your RCDC with any questions regarding vaccine interchangeability.
Contraindications	Pfizer-BioNTech COMIRNATY® COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container.
Side Effects	Some adverse events are commonly reported (defined as 10% or more) among all vaccine recipients. However, they are mild or moderate and transient, resolving within a few days. These include pain at the injection site, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.[2]
Precautions and uncommon, rare and very rare adverse events	Evidence on vaccine safety that informs precautions and additional notes for mRNA vaccines is available from COVID-19 clinical trials and post-licensure COVID-19 vaccine pharmacovigilance, which is ongoing. Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients and rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively.[2] **<u>Hypersensitivity and Allergies</u>** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container (e.g., PEG), consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. Please refer to *Anaphylaxis* section for more information. In individuals with mild to moderate immediate allergic reactions (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) to a previous dose of mRNA COVID-19 vaccine or any of its components, re-vaccination may be offered with the same vaccine or the same platform (i.e., mRNA). Individuals should be observed for at least 30 minutes after re-vaccination if known confirmed allergies to a component of the COVID-19 vaccine.[2] **<u>Myocarditis and pericarditis</u>** Rare cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart) have been reported following vaccination with COVID-19 mRNA vaccines. Cases following mRNA vaccination are consistently reported to have occurred more often after the second dose, usually within a week after vaccination, more often in males 12 to 29 years of age. Surveillance data suggests a higher rate of myocarditis/pericarditis cases reported after vaccination with Moderna SPIKEVAX® compared to Pfizer-BioNTech COMIRNATY® vaccine especially among 12- to 29-year-old males following a second dose of vaccine.

	While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, while hospitalized, have responded well to conservative therapy and tend to recover quickly.[2] Healthcare providers should consider myocarditis/pericarditis in their evaluation if the patient presents with clinically compatible symptoms (e.g., chest pain, shortness of breath, palpitations) after an mRNA COVID-19 vaccine regardless of timing from vaccination to symptom onset. Please reach out to the community physician if you have any questions regarding investigation for myocarditis and pericarditis. **Bell's Palsy** Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally. Bell's palsy is an episode of facial muscle weakness or paralysis. The condition is typically temporary. Symptoms appear suddenly and generally start to improve after a few weeks. Health care providers should consider Bell's Palsy in their evaluation if the patient presents with clinically compatible symptoms (e.g., uncoordinated movement of the muscles that control facial expressions, loss of feeling in the face, drooling, etc.) after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis. **Acute illness** As a precautionary measure and considering the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Hematologic** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.[2] ***Syncope*** Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.
Anaphylaxis	Anaphylaxis is a very rare, severe, life-threatening allergic reaction typically with a rapid onset that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis may include but are not limited to generalized urticaria; wheezing; swelling of the mouth, tongue, and throat; difficulty breathing; vomiting; diarrhea; hypotension; decreased level of consciousness; and shock.[2] Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with mRNA COVID-19 vaccines has been reported at an incidence between 2 to 10 cases per million doses of vaccine administered. Individuals tend to recover quickly with appropriate treatment and there have been no fatalities nor long-term morbidity observed with any of these severe immediate allergic reactions in Canada. Most of the reported cases have occurred within 30 minutes of vaccination.

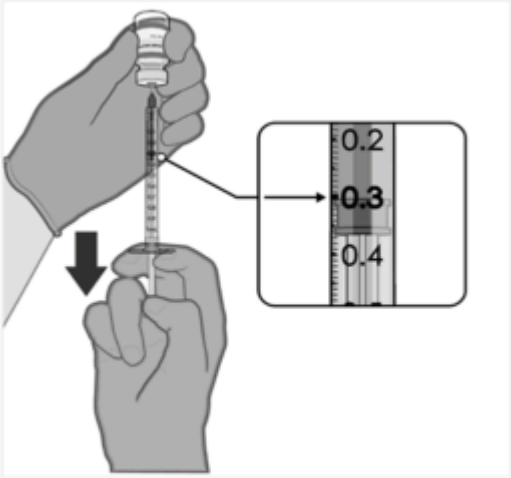
	Studies have shown that individuals with a severe immediate allergic reaction after a previous dose of mRNA vaccine can be re-vaccinated with the same vaccine or another mRNA vaccine following an appropriate medical assessment. Emerging evidence also suggests that most of the reported severe immediate allergic reactions following mRNA COVID-19 vaccines are likely not Immunoglobulin E (IgE)-mediated and therefore, have a low risk of recurrence following future vaccine doses.[2] Please refer to the *Nunavut Immunization Manual* section on anaphylaxis for further information and management advice. Microsoft Word - 3.0 Practice Guidelines TOC 16Feb2014 (gov.nu.ca)
Administration of other vaccines, drugs, or biological products	There have been no drug interaction studies performed to date. It is recommended that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma. Please reach out to the Office of the CPHO if there is a need to assess timing of COVID-19 vaccines after administration of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma.[2] **For individuals 6 months of age and older, COVID-19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines.** Vaccines administered during the same visit should be administered at different injection sites. As with other vaccines, when possible, administration on the same day is preferred to vaccines being given within a few days of each other. Studies looking at the simultaneous administration of COVID-19 vaccines with other vaccines are underway and ongoing. NACI will continue to monitor the evolving evidence and will update recommendations as needed.[2]
Tuberculin Skin Testing (TST) or interferon gamma release assay (IGRA)	There is a theoretical risk that mRNA vaccines may temporarily affect cell-mediated immunity, resulting in a false-negative tuberculin skin test (TST) or Interferon Gamma Release Assay (IGRA) results. However, the vaccines are not thought to cause false-positive TSTs/IGRAs.[2] In general, Nunavummiut at high risk for active or latent TB infection should continue to be investigated and managed according to the usual practices as outlined in the Nunavut TB manual. However, for low-risk people only, TSTs should be delayed until at least 4 weeks after COVID vaccine.[3] In cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations. However, re-testing (at least 4 weeks post immunization) of individuals with negative results for whom there is high suspicion of tuberculosis infection may be prudent to avoid missing cases due to potentially false-negative results. **Please refer to Appendix B - *Guidance on TSTs and COVID-19 Vaccines*** for additional guidance.
Reportable Adverse Events/Side Effects/Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Review section 3.5 *Management and Reporting of Adverse Events* in the Nunavut Immunization Manual: https://www.gov.nu.ca/sites/default/files/3.0_practice_guidelines_complete_may2020.pdf

	The AEFI form is available here: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-october-2021-eng.pdf Once the AEFI form has been submitted to the RCDC, the Public Health Officer will provide public health recommendations according to current best practice (e.g., if another dose is permitted). Please also see guidance document on the *Management of COVID-19 Vaccine Errors.* Complete an AEFI form and submit it to the RCDC only if the inadvertent vaccine administration error results in an AEFI.
Post-vaccination counselling	Oral analgesics or antipyretics may be considered for the management of vaccine side effects (e.g., pain or fever, respectively), if they occur after vaccination.[2] All vaccine recipients should be instructed to seek medical care if they develop signs or symptoms of a serious adverse event or an allergic reaction following vaccination. The Vaccine After Care Sheet should be given to clients following vaccination.
Vaccine Supply and Distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Additional questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
Documentation	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. Update recipient's Personal Immunization Record and provide date of next dose of vaccine. Follow operational guidance on processes to track and call back clients for subsequent dose. 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.[1]
Materials and resources	Nunavut Immunization Manual https://gov.nu.ca/health/information/manuals-guidelines Guidance Document on the Management of COVID-19 Vaccine Errors Summary Table(s) of mRNA Vaccine Recommendations Pfizer BioNtech Comirnaty® Vaccine Consent Form (with translations) Pfizer BioNtech Comirnaty® Vaccine Information Sheet (with translations) COVID-19 Vaccine After Care Sheet Adverse Events Following Immunization (AEFI) Reporting Form: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/aefi-form-october-2021-eng.pdf

	Vaccine protocols and materials (available on the Department of Health website): https://gov.nu.ca/health/information/manuals-guidelines
Appendices	Appendix A Preparation of Dose Appendix B Guidance on TSTs and COVID-19 Vaccines
References	1. COMIRNATY® (COVID-19 Vaccine, mRNA) Product Monograph 2022. Available: COMIRNATY_PM_EN.pdf (pfizer.ca) 2. COVID-19 Vaccine: Canadian Immunization Guide (2022). Available: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 3. Tuberculosis Services in Nunavut During the COVID-19 Pandemic (V2 2021.12.13).
Approved by Dr. Sean Wachtel, Chief Public Health Officer, on December 13, 2022. Department of Health, Government of Nunavut	

Appendix A – Preparation of Dose

For 12 Years of Age and Older: DO NOT DILUTE (Vials with Grey Cap and Grey Label Border)	
VIAL AND DOSE VERIFICATION	
 ✓ Gray plastic cap and gray label border	• Verify that the vial has a grey plastic cap and grey label border. • The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 12 months from the date of manufacture printed on the vial and carton, or 10 weeks from the date indicated by the territorial pharmacy.
 Gently × 10	• Before use, mix by gently inverting vaccine vial gently 10 times. • Do NOT shake. • Prior to mixing, the vaccine may contain white to off-white opaque amorphous particles. • After mixing, the vaccine should appear as a white to off-white suspension with no visible particles. • Do not use if liquid is discoloured or if particles are observed after mixing.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES	
 **Withdraw 0.3 mL dose of vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of COMIRNATY (grey cap formulation for 12 years of age and older) preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.3 mL of vaccine • 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. • Administer immediately and no later than 12 hours after the vials first puncture.
 **Record the date and time of first puncture** **Use within 12 hours after first puncture**	• Record the date and time of first vial puncture on the vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 12 hours after first puncture.

Appendix B

Guidance on TSTs and COVID-19 Vaccines

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

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

In general, Nunavummiut at high risk for active or latent TB infection should continue to be investigated and managed according to the usual practices as outlined in the Nunavut TB manual. However, for low-risk people only, TSTs should be delayed until at least 4 weeks after COVID vaccine.

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

The guidance below outlines the appropriate action in various scenarios.

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

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

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

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

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

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

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

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

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