Nunavut COVID-19 Immunization Manual

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PART TWO: COVID-19 Vaccine Product Protocols

Note: There is a vaccine product protocol for all the products that could possibly be used in Nunavut. Not all of these products will be available in health centres or at the regional pharmacies at all times.

Pediatric – Age: 6 months to <5 years

Moderna SpikeVax COVID-19 Vaccine (original) 6m to <6y Immunization Protocol - March 16, 2023

Pfizer-BioNTech Comirnaty COVID-19 Vaccine (original) 6m to <5 Immunization Protocol – May 25, 2023

Pediatric – Age: 5 years

Moderna SpikeVax COVID-19 Vaccine (original) 6m to <6y Immunization Protocol - March 16, 2023

Pfizer-BioNTech Cominarty COVID-19 Vaccine (original) 5y to <12y Immunization Protocol - March 16, 2023

Pfizer-BioNTech Comirnaty Bivalent COVID-19 Vaccine 5y to <12y Immunization Protocol - March 16, 2023

Pediatric – Age: 6 years to 11 years

Moderna SpikeVax COVID-19 Vaccine (original) 6y+ Immunization Protocol - March 16, 2023

Pfizer-BioNTech Comirnaty COVID-19 Vaccine (original) 5y to <12y Immunization Protocol - March 16, 2023

Pfizer-BioNTech Comirnaty Bivalent COVID-19 Vaccine 5y to <12y Immunization Protocol - March 16, 2023

Adolescent & Adult – Age: 12 years and older

Moderna SpikeVax COVID-19 Vaccine (original) 6y+ Immunization Protocol - March 16, 2023

Pfizer-BioNTech Cominarty COVID-19 Vaccine (original) 12y+ Immunization Protocol - March 16, 2023

Moderna SpikeVax Bivalent 18y+ COVID-19 Vaccine Immunization Protocol - March 16, 2023

Pfizer-BioNTech Cominarty Bivalent 12y+ COVID-19 Vaccine Immunization Protocol - March 16, 2023

1. Introduction

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1. Introduction

1.1 Epidemiology

Infectious agent

COVID-19 is caused by the SARS-CoV-2 virus, which was first recognized in Wuhan, China in December 2019.

Transmission

Current evidence suggests that SARS-CoV-2 is spread through respiratory droplets and aerosols created when an infected person breathes, coughs, sneezes, sings, shouts, or talks. A person may be infectious for up to 3 days before showing symptoms and most people are considered no longer infectious 10 days from onset of symptoms (or first detection of infection if asymptomatic).

Variants of concern

Genetic mutations in the SARS-CoV-2 virus have led to the designation of variants of concern (VOCs) and these variants are more transmissible than the original strain. Mutations in VOCs may also affect the severity of disease and the level of protection offered by vaccines.

Risk factors

Anyone can be infected with SARS-CoV-2. However, some populations are at increased risk of exposure to the virus (e.g., due to living or occupational settings), and some populations are at increased risk of severe disease and outcomes (e.g., hospitalization and death) due to biological factors (e.g., advanced age, pre-existing medical conditions, pregnancy) and social factors (e.g., socioeconomic status, belonging to a racialized population) that may intersect. Exposure and risk factors for severe disease may overlap, further increasing risk. Any combination of these factors, as well as varying access to health care services, has the potential for disproportionate consequences for specific populations characterized by increased rates of infection and disease, severe illness, hospitalizations, and/or deaths.

There is a spectrum of COVID-19 disease severity, ranging from asymptomatic to mild, moderate, severe and critical disease. Severe disease more often occurs in those with increasing age and those with underlying medical conditions, with the risk increasing with the number of underlying conditions.

1.2 Purpose

The purpose of this document is to present the basic protocol for Nunavut's COVID-19 immunization program. The COVID-19 immunization program is aimed at decreasing severe illness and death related to COVID-19 infection while also minimizing adverse society impacts from COVID-19 and the pandemic response.

1. Introduction

The Nunavut COVID-19 Immunization Manual is primarily taken from the Canadian Immunization Guide(CIG) COVID-19 chapter and related update statements authored by the National Advisory Committee on Immunization (NACI). Occasionally, Nunavut's Chief Public Health Officer (CPHO) may issue direction that differs from NACI guidance in the CIG to address the unique needs and challenges found in Nunavut.

The Nunavut COVID-19 Immunization Manual is designed as a quick reference for immunization providers and includes policies, programs, schedules and protocols specific to Nunavut. For more in-depth explanations and rationales for COVID-19 immunization guidance refer the CIG COVID chapter at https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html#a10. All health care providers giving any immunizations in Nunavut should be familiar with the Nunavut Immunization Manual (for routine immunizations) that lays out in depth, the protocols and standards for all of Nunavut's immunization programs including the COVID-19 immunization program. The Nunavut Immunization Manual can be found at https://www.gov.nu.ca/health/information/manuals-guidelines.

1.3 National Advisory Committee on Immunization (NACI)

NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted. The committee reviews the available epidemiology and evidence on vaccine protection and immunity, including the performance of vaccines based on clinical trial data and real-world evidence from observational studies. NACI knowledge syntheses, analyses and recommendations on vaccine use in Canada are published in literature reviews, statements and updates. NACI recommendations are also published in vaccine-specific chapters of the Canadian Immunization Guide (https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html).

2. COVID-19 Immunization Schedules

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2. COVID-19 Immunization Schedules

The immunizations schedules outlined in this section are tools to help you select the right COVID-19 vaccine product for your patient. Please review the appropriate individual vaccine product protocol and product monograph before administering a COVID-19 vaccine to your patient. Protocols for all the vaccines available in Nunavut can be found in the 'PART TWO: COVID-19 Vaccine Product Protocols' section of this manual.

2.1 Primary Series for the General Population

Primary series are always made up of the original form of the mRNA vaccine. Bivalent vaccines are only given as booster doses (see section 2.2 below).

*Table 1: COVID-19 Vaccination Primary Series: Individuals who are **NOT** immunocompromised*

Age	Authorized Vaccine Products Available in Nunavut	Dose	Dilution	Number of Doses	Optimal Interval* Between Doses
6 months to <5 years	**Pfizer-BioNTech Comirnaty (original)** Pediatric (6 months to <5 years formulation Vial: maroon cap, maroon label	10mcg **0.2ml**	2.2mL diluent per vial	3 doses	3 weeks between dose 1 and 2 8 weeks between dose 2 and 3
5 years	**Pfizer-BioNTech Comirnaty (original)** Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	2 doses	8 weeks
6 years to <12 years	**Pfizer-BioNTech Comirnaty (original)** Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	2 doses	8 weeks
12 years to <18 years	**Pfizer-BioNTech Comirnaty (original)** Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	2 doses	8 weeks
18 years and older	**Pfizer-BioNTech Comirnaty (original)~** Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	2 doses	8 weeks

*The recommended interval of 8 weeks provides a better immune response however second doses may be offered at a shorter interval of a minimum of 28 days for Moderna products or 21 days for Pfizer products under special circumstances.

~Pfizer-BioNTech Comirnaty (original) is the preferred product for those between 18 and 29 years old who are not immunocompromised.

- **Bold text indicates preferred product if available**.

2. COVID-19 Immunization Schedules

2.2 Booster Doses for the General Population

A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given (see section 2.1 above).

Bivalent Omicron-containing products are preferred for booster doses for the authorized ages. If the bivalent Omicron- containing mRNA COVID-19 vaccine is not readily available, an original mRNA COVID-19 vaccine should be offered to ensure timely protection.

*Table 2: COVID-19 Vaccination Booster Doses: Individuals who are **NOT** immunocompromised*

Age	Authorized Vaccine Products Available in Nunavut	Dose	Dilution	Number of Doses	Interval Between End of Primary Series and Booster Dose	Interval Between Subsequent Booster Doses
6 months to <5 years	No booster doses are approved for this age group at this time					
5 years	**Pfizer-BioNTech Comirnaty Bivalent** (original & Omicron) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose~	6 months*	N/A
	Pfizer-BioNTech Comirnaty (original) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose~	6 months*	N/A
6 years to <12 years	**Pfizer-BioNTech Comirnaty Bivalent** (original & Omicron) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose~	6 months*	N/A
	Pfizer-BioNTech Comirnaty (original) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose~	6 months*	N/A
12 years to <18 years	**Pfizer-BioNTech Cominarty Bivalent** (original & Omicron) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	At least 1 booster dose then every 6 months	6 months*	6 months*
	Pfizer-BioNTech Comirnaty (original) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	At least 1 booster dose	6 months*	6 months*

				then every 6 months		
18 years and older	**Pfizer-BioNTech Cominarty Bivalent** (original & Omicron) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	At least 1 booster dose then every 6 months	6 months*	6 months*
	Pfizer-BioNTech Comirnaty (original) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	At least 1 booster dose then every 6 months	6 months*	6 months*

*The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).
~A bivalent Omicron-containing vaccine is preferred for children 5 years to <12 who have not yet had a booster dose. Children in this group who already received a booster dose with an original COVID-19 mRNA vaccine may receive one bivalent Omicron-containing booster a minimum of 6 months after previous booster.

- **Bold text indicates preferred product if available.**

2.3 Primary Series for Those Who Are Moderately or Severely Immunocompromised

Refer to section 4.3 of the Nunavut COVID-19 Immunization Manual for a list of conditions under which an individual would be considered to be moderately or severely immunocompromised.

Primary series are always made up of the original form of the mRNA vaccine. Bivalent vaccines are only given as booster doses (see section 2.4 below).

*Table 3: COVID-19 Vaccination Primary Series: Individuals who **ARE** moderately or severely immunocompromised*

Age	Authorized Vaccine Products Available in Nunavut	Dose	Dilution	Number of Doses	Optimal Interval Between Doses
6 months to <5 years	Moderna Spikevax (original) 0.1mg/ml formulation Vial: blue cap, purple label	25mcg **0.25ml**	N/A	3 doses	4-8* weeks

	Pfizer-BioNTech Comirnaty (original) Pediatric (6 months to <5 years formulation Vial: maroon cap, maroon label	10mcg **0.2ml**	2.2mL diluent per vial	4 doses	4-8* weeks
5 years	**Pfizer-BioNTech Comirnaty (original)** Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	3 doses	4-8* weeks
6 years to <12 years	**Pfizer-BioNTech Comirnaty (original)** Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	3 doses	4-8* weeks
12 years to <18 years	**Pfizer-BioNTech Comirnaty (original)** Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	3 doses	4-8* weeks
18 years and older	**Pfizer-BioNTech Comirnaty (original)** Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	3 doses	4-8* weeks

*For immunocompromised individuals, providers should aim to provide each dose of the primary series 4 to 8 weeks apart from each other. An interval longer than 4 weeks between each dose is likely to result in a more robust and durable immune response, potentially higher vaccine effectiveness and a lower risk of myocarditis/pericarditis. However, if a longer interval is being considered, risk factors for exposure and risk of severe disease should also be taken into account.

- **Bold text indicates preferred product if available**.

2.4 Booster Doses for Those Who Are Moderately or Severely Immunocompromised

Refer to section 4.3 of the Nunavut COVID-19 Immunization Manual for a list of conditions under which an individual would be considered to be moderately or severely immunocompromised.

A primary series with the original formulation of a mRNA vaccine must be completed before a booster doses can be given (see section 2.3 above).

Bivalent Omicron-containing products are preferred for booster doses for the authorized ages. If the bivalent Omicron- containing mRNA COVID-19 vaccine is not readily available, an original mRNA COVID-19 vaccine should be offered to ensure timely protection.

2. COVID-19 Immunization Schedules

*Table 4: COVID-19 Vaccination Booster Doses: Individuals who **ARE** moderately or severely immunocompromised*

Age	Authorized Vaccine Products Available in Nunavut	Dose	Dilution	Number of Doses	Interval Between End of Primary Series and Booster Dose	Interval Between Subsequent Booster Doses
6 months to <5 years	No booster doses are approved for this age group at this time					
5 years	**Pfizer-BioNTech Comirnaty Bivalent** (original & Omicron) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose	6 months*	N/A
	Pfizer-BioNTech Comirnaty (original) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose	6 months*	N/A
6 years to <12 years	**Pfizer-BioNTech Comirnaty Bivalent** (original & Omicron) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose	6 months*	N/A
	Pfizer-BioNTech Comirnaty (original) Pediatric Formulation Vial: orange cap, orange label	10mcg **0.2ml**	1.3mL diluent per vial	1 booster dose	6 months*	N/A
12 years to <18 years	**Pfizer-BioNTech Cominarty Bivalent** (original & Omicron) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	At least 1 booster dose then every 6 months	6 months*	6 months*
	Pfizer-BioNTech Comirnaty (original) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A			
18 years and older	**Pfizer-BioNTech Cominarty Bivalent** (original & Omicron) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A	At least 1 booster dose then every 6 months	6 months*	6 months*
	Pfizer-BioNTech Comirnaty (original) Adult Formulation Vial: gray cap, gray label	30mcg **0.3ml**	N/A			

2. COVID-19 Immunization Schedules

*The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).
~A bivalent Omicron-containing vaccine is preferred for children 5 years to <12 who have not yet had a booster dose. Children in this group who already received a booster dose with an original COVID-19 mRNA vaccine are not recommended to receive a bivalent Omicron-containing booster (except at the discretion of the CPHO for those at high risk for severe illness).

- **Bold text indicates preferred product if available.**

3.0 Administration of COVID-19 Vaccines

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3.0 Administration of COVID-19 Vaccines

This section outlines COVID-19 vaccine administration information common across all COVID-19 vaccine products. Please review the appropriate individual vaccine product protocol and product monograph for vaccine product specific information before administering a COVID-19 vaccine to your patient. Protocols for all the vaccines available in Nunavut can be found in the 'PART TWO: COVID-19 Vaccine Product Protocols' section of this manual.

3.1 Informed 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.

Refer to the Nunavut Immunization Manual (for routine immunizations) - Section 3.2 to review the principles of informed consent.

3.2 Administration Practices

Administer COVID-19 mRNA vaccines intramuscularly. The deltoid muscle of the arm is the preferred injection site for those 12 months and older. The anterolateral thigh should be used for infants 6 months to <12 months old or for individuals for whom vaccination in the deltoid is not possible. Do not inject the vaccine intravascularly, subcutaneously, or intradermally.

The volume (mL) required for primary series and booster dosing may be different depending on which presentation of the vaccine is being administered. Careful attention should be paid to the vial and carton label, vial cap colour, label border colour and corresponding dose volumes.

Do not administer the vaccine if the storage and handling guidance has not been followed.

Visually inspect each dose in the dosing syringe prior to administration to verify correct dosing volume and confirm that no particulates or discolouration is observed.

Special precaution should be taken to ensure the correct dose is taken from multi-dose vials. It is helpful to use low-dead-volume syringes and/or needles.

3.3 Interchangeability of Vaccines

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.

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. If a bivalent vaccine is inadvertently used in the primary series, it is considered valid as long as a valid dosage was used.

3.0 Administration of COVID-19 Vaccines

Bivalent Omicron-containing mRNA vaccines are the preferred booster products for the authorized age groups; however, original strain mRNA vaccines used as a booster dose are considered valid.

Please contact your RCDC with any questions regarding vaccine interchangeability.

3.4 Pre-vaccination Assessment

Prior to vaccination, the vaccine provider should:

- assess the vaccine recipient's current state of health, included past COVID-19 infection;
- provide information regarding the benefits and risks of receiving or not receiving the vaccine using content and language appropriate to the vaccine recipient or caretaker;
- assess contraindications and precautions to receiving the vaccine, including any history of potential immediate or anaphylactic hypersensitivity to a previous dose of the vaccine or to any of the vaccine components outlined in the vaccine product protocols*;
- evaluate reactions to previous vaccinations;
- discuss frequently occurring minor adverse events and potential rare severe adverse events outlined in the vaccine product protocols*;
- provide an opportunity for the vaccine recipient or guardian to ask questions;
- assess that the vaccine recipient is capable of consenting to the procedure or that, when required, an appropriate guardian or substitute decision-maker gives consent;
- obtain informed consent.

*Anyone receiving any mRNA COVID-19 vaccine should be informed of the risks associated with mRNA COVID-19 vaccines: myocarditis/pericarditis, Bell's palsy and anaphylaxis, and be advised to seek medical attention if they develop signs or symptoms suggestive of these conditions.

3.5 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, volume of administered dose, anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

3.6 Reporting Adverse Events and Immunization 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 (for routine immunizations).

The form for reporting Adverse Events Following Immunization (AEFI) 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).

In the case of immunization errors, please also see the NACI Statement: COVID-19 vaccines: Planning guidance for immunization clinics: Managing vaccine administration errors or deviations. An incident report should be completed and submitted as per organizational policy for all medication errors. Complete an AEFI form and submit it to the RCDC only if the inadvertent vaccine administration error results in an AEFI.

3.7 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 Section 3.7 -Management of Anaphylaxis in the Nunavut Immunization Manual (for routine immunizations) for further information and management advice.

4. COVID-19 Vaccination of Specific Populations

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4. COVID-19 Vaccination of Specific Populations

4.1 Pregnancy & 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 booster doses.

4.2 Individuals Previously Infected with SARS-CoV-2

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

The National Advisory Committee on Immunization (NACI) has suggested intervals between previous COVID-19 infection and COVID-19 vaccination. Previous infection is defined as:

- Confirmed by a molecular (e.g., PCR) or Health Canada-approved antigen detection-based test; or
- Symptomatic disease compatible with COVID-19 AND exposure to a confirmed COVID-19 case.

Table 1: Recommended Intervals Between Infection and Vaccination

COVID-19 infection timing relative to COVID-19 vaccination	**Population**	**Suggested interval between COVID-19 infection and vaccination**
Infection prior to initiation or completion of a primary vaccination series	Individuals 6 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) or adults (MIS-A)	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 or MIS-A	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 or MIS-A (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥ 90 days since the diagnosis of MIS-C or MIS-A, whichever is longer
Infection after primary series but before a booster dose, or after a booster dose but before a next booster dose	Individuals 5 years of age and older currently eligible for a booster dose	6 months since infection unless a shorter interval of 3 to <6 months is warranted in the context of heightened epidemiological risk

4. COVID-19 Vaccination of Specific Populations

4.3 Immunocompromised persons

Immunocompromised individuals, including those receiving immunosuppressive therapy, are at increased risk for prolonged infection and serious complications from SARS-CoV-2 infection.

It is recommended that for moderately to severely immunocompromised individuals 6 months of age and older, a primary series of 3 doses with the original formulation of an mRNA COVID-19 vaccine plus booster doses (as eligible) should be preferentially offered. Refer to the Nunavut COVID-19 Immunization Manual PART ONE: section 3.3 and 3.4 to determine which COVID-19 vaccine products are most appropriate for your immunocompromised patient.

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.

To qualify as being immunocompromised, individuals must meet the moderately to severely immunocompromised criteria:

a. Active treatment for solid tumour or hematologic malignancies;
b. Receipt of solid-organ transplant and taking immunosuppressive therapy;
c. Receipt of hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy);
d. Receipt of chimeric antigen receptor (CAR)-T-cell therapy;
e. Moderate to severe primary immunodeficiency with associated humoral and/or cell-mediated immunodeficiency or immune dysregulation;
f. HIV with AIDS-defining illness or HIV with TB diagnosis in last 12 months before starting vaccine series, or severe immune compromise with CD4<200 cells/uL or CD4%<15%, OR without HIV viral suppression;
g. Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high- dose systemic corticosteroids, alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

Please note: other jurisdictions may have a slightly different list of medical conditions to qualify an individual for an additional dose.

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 immunizing immunocompromised individuals.

4.4 Persons with an Autoimmune Conditions

It is recommended that mRNA COVID-19 vaccines should be offered to individuals in the authorized age group with an autoimmune condition. If their condition or medications make them moderately to severely immunocompromised (see section 4.3 above for definition), they should follow the recommended schedule for this group as laid out in the Nunavut COVID-19 Immunization Manual PART ONE sections 2.3 and 2.4.

4. COVID-19 Vaccination of Specific Populations

4.5 Persons Vaccinated Outside of Nunavut

mRNA vaccines are the preferred product for optimal immune response and are the only COVID-19 vaccine products available in Nunavut. Individuals may have received a Health Canada authorized viral vector vaccine (Vaxzeria(AstraZeneca) or Jcovden (Janssen Inc.) or protein subunit vaccine (Nuvaxovid (Novovax)) outside of Nunavut. An mRNA Bivalent may be offered as a booster dose to eligible individuals who are planning to live, work or study in Canada and who have received a Health Canada authorized COVID-19 vaccine primary series.

Individuals vaccinated outside of Canada who have had a complete or incomplete series of a non-Health Canada authorized COVID-19 vaccine, should be offered an additional dose of an mRNA vaccine, unless they have already received 3 doses of a COVID-19 vaccine that is not currently authorized for use in Canada.

Please contact your Regional Communicable Disease Coordinator for vaccination recommendations for individuals with COVID-19 immunization schedules that do not align with the schedule outlined in the Nunavut COVID-19 Immunization Manual PART ONE section 2 or the vaccine product protocols in Part Two.

5. Storage and Handling of COVID-19 Vaccines

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5. Storage and Handling of COVID-19 Vaccines

5.1 Storage

Each COVID-19 vaccine product has different storage requirements and expiry intervals based on temperature, dilution, and vial puncture.

Table 1: COVID-19 Vaccine Product Description and Maximum Storage Times

Product	Format	Cap	Label	Diluent	Maximum Storage Times		
					Freezer -25^0C to -15^0C	Fridge $+2^0$C to $+8^0$C	Room Temp. $+9^0$C to $+25^0$C
Moderna Spikevax Bivalent (original/Omicron BA.4/5)	0.1mg/mL	royal blue	grey	N/A	Until expires	30 days	24h pre-puncture 12h post-puncture *Total time at room temp. pre+post puncture cannot exceed 24 hrs
Pfizer-BioNTech Comirnaty (original)	Pediatric (6 months to <5 years)	maroon	maroon	Yes*	N/A (vaccine arrives at health centre in thawed/ thawing state)	10 weeks	12h pre-dilution / 12h post-dilution
Pfizer-BioNTech Comirnaty (original)	Pediatric	orange	orange	Yes*			
Pfizer-BioNTech Comirnaty Bivalent (original/Omicron BA.4/5)	Pediatric	orange	orange	Yes*			
Pfizer-BioNTech Comirnaty (original)	Adult	gray	gray	N/A			12h post-puncture
Pfizer-BioNTech Comirnaty Bivalent (original/Omicron BA.4/5)	Adult	gray	gray	N/A			
*1.3mL sterile 0.9% Sodium Chloride Injection, USP per vial. See Appendix A of Immunization Protocol for Pfizer-BioNTech COMIRNATY®(original) COVID- 19 Vaccine – Children for dilution instructions.							

Refer to the COVID-19 Vaccine Product Protocols found in Part Two of this manual for proper storage practices for each vaccine product.

5.2 Reporting a Break in Cold Chain

"Cold chain" refers to the process used to maintain optimal conditions, particularly temperature, during the transport, storage and handling of vaccines, beginning at the manufacturer and ending with administration of the vaccine to the vaccine recipient. Vaccines exposed to temperatures outside the recommended temperature range may experience some loss of potency with each episode of exposure.

If there is a breach in the cold chain, this failure should be documented using the form: Incident Report – Vaccine Cold Chain Failure.

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

Last updated: Jun 06, 2022

Contents

5. Storage and Handling of COVID-19 Vaccines

Background:

All Moderna Spikevax vaccines are shipped frozen (-15 C to -25 C) from the supplier to the regional pharmacies and from the regional pharmacies to the communities.

All Pfizer Comirnaty vaccines are shipped on dry ice (-60 C to -90 C) from the supplier to the regional pharmacies and fridge (+2 C to +8 C) from the regional pharmacies to the communities.

Key information on vaccine transportation:

- Vials should never be transported at room temperature between sites.
- Punctured vials should never be transported between sites.
- COVID-19 vaccine will be stored in the Regional Pharmacy Hubs in Iqaluit, Rankin Inlet and Cambridge Bay. These communities will act as regional distribution sites.
- It is important to ensure that the vial(s) are kept at the appropriate temperature. If there is a breach in the cold chain, this failure should be documented using the form: *Incident Report – Vaccine Cold Chain Failure*.
- For additional information on storage temperatures for the Moderna SPIKEVAX® and Pfizer-BioNTech COMIRNATY® COVID-19 vaccines, please see the respective COVID-19Vaccine Product Protocol in Part TWO of the Nunavut COVID-19 Immunization Manual.

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

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

The purpose of this document is to provide information on transport of COVID-19 vaccine vials within the territory. For additional information on vaccine storage and handling refer to the Nunavut Immunization Manual (for routine immunizations) Section 3.0.

Transport into Territory:

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

Transport from Regional Hubs to Community:

All Moderna Spikevax vaccines are shipped frozen (-15 C to -25 C) from the supplier to the regional pharmacies and from the regional pharmacies to the communities. All Pfizer Comirnaty vaccines are shipped on dry ice (-60 C to -90 C) from the supplier to the regional pharmacies and fridge (+2 C to +8 C) from the regional pharmacies to the communities.

Transport at the appropriate temperature is achieved by transporting the vials in a portable Crēdo Cubes or coolers. The Cube(s) is returned to the Regional Pharmacy after transport. Pharmacy

technicians are responsible to pack the vaccine in the Crēdo Cube or cooler for transport to communities.

Transporting the vials:

- Use the COVID-19 Vaccine Vial Inventory Log to document the number of vials taken out of the freezer in the Regional Hub.
- Vials are ideally transported in their original packaging and if this is not possible then remove from packaging, wrap in bubble wrap, and protect from light by placing in an opaque or amber bag.
- Vials are packed securely into a transport container with packing material around them so that they do not move at all during transit. Cold packs can also be placed around packing material in case of transportation delays or equipment failure (Appendix 3 for Transport Container Protocol).
- The TempTale TMD is packed with the vials in the container.
- Once the transport container is opened to access the vials - retrieve the TempTale TMD. This data will inform the temperature of the vials during transport. ***DO NOT STOP THE TMD***
- Appendix 4 provides instructions on downloading information from the TMD and sharing it with pharmacy technicians at regional pharmacy hubs.
- When the vials are moved into the freezer or vaccine fridge at the health centre, the TempTale TMD should be placed in the same freezer or fridge to continue recording temperature data.
- Check the number of vials received against the Vaccine Shipping Log.
- If the vaccine arrives frozen, with no breach of cold chain, and is placed directly in the freezer then it can be stored as follows:
    - Moderna SPIKEVAX®: until the expiry dates indicated on the label, unless otherwise advised by pharmacy. If there has been a breach of cold chain, it must be stored in the vaccine fridge (+2°C to +8°C) and used within 30 days or otherwise as directed by pharmacy. Thawed vials of vaccine cannot be moved to the next community. Determine if vaccine is thawing by checking TempTale TMD at arrival.
    - All Pfizer BioNTech COMIRNATY ® will arrive between **+2°C to +8°C** (fridge temperature), if no breach of cold chain, and is placed directly in the fridge then it can be stored as follows:
        i. For 10 weeks at fridge temperature **+2°C to +8°C**.
        ii. **DO NOT** store vials at -25°C to -15°C (freezer).
- **DO NOT** shake or drop the vaccine
- Use the COVID-19 Vaccine Vial Inventory Log to document the number of vials placed into the freezer or vaccine fridge.

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

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

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

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

Planning for transport:

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

- Notify the person in charge of ordering the vaccine that an identified number of vials will be required for administration of vaccine off-site so the vial(s) will be available in the freezer or vaccine fridge on that day.
- Take the minimum amount of vaccine required to the clinic to prevent any wastage. Document on the COVID-19 Vaccine Inventory Log the number of vials removed from the freezer of fridge.
- To transport *frozen* vaccine the cooling packs for the refrigeration pack are placed in a separate freezer – not the vaccine freezer - the day before transport.
- To transport *thawed* vaccine the cooling packs for the refrigeration pack are placed into the refrigerator the day before transport.
- Place the packing materials such as packing peanuts, bubble wrap, blue pads or other packing materials in the refrigerator (+2°C to +8° C) for conditioning the day before.
- Before the vial(s) is to be transported, the cooler is assembled to allow interior to cool (see Appendix E for details on assembling pack).
- *Frozen vial(s)* must stay at **-25°C to -15°C** throughout transportation.
- *Thawed vials* must stay at **+2°C to +8°C** throughout transportation.
- Room temperature is **+8°C to +25°C** – vaccine vials should not be transported at room temperature.

Transporting the vial(s):

- Vial(s) will be signed out on the COVID-19 Vaccine Vial Inventory Log.

5. Storage and Handling of COVID-19 Vaccines

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

Appendix 1 COVID19 Vaccine Vial Shipping Log

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

Appendix 2: COVID19 Vaccine Vial Inventory for Freezers Log

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

Appendix 3 Transport Container Protocol

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

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

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

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

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

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

PLEASE EXECUTE THE FOLLOWING STEPS:

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

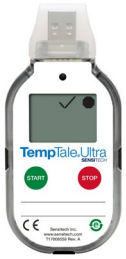
2. Plug reader into a computer's USB port and send the files to the Regional Pharmacy Technician. (**Michael Gauvin** mgauvin@gov.nu.ca for the **Qikiqtaaluk** region and **Amanda Arsenault** aarsenault@gov.nu.ca for the **Kivalliq** and **Kitikmeot** regions.). These should be upon receipt of the vccine, any major transport, any temperature excursions, and at least once weekly. **Any major temperature excursions should be reported immediately to CPHO/DCPHO.**

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

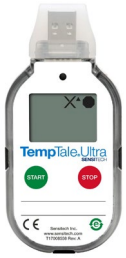
b) **If** ? icon appears, the product has stayed within the temperature and can be accepted. Return TempTale® to shipping freezer.

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

No Alarm



Alarm



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

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

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

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

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

Appendix 5: Immunization Manual 3.1.7 Maintaining Cold Chain during Transport

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

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

Hard-sided plastic insulated container

Refrigerator-conditioned cold packs

Newer Styrofoam cooler with walls at least 2 inches thick

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

Container for transport

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

Cooling Packs

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

Frozen Packs

5. Storage and Handling of COVID-19 Vaccines

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.

6. Interactions Between COVID-19 Vaccines and Other Pharmaceutical or Diagnostic Products

Contents

6. Interactions Between COVID-19 Vaccines and Other Pharmaceutical or Diagnostic Products

6.1 Concurrent Administration with Other Vaccines

In general, for individuals 6 months of age and older, COVID-19 vaccines may be given concurrently with (i.e., same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Concurrent administration will reduce barriers to the provision of routine childhood immunizations and seasonal influenza immunization.

No specific safety concerns have been identified to date, but studies and surveillance activities to assess the safety and immunogenicity of concurrent administration of COVID-19 vaccines with other vaccines are ongoing. Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines at the same time as, or shortly before or after, other vaccines.

If more than one type of vaccine is administered at a single visit, they should be administered at different injection sites using separate injection equipment. Preferably this is in different limbs, however if the same limb must be used, the injection sites should be separated by at least 2.5 cm (1 inch).

6.2 Drug Interactions

There have been no drug interaction studies performed to date.

6.3 Tuberculin Skin Testing (TST) & Interferon Gamma Release Assay (IGRA)

There is a theoretical risk that mRNA vaccines could temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. However, there is no direct evidence for this interaction. Therefore, in the absence of data and acknowledging the importance of both timely tuberculosis testing and immunization, vaccination with COVID-19 vaccines may take place at any time before, after or at the same visit as the TST or IGRA test. Repeat tuberculin skin testing or IGRA (at least 4 weeks post- COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis infection.

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.

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.

6.4 COVID-19 Vaccination & anti-SAR-CoV-2 Monoclonal Antibodies

It is recommended that COVID-19 vaccines should not be given simultaneously with monoclonal antibodies or convalescent plasma.

Please reach out to the Regional Communicable Disease Coordinator (RCDC) if there is a need to assess timing of COVID-19 vaccines after administration of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma.

7. References

National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html

National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19

Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines

Health Canada. COVID-19 Vaccines: Authorized Vaccines - Moderna Spikevax COVID-19 vaccines. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html

Health Canada. COVID-19 Vaccines: Authorized Vaccines - Pfizer-BioNTech Comirnaty COVID-19 vaccine. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html

ModernaTX, Inc. Product monograph - SPIKEVAX™. January 12, 2023.

Pfizer Canada ULC. Product monograph - COMIRNATY® Original & Omicron BA.4/BA.5. February 9, 2023.

Pfizer Canada ULC. Product monograph - COMIRNATY™. September 9, 2022.

Immunization Protocol for Moderna SPIKEVAX®(original) COVID- 19 Vaccine – Pediatric

Age: 6 months to <6 years
Packaging: blue vial cap, purple label border
Presentation: 0.1mcg/mL*

***Note:** SPIKEVAX® is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. Pay careful attention to the vial cap colour and the corresponding dose volume.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndromic coronavirus 2 (SARS-CoV-2) virus in individuals 6 months of age to <6 years of age.
Eligibility	Individuals 6 months of age to<6 years of age without contraindications to the vaccine.
Product	Moderna SPIKEVAX® (original) COVID-19 vaccine (mRNA SARS-CoV-2 vaccine) Vaccine Presentation: 0.1mg mRNA/ml
Vaccine Type	Elasomeran messenger ribonucleir acid (mRNA) vaccine
Vaccine Components	*Medicinal ingredients:* Elasomeran (mRNA), encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2). *Non-medicinal ingredients:* Acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection. The vial stopper does not contain natural rubber latex.
Formats Available	Moderna SPIKEVAX® (original) multidose vial of the 0.1mg mRNA/ml formulation contains a volume of 2.5mL supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 10 doses of 0.25mL volume (25mcg of COVID-19 mRNA) each for 6 months to 5 years. This product does not need to be diluted.
Manufacturer	ModernaTX, Inc. 200 Technology Square Cambridge, MA, USA, 02139
Storage & Handling Storage of vials prior to use	Moderna SPIKEVAX® (original) vials should be stored between -25° to -15° until needed. Store in the original carton to protect from light. **Unpunctured vials can be stored:** • **-25°C to -15°C (frozen) until the expiration date** • **2°C to 8°C (refrigerated) for up to 30 days** • **8°C to 25°C (room temperature) for a total of 24 hours**
Thawing vials	Thaw each vial before use: • Thaw in refrigerated conditions between 2°C and 8°C for 2.5 hours. Let each vial stand at room temperature for 15 minutes before administering.

<table>
<tr><td></td><td>

- Alternatively, thaw at room temperature between 15°C to maximum 25°C for 45 minutes
- Do not re-freeze vials after thawing.

</td></tr>
<tr><td>Storing and handling thawed punctured vials</td><td>Once the vial has been entered (needle-punctured), it can be stored at <u>room temperature or refrigerated for 24 hours</u>. Do not refreeze.
Thawed vials and filled syringes can be handled in room light conditions.

Do not puncture the vial more than 20 times.</td></tr>
<tr><td>Disposal of unused vaccine</td><td>Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes</td></tr>
<tr><td>Consent</td><td>Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual – Section 3.2 to review the principles of informed consent.</td></tr>
<tr><td>Administration</td><td>Review the Nunavut Immunization Manual (for routine immunizations) – Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents.

Moderna SPIKEVAX® (original) must not be reconstituted, mixed with other medicinal products, or diluted. No dilution is required prior to administration.

It is possible that one 5mL vial of Moderna SPIKEVAX® (original) may yield a mix and match of 0.5mL and 0.25mL doses as the dosing considerations vary for different populations. However, one dose should not be drawn from more then one vial (Note: this advice differs from guidance given in the Nunavut Immunization Manual (for routine immunizations) – Section 3.3). Do not puncture the vial more than 20 times.

Visually inspect the vials for foreign particulate matter and/or discolouration prior to administration. Moderna SPIKEVAX® (original) is a white to off-white dispersion. It may contain white or translucent product-related particulates. If either of these conditions exists, the vaccine should not be administered.

Swirl the vial of Moderna SPIKEVAX® (original) gently after thawing and between each withdrawal. Do not shake. Shaking the vial can make the vaccine less or not effective.[1]

Administer Moderna SPIKEVAX® (original) intramuscularly (IM) only. The preferred site is the deltoid muscle of the upper arm for children 12 months and over. The anterolateral thigh should be used for infants 6 to 12 months and when muscle mass in the deltoid is not adequate or vaccination in that site is not possible. Do not inject the vaccine intravascularly, subcutaneously or intradermally.</td></tr>
<tr><td>Dose Series</td><td>Moderna Spikevax (original) Administration Schedule
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td rowspan="2">6 months to <6 years</td><td>Primary Series</td><td>2 doses</td><td>8 weeks apart</td><td>25mcg</td><td>0.25ml</td></tr>
<tr><td>Booster Doses</td><td colspan="4">No booster doses are approved for this age</td></tr>
<tr><td>Immunocompromised Individuals*:</td><td>Primary Series</td><td>3 doses</td><td>4-8 weeks apart</td><td>25mcg</td><td>0.25ml</td></tr>
</table></td></tr>
</table>

	<table><tr><td>6 months to <5 years</td><td>Booster Doses</td><td>No booster doses are approved for this age</td></tr></table> **Refer to section 4.3 in PART ONE of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.*
Additional Notes COVID-19 Vaccination & SARS-CoV-2 Infection	Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.
Vaccine Interchangeability	If readily available, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.
Concurrent administration of other vaccines	COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.
Contraindications	Moderna SPIKEVAX® (original) 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.
Very common and common adverse events	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. The most frequently reported solicited local and systemic adverse reactions were irritability/crying, pain, sleepiness, and loss of appetite. Fatigue was the most frequently reported systemic adverse reaction in those 37 months to 5 years of age. Some additional side effects include pain at the injection site, redness and swelling at the injection site, headache, muscle pain, chills, joint pain, and fever.
Uncommon, rare and very rare adverse events	Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. **<u>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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 COVID-19 vaccination are consistently reported to have occurred: • More often after the second dose • Usually within a week after vaccination • More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **<u>Bell's palsy following vaccination with an mRNA COVID-19 vaccine</u>** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks.

	Multisystem inflammatory syndrome in children (MIS-C) following vaccination with an mRNA COVID-19 vaccine Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**Hypersensitivity and Allergies** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **Acute illness** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Bleeding disorders** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **Myocarditis and pericarditis** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed.

	Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. **<u>Guillain-Barrré syndrome (GBS)</u>** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **<u>Bell's Palsy</u>** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis. **<u>Multisystem Inflammatory Syndrome in Children (MIS-C)</u>** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immunizations)– Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf

	Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
Documentation	Health care professionals need to document COVID-19 vaccination in Meditech, including the time and date of administration, volume of administered dose, anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date in Meditech. The consent form is completed and stored according to health centre processes. Update the recipient's Personal Immunization Record (i.e. immunization card) and follow operational team guidance on processes to track and call clients back for follow up doses.
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19 3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines 4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Moderna Spikevax COVID-19 vaccines. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html 5. ModernaTX, Inc. Product monograph - SPIKEVAX™. January 12, 2023.
Approved by the Chief Public Health Officer on XX Department of Health, Government of Nunavut	

Immunization Protocol for Pfizer-BioNTech COMIRNATY®(original) COVID- 19 Vaccine – Pediatric

Age: 6 months to <5 years
Packaging: maroon vial cap, maroon label border*
Presentation: Pediatric Formulation

!! This product must be diluted before use !!

***Note:** COMIRNATY is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. In particular, it should be noted that both the Pfizer-BioNTech COMIRNATY (original) (pediatric formulation) and Pfizer-BioNTech COMIRNATY Bivalent (pediatric formulation) have orange vial caps and orange labels.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 months to <5 years of age.
Eligibility	Individuals aged 6 months to <5 years without contraindications to the vaccine. Refer to the *Contraindications* section of this protocol for more information.
Product	Pfizer-BioNTech COMIRNATY® COVID-19 (original) Paediatric Vaccine (BNT162b2-mRNA SARS-CoV-2 vaccine)
Vaccine type	Messenger ribonucleic acid (mRNA) vaccine
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 The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 0.9 mg sodium chloride per dose. The vial stopper does not contain natural rubber latex

Formats available	Pfizer-BioNTech Comirnaty® (original) Pediatric Vaccine (age 6 months to <5 years) multidose vial supplied as a dispersion that does not contain preservative. Each vial contains enough vaccine for 10 doses* of 0.2mL volume (10mcg of COVID-19 mRNA) each for 6 months to <5 years once the product has been diluted. *Each diluted vial contains up to 10 doses of 0.2 mL using low-dead volume syringes and/or needles; fewer 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 & Handling Storage of 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.** **Unpunctured vials can be stored:** • **2°C to 8°C (refrigerated) for up to 10 weeks.** The 10-week refrigerated expiry date will be noted in the transport container by the territorial pharmacy. ***Transportation of Vials*** If local redistribution is needed, full cartons containing unpunctured, undiluted vials may be transported at 2°C to 8°C, preferably in original cartons.
Dilution	Refer to Appendix A (of this protocol) - *Dilution and Preparation of Dose (below)* for important information specific to preparing the Pfizer-BioNTech Comirnaty (original) Pediatric for administration. **Once punctured, the vial must be used within 12 hours. The total combined unpunctured and punctured room temperature time cannot exceed 24 hours.** Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this protocol supersedes the number of hours printed on vial labels and cartons. Diluted vials can be handled in room light conditions.
Consent	Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunizations)– Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. **Administer Pfizer BioNTech Comirnaty (original) intramuscularly (IM) only.** In individuals age 6 to less than 12 months of age, the recommended site is the anterolateral aspect of the thigh. In individuals 1 year of age and older, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

<table>
<tr><td>Dose series</td><td>
Pfizer-BioNTech Comirnaty (original) Pediatric Administration Schedule
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td>6 months to <5 years</td><td>Primary Series</td><td>3 doses</td><td>Dose 1 and 2: 3 weeks apart

Dose 3: 8 weeks after the second dose</td><td>10mcg</td><td>0.2ml</td></tr>
<tr><td>Immunocompromised Individuals*:
6 months to <5 years</td><td>Primary Series</td><td>4 doses</td><td>4-8 weeks apart</td><td>10mcg</td><td>0.2ml</td></tr>
</table>
*Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.
</td></tr>
<tr><td>Additional Notes
COVID-19 Vaccination & SARS-CoV-2 Infection</td><td>Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.</td></tr>
<tr><td>Vaccine interchangeability</td><td>The National Advisory Committee on Immunizations (NACI) suggests that if readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage), the same mRNA COVID-19 vaccine product should be offered for any subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine 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.</td></tr>
<tr><td>Concurrent administration of other vaccines</td><td>COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.</td></tr>
<tr><td>Contraindications</td><td>Pfizer COMIRNATY (original) Paediatric 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.</td></tr>
<tr><td>Very Common and Common Adverse Events</td><td>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.</td></tr>
<tr><td>Uncommon, rare and very rare adverse events</td><td>Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. 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>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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 COVID-19 vaccination are consistently reported to have occurred:
• More often after the second dose
• Usually within a week after vaccination</td></tr>
</table>

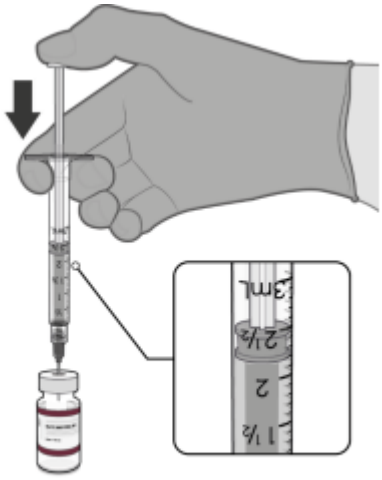
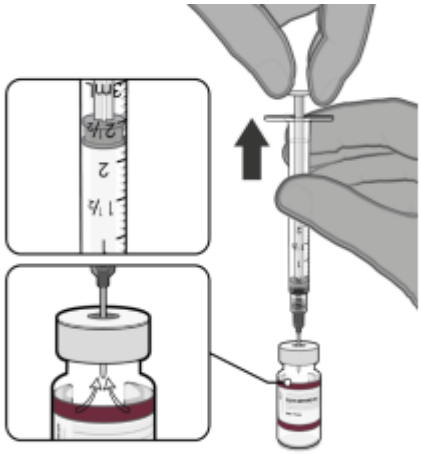
	• More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **Bell's palsy following vaccination with an mRNA COVID-19 vaccine** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **Multisystem inflammatory syndrome in children (MIS-C) following vaccination with an mRNA COVID-19 vaccine** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**Hypersensitivity and Allergies** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **Acute illness** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine.

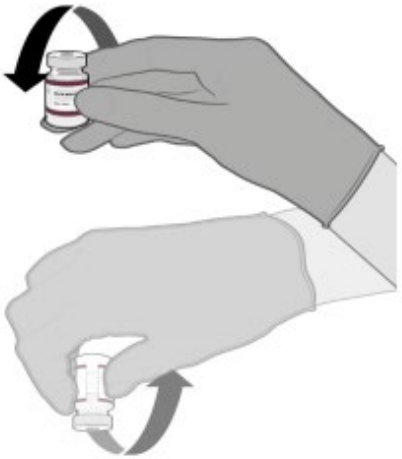
	Bleeding disorders In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **Myocarditis and pericarditis** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. <CIG> **Guillain-Barrré syndrome (GBS)** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **Bell's Palsy** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG> **Multisystem Inflammatory Syndrome in Children (MIS-C)** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immunizations)– Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre-vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following vaccination.

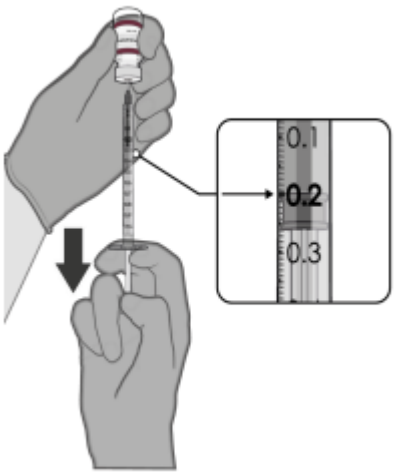
	Oral analgesics or antipyretics may be considered for the management of vaccine side effects (e.g., pain or fever, respectively), if they occur after vaccination. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
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, volume 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.
Appendices	Appendix A Dilution and Preparation of Dose
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed May 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed May 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19 3. Nunavut Immunization Manual (2013). Accessed May 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines 4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Pfizer-BioNTech Comirnaty COVID-19 vaccine. Accessed May 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html 5. Pfizer Canada ULC. Product monograph - COMIRNATY™. March 21, 2023.
Approved by the Chief Public Health Officer on 29 May 2023 Department of Health, Government of Nunavut	

Appendix A – Dilution and Preparation of Vaccine (Individuals 6 months to <5 years)

DILUTION AND PREPARATION INSTRUCTIONS	
COMIRNATY® COVID-19 PAEDIATRIC (6 months to < 5 years) Vaccine Vial with Maroon cap and Label with Maroon Border	
VIAL AND DOSE VERIFICATION	
 ✓ **Maroon plastic cap and maroon label border**	• Verify that the vial of COMIRNATY® COVID-19 Paediatric (6 months to <5 years) Vaccine has a **maroon** plastic cap and a label with a **maroon** border. The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 18 months from the date of manufacture printed on the vial and carton.
For Age 6 months to <5 years: DILUTE PRIOR TO USE (vials with MAROON cap and MAROON label border)	
 **Gently × 10**	• Before dilution, mix by inverting 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 amorphous particles. • Do not use if liquid is discoloured or if other particles are observed.

DILUTION (Individuals aged 6 months to <5 years)	
 **Add 2.2 mL of Sterile 0.9% Sodium Chloride Injection, USP**	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 2.2 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 2.2 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 **Pull back plunger to 2.2 mL to remove air from vial**	• Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 mL air into the empty diluent syringe.

 **Gently × 10**	• Gently invert the vial containing the COMIRNATY® COVID-19 Paediatric (6 months to <5 years) vaccine 10 times to mix. • <u>Do not shake</u>. • Inspect the vaccine in the vial. • The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
 **Record the date and time of dilution** **Use within 12 hours after dilution**	• Record the date and time of first vial puncture on the COMIRNATY (for age 6 months to <5 years) to vial label. • Store between 2°C to 25°C. • Discard any unused vaccine 12 hours after dilution.

WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 **Withdraw 0.2 mL dose of vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the COMIRNATY®COVID-19 Paediatric (6 months to <5 years) Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately.

Immunization Protocol for Pfizer-BioNTech COMIRNATY®(original) COVID- 19 Vaccine – Children

Age: 5 to <12 years
Packaging: orange vial cap, orange label border*
Presentation: Pediatric Formulation

!! This product must be diluted before use !!

***Note:** COMIRNATY is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. In particular, it should be noted that both the Pfizer-BioNTech COMIRNATY (original) (pediatric formulation) and Pfizer-BioNTech COMIRNATY Bivalent (pediatric formulation) have orange vial caps and orange labels.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 5 to <12 years of age.
Eligibility	Individuals aged 5 to <12 years without contraindications to the vaccine. Refer to the *Contraindications* section of this protocol for more information.
Product	Pfizer-BioNTech COMIRNATY® COVID-19 (original) Paediatric Vaccine (BNT162b2-mRNA SARS-CoV-2 vaccine)
Vaccine type	Messenger ribonucleic acid (mRNA) vaccine
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 The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 0.9 mg sodium chloride per dose. The vial stopper does not contain natural rubber latex

Formats available	Pfizer-BioNTech Comirnaty® (original) Pediatric Vaccine multidose vial of the adult formulation supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 10 doses* of 0.2mL volume (10mcg of COVID-19 mRNA) each for 5 to <12 years once the product has been diluted *Each diluted vial contains up to 10 doses of 0.2 mL using low-dead volume syringes and/or needles; fewer 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 & Handling Storage of 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.** **Unpunctured vials can be stored:** • **2°C to 8°C (refrigerated) for up to 10 weeks.** The 10-week refrigerated expiry date will be noted in the transport container by the territorial pharmacy. ***Transportation of Vials*** If local redistribution is needed, full cartons containing unpunctured, undiluted vials may be transported at 2°C to 8°C, preferably in original cartons.
Dilution	Refer to Appendix A (of this protocol) - *Dilution and Preparation of Dose (below)* for important information specific to preparing the Pfizer-BioNTech Comirnaty (original) Pediatric for administration. **Once punctured, the vial must be used within 12 hours. The total combined unpunctured and punctured room temperature time cannot exceed 24 hours.** Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this protocol supersedes the number of hours printed on vial labels and cartons. Diluted vials can be handled in room light conditions.
Consent	Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunizations)– Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. **Administer Pfizer BioNTech Comirnaty (original) intramuscularly (IM) only.** The preferred site is the deltoid muscle of the upper arm unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

<table>
<tr><td>Dose series</td><td>A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given.

Pfizer-BioNTech Comirnaty (original) Pediatric Administration Schedule
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td rowspan="2">5 to <12 years</td><td>Primary Series</td><td>2 doses</td><td>8 weeks apart</td><td>10mcg</td><td>0.2ml</td></tr>
<tr><td>Booster Doses</td><td>1 dose</td><td>6 months~ from end of primary series</td><td>10mcg</td><td>0.2ml</td></tr>
<tr><td rowspan="2">Immunocompromised Individuals*:
5 to <12 years</td><td>Primary Series</td><td>3 doses</td><td>4-8 weeks apart</td><td>10mcg</td><td>0.2ml</td></tr>
<tr><td>Booster Doses</td><td>1 dose</td><td>6 months~ from end of primary series</td><td>10mcg</td><td>0.2ml</td></tr>
</table>
*Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).</td></tr>
<tr><td>Additional Notes
COVID-19 Vaccination & SARS-CoV-2 Infection</td><td>Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.</td></tr>
<tr><td>Vaccine interchangeability</td><td>The National Advisory Committee on Immunizations (NACI) suggests that if readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage), the same mRNA COVID-19 vaccine product should be offered for any subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine 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.

Children who receive the 10 mcg COMIRNATY COVID-19 (original) PAEDIATRIC vaccine for their first dose and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg COMIRNATY COVID-19 vaccine that is authorized for individuals aged 12 years and older to complete their primary series. If the second dose of 10 mcg is given, the dose should still be considered valid and the series complete.</td></tr>
<tr><td>Concurrent administration of other vaccines</td><td>COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.</td></tr>
<tr><td>Contraindications</td><td>Pfizer COMIRNATY (original) Paediatric 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.</td></tr>
<tr><td>Very Common and Common Adverse Events</td><td>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.</td></tr>
</table>

Uncommon, rare and very rare adverse events	Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. 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>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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 COVID-19 vaccination are consistently reported to have occurred: • More often after the second dose • Usually within a week after vaccination • More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **<u>Bell's palsy following vaccination with an mRNA COVID-19 vaccine</u>** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **<u>Multisystem inflammatory syndrome in children (MIS-C) following vaccination with an mRNA COVID-19 vaccine</u>** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **<u>Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines</u>** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**<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, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **Acute illness** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Bleeding disorders** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **Myocarditis and pericarditis** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. <CIG> **Guillain-Barrré syndrome (GBS)** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **Bell's Palsy** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG> **Multisystem Inflammatory Syndrome in Children (MIS-C)** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has

	been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immunizations)– Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
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, volume 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.
Appendices	Appendix A Dilution and Preparation of Dose
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-

immunization-naci.html#covid-19

3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines

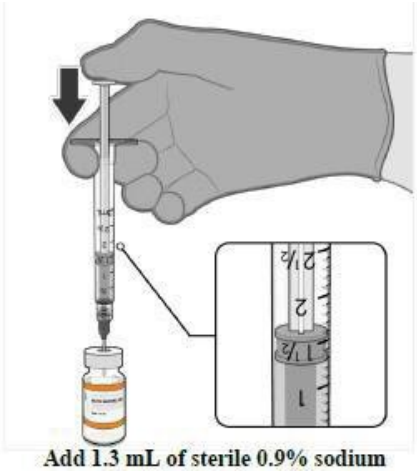
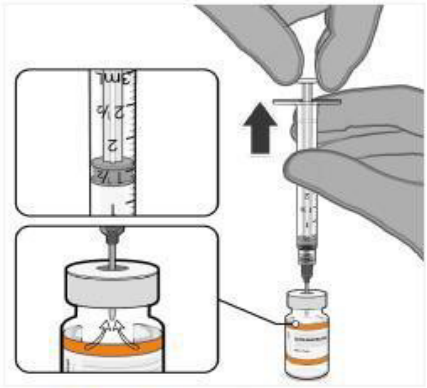
4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Pfizer-BioNTech Comirnaty COVID-19 vaccine. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html

5. Pfizer Canada ULC. Product monograph - COMIRNATY™. September 9, 2022.

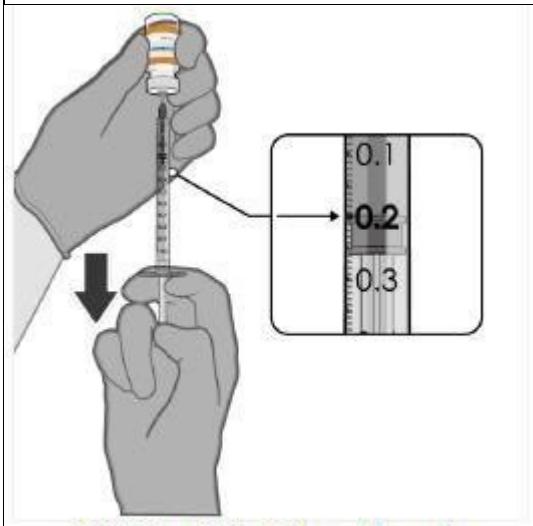
Approved by the Chief Public Health Officer on XX Department of Health, Government of Nunavut

Appendix A – Dilution and Preparation of Vaccine (Individuals 5 years to <12)

<table>
<tr><th colspan="2">DILUTION AND PREPARATION INSTRUCTIONS</th></tr>
<tr><td colspan="2">COMIRNATY® COVID-19 PAEDIATRIC Vaccine Vial with ORANGE cap and Label with ORANGE Border VIAL VERIFICATION</td></tr>
<tr><td> 
✓ Orange plastic cap and label with orange border.</td><td>• Verify that the vial of COMIRNATY® COVID-19 Paediatric Vaccine has an ORANGE plastic cap and a label with an orange plastic cap and states “Age 5y to < 12y”.
• The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 6 months from the date of manufacture printed on the vial and carton.</td></tr>
<tr><td> 
Gently × 10</td><td>• Before dilution, mix by inverting 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 amorphous particles.
• Do not use if liquid is discoloured or if other particles are observed.</td></tr>
</table>

DILUTION (Individuals aged 5 years to <12)	
 **Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.**	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 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 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.

 Gently × 10	• Gently invert the vial containing the COMIRNATY® COVID-19 Paediatric Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
 Use within 12 hours after dilution.	• Record the date and time of first vial puncture on the COMIRNATY (for age 5 years to vial label. • Store between 2°C to 25°C. • Discard any unused vaccine 12 hours after dilution.

WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 **Withdraw 0.2 mL dose of vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the COMIRNATY® COVID-19 Paediatric Vaccine preferentially using a low dead- volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately.

Immunization Protocol for Moderna SPIKEVAX®(original) COVID- 19 Vaccine – Older Pediatric, Adolescent & Adult

Age: 6 years and older
Packaging: red vial cap, blue label border
Presentation: 0.2mcg/mL*

***Note:** SPIKEVAX® is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. Pay careful attention to the vial cap colour and the corresponding dose volume.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 years of age and older.
Eligibility	Individuals 6 years of age and older without contraindications to the vaccine.
Product	Moderna SPIKEVAX® (original) COVID-19 vaccine (mRNA SARS-CoV-2 vaccine) Vaccine Presentation: 0.2mg mRNA/ml
Vaccine Type	Elasomeran messenger ribonucleic acid (mRNA) vaccine
Vaccine Components	*Medicinal ingredients:* Elasomeran (mRNA), encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2). *Non-medicinal ingredients:* Acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-rac-glycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection. The vial stopper does not contain natural rubber latex.
Formats Available	Moderna SPIKEVAX® (original) multidose vial of the 0.2mg mRNA/ml formulation contains a volume of 5mL supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 10 doses of 0.5mL volume (100mcg of COVID-19 mRNA) each for 12years and older or a maximum of 20 doses of 0.25mL volume (50mcg of COVID-19 mRNA) for 6 to <12year olds. This product does not need to be diluted.
Manufacturer	ModernaTX, Inc. 200 Technology Square Cambridge, MA, USA, 02139
Storage & Handling Storage of vials prior to use	Moderna SPIKEVAX (original) vials should be stored between -25° to -15° until needed. Store in the original carton to protect from light. **Unpunctured vials can be stored:** • **-25°C to -15°C (frozen) until the expiration date** • **2°C to 8°C (refrigerated) for up to 30 days** • **8°C to 25°C (room temperature) for a total of 24 hours**
Thawing vials	Thaw each vial before use: • Thaw in refrigerated conditions between 2°C and 8°C for 2.5 hours. Let each vial

	stand at room temperature for 15 minutes before administering. • Alternatively, thaw at room temperature between 15°C to maximum 25°C for 1 hour. • Do not re-freeze vials after thawing.
Storing and handling thawed punctured vials	Once the vial has been entered (needle-punctured), it can be stored at **room temperature or refrigerated for 24 hours**. Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions. Do not puncture the vial more than 20 times.
Disposal of unused vaccine	Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes.
Consent	Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunization) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunization) – Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. Moderna SPIKEVAX® (original) must not be reconstituted, mixed with other medicinal products, or diluted. No dilution is required prior to administration. It is possible that one 5mL vial of Moderna SPIKEVAX® (original) may yield a mix and match of 0.5mL and 0.25mL doses as the dosing considerations vary for different populations. However, one dose should not be drawn from more then one vial (Note: this advice differs from guidance given in the Nunavut Immunization Manual (for routine immunization)– Section 3.3). Do not puncture the vial more than 20 times. Visually inspect the vials for foreign particulate matter and/or discolouration prior to administration. Moderna SPIKEVAX® (original) is a white to off-white dispersion. It may contain white or translucent product-related particulates. If either of these conditions exists, the vaccine should not be administered. Swirl the vial of Moderna SPIKEVAX® (original) gently after thawing and between each withdrawal. Do not shake. Shaking the vial can make the vaccine less or not effective. **Administer Moderna SPIKEVAX® (original) intramuscularly (IM) only.** The preferred site is the deltoid muscle of the upper arm unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used. Do not inject the vaccine intravascularly, subcutaneously or intradermally.
Dose Series	Primary series are always made up of the original form of the mRNA vaccine. Bivalent vaccines are only given as booster doses. A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given.

	An Omicron-containing bivalent mRNA vaccine is preferred for booster doses for those 12 years and older but Moderna Spikevax (original) can be used as a booster dose if a bivalent vaccine is not available. **Moderna Spikevax (original) Administration Schedule**

Age	*Vaccination*	*# of Doses*	*Interval*	*mRNA Dose*	*Dose Volume*
6 to <12 years	Primary Series	2 doses	8 weeks apart	50mcg	0.25ml
	Booster Doses	Moderna Spikevax (original) is not approved as a booster for this age group			
12 years and older	Primary Series	2 doses	8 weeks apart	100mcg	0.5ml
	Booster Doses	6 months~ after end of primary series then every 6 months		50mcg	0.5ml
Immunocompromised Individuals*: 6 to <12 years	Primary Series	3 doses	4-8 weeks apart	50mcg	0.25ml
	Booster Doses	Moderna Spikevax (original) is not approved as a booster for this age group			
Immunocompromised Individuals*: 12 years and older	Primary Series	3 doses	4-8 weeks apart	100mcg	0.5ml
	Booster Doses	6 months~ after end of primary series then every 6 months		50mcg	0.5ml

**Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.*
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).

Additional Notes COVID-19 Vaccination & SARS-CoV-2 Infection	Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.
Vaccine Interchangeability	If readily available, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.
Concurrent administration of other vaccines	COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in PART ONE of the Nunavut COVID-19 Immunization Manual for more information.
Contraindications	Moderna SPIKEVAX® (original) 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.
Very common and common adverse events	Some adverse events are commonly reported among 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, lymphadenopathy, fatigue, headache, muscle pain, chills, joint pain, and fever.
Uncommon, rare and very rare adverse events	Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively.

	Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine 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 COVID-19 vaccination are consistently reported to have occurred: • More often after the second dose • Usually within a week after vaccination • More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **Bell's palsy following vaccination with an mRNA COVID-19 vaccine** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **Multisystem inflammatory syndrome in children or in adults (MIS-C or MIS-A) following vaccination with an mRNA COVID-19 vaccine** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**Hypersensitivity and Allergies** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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.

	Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **Acute illness** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Bleeding disorders** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **Myocarditis and pericarditis** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. **Guillain-Barrré syndrome (GBS)** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **Bell's Palsy** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG> **Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A)** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.

Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 in PART ONE of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
Documentation	Health care professionals need to document COVID-19 vaccination in Meditech, including the time and date of administration, quantity of administered dose, anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date in Meditech. The consent form is completed and stored according to health centre processes. Update the recipient's Personal Immunization Record (i.e. immunization card) and follow operational team guidance on processes to track and call clients back for follow up doses.
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19 3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines 4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Moderna Spikevax COVID-19 vaccines. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html

	5. ModernaTX, Inc. Product monograph - SPIKEVAX™. January 12, 2023.
Approved by the Chief Public Health Officer on XX Department of Health, Government of Nunavut	

Immunization Protocol for Pfizer-BioNTech COMIRNATY® Bivalent COVID- 19 Vaccine – Children

Age: 5 to <12 years
Packaging: orange vial cap, orange label border*
Presentation: Pediatric Formulation (Original & Omicron BA.4/5 strains)

!! This product must be diluted before use !!

***Note:** COMIRNATY is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. In particular, it should be noted that both the Pfizer-BioNTech COMIRNATY (original) (pediatric formulation) and Pfizer-BioNTech COMIRNATY Bivalent (pediatric formulation) have orange vial caps and orange labels.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 5 to <12 years of age.
Eligibility	Individuals aged 5 to <12 years who have received their primary series and without contraindications to the vaccine. Refer to the *Contraindications* section of this protocol for more information.
Product	Pfizer-BioNTech COMIRNATY® BIVALENT COVID-19 Paediatric Vaccine (BNT162b2-mRNA SARS- CoV-2 vaccine)
Vaccine type	Messenger ribonucleic acid (mRNA) vaccine
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 The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 0.9 mg sodium chloride per dose. The vial stopper does not contain natural rubber latex

Formats available	Pfizer-BioNTech Comirnaty® Bivalent Pediatric Vaccine multidose vial of the adult formulation supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 10 doses* of 0.2mL volume (10mcg of COVID-19 mRNA) each for 5 to <12 years once the product has been diluted *Each diluted vial contains up to 10 doses of 0.2 mL using low-dead volume syringes and/or needles; fewer 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 & Handling Storage of 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.** **Unpunctured vials can be stored:** • **2°C to 8°C (refrigerated) for up to 10 weeks.** The 10-week refrigerated expiry date will be noted in the transport container by the territorial pharmacy. ***Transportation of Vials*** If local redistribution is needed, full cartons containing unpunctured, undiluted vials may be transported at 2°C to 8°C, preferably in original cartons.
Dilution	Refer to Appendix A (of this protocol) - *Dilution and Preparation of Dose (below)* for important information specific to preparing the Pfizer-BioNTech Comirnaty Bivalent Pediatric for administration. **Once punctured, the vial must be used within 12 hours. The total combined unpunctured and punctured room temperature time cannot exceed 24 hours.** Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this protocol supersedes the number of hours printed on vial labels and cartons. Diluted vials can be handled in room light conditions.
Consent	Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunizations)– Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. **Administer Pfizer BioNTech Comirnaty Bivalent intramuscularly (IM) only.** The preferred site is the deltoid muscle of the upper arm unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

<table>
<tr><td>Dose series</td><td>A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given.

Pfizer-BioNTech Comirnaty Bivalent Pediatric Administration Schedule
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td>5 to <12 years</td><td>Booster Doses</td><td>1 dose^</td><td>6 months~ from end of primary series</td><td>10mcg</td><td>0.2ml</td></tr>
<tr><td>Immunocompromised Individuals*:
5 to <12 years</td><td>Booster Doses</td><td>1 dose^</td><td>6 months~ from end of primary series</td><td>10mcg</td><td>0.2ml</td></tr>
</table>
*Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.
^ Children 5 to 11 years of age who already received a booster dose with an original COVID-19 mRNA vaccine are not recommended to receive an additional bivalent Omicron-containing booster. However, at the CPHO's discretion, a bivalent booster dose could be offered to children considered at high risk of severe COVID-19 who have previously received a booster dose with the original Pfizer-BioNTech Comirnaty mRNA vaccine.
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).</td></tr>
<tr><td>Additional Notes
COVID-19 Vaccination & SARS-CoV-2 Infection</td><td>Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.</td></tr>
<tr><td>Vaccine interchangeability</td><td>The National Advisory Committee on Immunizations (NACI) suggests that if readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage), the same mRNA COVID-19 vaccine product should be offered for any subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine 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.</td></tr>
<tr><td>Concurrent administration of other vaccines</td><td>COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.</td></tr>
<tr><td>Contraindications</td><td>Pfizer COMIRNATY Bivalent Paediatric 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.</td></tr>
<tr><td>Very Common and Common Adverse Events</td><td>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.</td></tr>
<tr><td>Uncommon, rare and very rare adverse events</td><td>Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. 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>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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</td></tr>
</table>

	COVID-19 mRNA vaccines. Cases following mRNA COVID-19 vaccination are consistently reported to have occurred: • More often after the second dose • Usually within a week after vaccination • More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **Bell's palsy following vaccination with an mRNA COVID-19 vaccine** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **Multisystem inflammatory syndrome in children (MIS-C) following vaccination with an mRNA COVID-19 vaccine** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**Hypersensitivity and Allergies** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine.

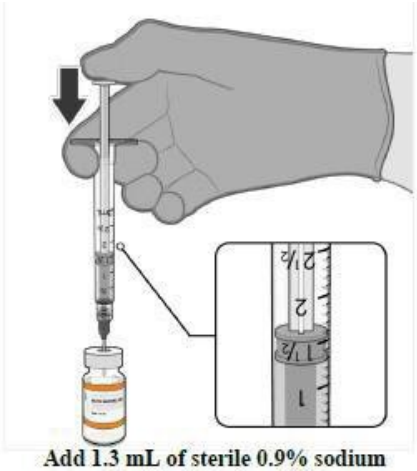
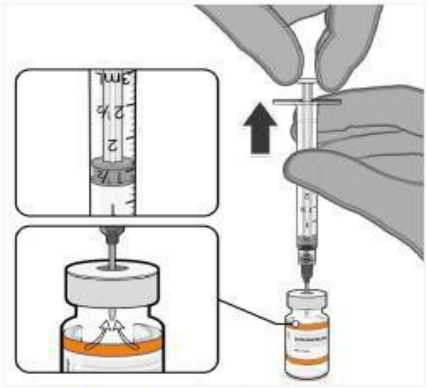
	Acute illness As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Bleeding disorders** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **Myocarditis and pericarditis** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. <CIG> **Guillain-Barrré syndrome (GBS)** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **Bell's Palsy** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG> **Multisystem Inflammatory Syndrome in Children (MIS-C)** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immunizations)– Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment.

	Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
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, volume 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.
Appendices	Appendix A Dilution and Preparation of Dose
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19 3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines 4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Pfizer-BioNTech Comirnaty COVID-19 vaccine. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-

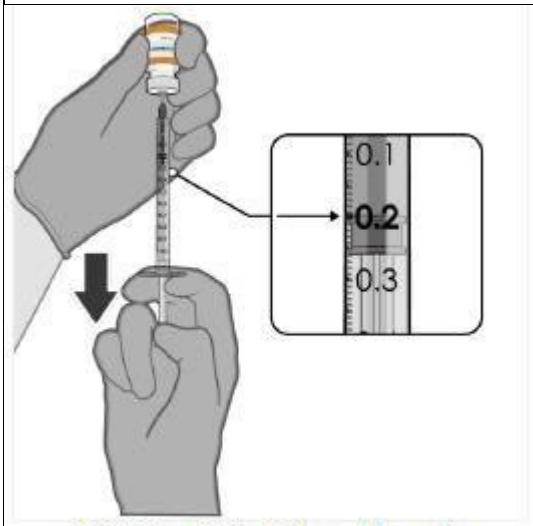
	products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html 5. Pfizer Canada ULC. Product monograph - COMIRNATY™. September 9, 2022.
Approved by the Chief Public Health Officer on XX Department of Health, Government of Nunavut	

Appendix A – Dilution and Preparation of Vaccine (Individuals 5 years to <12)

<table>
<tr><td colspan="2">DILUTE AND PREPARATION INSTRUCTIONS</td></tr>
<tr><td colspan="2">COMIRNATY® COVID-19 PAEDIATRIC Vaccine Vial with ORANGE cap and Label with ORANGE Border VIAL VERIFICATION</td></tr>
<tr><td> 
✓ Orange plastic cap and label with orange border.</td><td>• Verify that the vial of COMIRNATY® COVID-19 Paediatric Vaccine has an ORANGE plastic cap and a label with an orange plastic cap and states “Age 5y to < 12y”.
• The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 6 months from the date of manufacture printed on the vial and carton.</td></tr>
<tr><td> 
Gently × 10</td><td>• Before dilution, mix by inverting 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 amorphous particles.
• Do not use if liquid is discoloured or if other particles are observed.</td></tr>
</table>

DILUTION (Individuals aged 5 years to <12)	
 **Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.**	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 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 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 **Pull back plunger to 1.3 mL to remove air from vial.**	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.

 Gently × 10	• Gently invert the vial containing the COMIRNATY® COVID-19 Paediatric Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
 Use within 12 hours after dilution.	• Record the date and time of first vial puncture on the COMIRNATY (for age 5 years to vial label. • Store between 2°C to 25°C. • Discard any unused vaccine 12 hours after dilution.

WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 **Withdraw 0.2 mL dose of vaccine**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the COMIRNATY® COVID-19 Paediatric Vaccine preferentially using a low dead- volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately.

Immunization Protocol for Pfizer-BioNTech COMIRNATY®(original) COVID- 19 Vaccine – Adolescent & Adult

Age: 12 years and older
Packaging: gray vial cap, gray label border*
Presentation: Adult Formulation

***Note:** COMIRNATY® is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. In particular, it should be noted that both the Pfizer-BioNTech COMIRNATY®(original) (adult formulation) and Pfizer-BioNTech COMIRNATY®Bivalent (adult formulation) have gray vial caps and gray labels.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older.
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.
Product	Pfizer BioNTech COMIRNATY®(original) COVID-19 vaccine (mRNA SARS-CoV-2 vaccine)
Vaccine type	Messenger ribonucleic acid (mRNA) vaccine
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 The vial stopper does not contain natural rubber latex
Formats available	Pfizer-BioNTech Comirnaty® (original) multidose vial of the adult formulation is supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 6 doses* of 0.3mL volume (30mcg of COVID-19 mRNA) each for 12years+. This product does not need to be diluted. *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 & Handling Storage of 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.** **Unpunctured vials can be stored:** • **2°C to 8°C (refrigerated) for up to 10 weeks.** The 10-week refrigerated expiry date will be noted in the transport container by the territorial pharmacy. ***Transportation of Vials*** • If local redistribution is needed, full cartons containing unpunctured vials may be transported at 2°C to 8°C preferably in original cartons.
Storing and handling thawed punctured vials	After first puncture, store vials in the fridge or at room temperature between 2°C and 25°C. Use within 12 hours from the time of first puncture. Any vaccine remaining in vials must be discarded after 12 hours. Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions.
Disposal of unused vaccine	Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes.
Consent	Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunizations) – Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. Refer to Appendix A - *Preparation of Dose (below)* for information specific to preparing the Pfizer-BioNTech Comirnaty (original) (adult formulation) for administration. **Administer Pfizer BioNTech Comirnaty (original) intramuscularly (IM) only.** The preferred site is the deltoid muscle of the upper arm unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used. Do not inject the vaccine intravascularly, subcutaneously or intradermally.
Dose Series	Primary series are always made up of the original form of the mRNA vaccine. Bivalent vaccines are only given as booster doses. A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given. An Omicron-containing bivalent mRNA vaccine is preferred for booster doses for those 12 years and older but Pfizer-BioNTech Comirnaty (original) can be used as a booster dose if a bivalent vaccine is not available. **Pfizer-BioNTech Comirnaty (original) (adult formulation) Administration Schedule**

<table>
<tr><td></td><td>
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td rowspan="2">12 years and older</td><td>Primary Series</td><td>2 doses</td><td>8 weeks apart</td><td>30mcg</td><td>0.3ml</td></tr>
<tr><td>Booster Doses</td><td colspan="2">6 months~ after end of primary series then every 6 months</td><td>30mcg</td><td>0.3ml</td></tr>
<tr><td rowspan="2">Immunocompromised Individuals*:
12 years and older</td><td>Primary Series</td><td>3 doses</td><td>4-8 weeks apart</td><td>30mcg</td><td>0.3ml</td></tr>
<tr><td>Booster Doses</td><td colspan="2">6 months~ after end of primary series then every 6 months</td><td>30mcg</td><td>0.3ml</td></tr>
</table>
*Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).
</td></tr>
<tr><td>Additional Notes
COVID-19 Vaccination & SARS-CoV-2 Infection</td><td>Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.</td></tr>
<tr><td>Vaccine Interchangeability</td><td>If readily available, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.</td></tr>
<tr><td>Concurrent administration of other vaccines</td><td>COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.</td></tr>
<tr><td>Contraindications</td><td>Pfizer-BioNTech Comirnaty (original) 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.</td></tr>
<tr><td>Very common and common adverse events</td><td>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.</td></tr>
<tr><td>Uncommon, rare and very rare adverse events</td><td>Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively.

<u>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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.</td></tr>
</table>

	Cases following mRNA COVID-19 vaccination are consistently reported to have occurred: • More often after the second dose • Usually within a week after vaccination • More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **Bell's palsy following vaccination with an mRNA COVID-19 vaccine** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **Multisystem inflammatory syndrome in children or in adults (MIS-C or MIS-A) following vaccination with an mRNA COVID-19 vaccine** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**Hypersensitivity and Allergies** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **Acute illness**

	As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Bleeding disorders** In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy. **Myocarditis and pericarditis** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. **Guillain-Barrré syndrome (GBS)** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **Bell's Palsy** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis. **Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A)** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual – Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/Side Effects/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 in PART ONE of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
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, volume 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.
Appendices	Appendix A: Preparation of Dose
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19 3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines 4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Pfizer-BioNTech Comirnaty COVID-19 vaccine. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html

	5. Pfizer Canada ULC. Product monograph - COMIRNATY™. September 9, 2022.

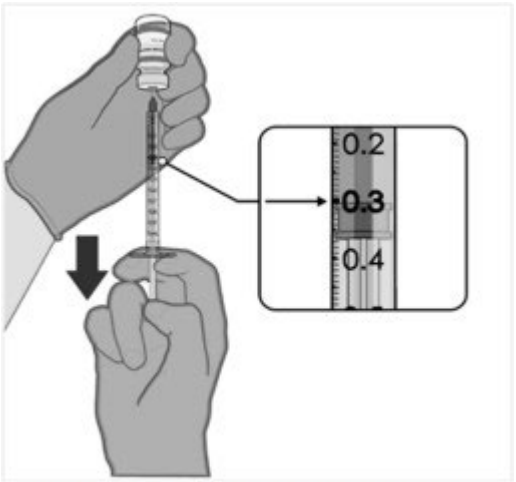
Approved by the Chief Public Health Officer, on XX. Department of Health, Government of Nunavut

Appendix A – Preparation of Dose

<table>
<tr><td colspan="2">For 12 Years of Age and Older: DO NOT DILUTE (Vials with Grey Cap and Grey Label Border)</td></tr>
<tr><td colspan="2">VIAL AND DOSE VERIFICATION</td></tr>
<tr><td> 

✓ Gray plastic cap and gray label border</td><td>• 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.</td></tr>
<tr><td> 
Gently × 10</td><td>• 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.</td></tr>
</table>

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.

Immunization Protocol for Pfizer-BioNTech COMIRNATY Bivalent COVID-19 Vaccine – Adolescent & Adult

Age: 12 years and older

Packaging: gray vial cap, gray label border*

Presentation: Adult Formulation (Original & Omicron BA.4/5 strains)

***Note:** COMIRNATY® is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. In particular, it should be noted that both the Pfizer-BioNTech COMIRNATY®(original) (adult formulation) and Pfizer-BioNTech COMIRNATY®Bivalent (adult formulation) have gray vial caps and gray labels.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 12 years of age and older.[1]
Eligibility	Individuals aged 12 years of age and older without contraindications to the vaccine. Refer to the *Contraindications* section of this protocol for more information.
Product	Pfizer BioNTech COMIRNATY®BIVALENT COVID-19 vaccine (mRNA SARS-CoV-2 vaccine)
Vaccine type	Messenger ribonucleic acid (mRNA) vaccine
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. The vial stopper does not contain natural rubber latex.
Formats available	Pfizer-BioNTech Comirnaty® Bivalent (adult) multidose vial of the adult formulation is supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 6 doses* of 0.3mL volume (30mcg of COVID-19 mRNA – 15mcg of original strain and 15mcg of Omicron BA.1/5 variant strain) each for 12years+. This product does not need to be diluted. *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

<table>
<tr><td>Storage & Handling
Storage of vials prior to use</td><td>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.

Unpunctured vials can be stored:
2°C to 8°C (refrigerated) for up to 10 weeks. The 10-week refrigerated expiry date will be noted in the transport container by the territorial pharmacy.
<u>Transportation of Vials</u>
If local redistribution is needed, full cartons containing unpunctured vials may be transported at 2°C to 8°C.</td></tr>
<tr><td>Storing and handling thawed punctured vials</td><td>After first puncture, store vials in the fridge or at room temperature between 2°C and 25°C.

Use within 12 hours from the time of first puncture. Any vaccine remaining in vials must be discarded after 12 hours. Do not refreeze.

Thawed vials and filled syringes can be handled in room light conditions.</td></tr>
<tr><td>Disposal of unused vaccine</td><td>Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes.</td></tr>
<tr><td>Consent</td><td>Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.</td></tr>
<tr><td>Administration</td><td>Review the Nunavut Immunization Manual (for routine immunizations) – Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents.

Refer to Appendix A - Preparation of Dose (below) for information specific to preparing the Pfizer-BioNTech Comirnaty Bivalent(adult formulation) for administration.

Administer Pfizer BioNTech Comirnaty Bivalent intramuscularly (IM) only. The preferred site is the deltoid muscle of the upper arm unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used.[1] Do not inject the vaccine intravascularly, subcutaneously or intradermally.</td></tr>
<tr><td>Dose Series</td><td>Primary series are always made up of the original form of the mRNA vaccine. Bivalent vaccines are only given as booster doses.

A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given.

Pfizer-BioNTech Comirnaty Bivalent (adult formulation) Administration Schedule
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td>12 years and older</td><td>Booster Doses</td><td colspan="2">6 months~ after end of primary series then every 6 months</td><td>30mcg</td><td>0.3ml</td></tr>
</table></td></tr>
</table>

	Immunocompromised Individuals*: 12 years and older	Booster Doses	6 months~ after end of primary series then every 6 months	30mcg	0.3ml

**Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.*
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).

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. 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). 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.
Additional Notes COVID-19 Vaccination & SARS-CoV-2 Infection	Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.
Vaccine Interchangeability	If readily available, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.
Concurrent administration of other vaccines	COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.
Contraindications	Pfizer-BioNTech Comirnaty Bivalent 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.

Very common and common adverse events	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.
Uncommon, rare and very rare adverse events	Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively. **<u>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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 COVID-19 vaccination are consistently reported to have occurred: • More often after the second dose • Usually within a week after vaccination • More often in those 12 to 29 years of age • More often in males While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **<u>Bell's palsy following vaccination with an mRNA COVID-19 vaccine</u>** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **<u>Multisystem inflammatory syndrome in children or in adults (MIS-C or MIS-A) following vaccination with an mRNA COVID-19 vaccine</u>** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **<u>Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines</u>** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**<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, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine.

Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components

A mild to moderate immediate allergic reaction is 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. In these cases, 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.

Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine.

Acute illness

As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine.

Bleeding disorders

In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their anticoagulation therapy.

Myocarditis and pericarditis

If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed.

Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine.

Guillain-Barrré syndrome (GBS)

Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine.

Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided.

Bell's Palsy

Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG>

	<u>Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A)</u> For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immuniations)– Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.
Reportable Adverse Events/Side Effects/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine Supply and Distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: <u>https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf</u> 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.
Appendices	Appendix A Preparation of Dose
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-

health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html

2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19

3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines

4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Pfizer-BioNTech Comirnaty COVID-19 vaccine. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/pfizer-biontech.html

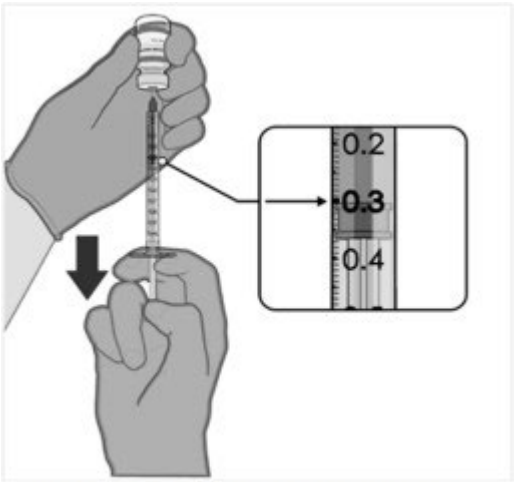
5. Pfizer Canada ULC. Product monograph - COMIRNATY® Original & Omicron BA.4/BA.5. February 9, 2023.

Approved by the Chief Public Health Officer, on XX Department of Health, Government of Nunavut

Appendix A – Preparation of Dose

<table>
<tr><td colspan="2">For 12 Years of Age and Older: DO NOT DILUTE (Vials with Grey Cap and Grey Label Border)</td></tr>
<tr><td colspan="2">VIAL AND DOSE VERIFICATION</td></tr>
<tr><td> 

✓ Gray plastic cap and gray label border</td><td>• 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.</td></tr>
<tr><td> 
Gently × 10</td><td>• 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.</td></tr>
</table>

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.

Immunization Protocol for Moderna SPIKEVAX® Bivalent COVID- 19 Vaccine –Adult

Age: 18 years and older
(12 years and older for those who are immunocompromised)
Packaging: blue vial cap, green label border
Presentation: 0.1mcg/mL (Original and Omicron BA.1 strains)

Note: SPIKEVAX is available in multiple presentations within Nunavut. Dose volume will be different based on which presentation is being administered. Pay careful attention to the vial cap colour and the corresponding dose volume.

Purpose	To provide information and guidance for the COVID19 Immunization Program in Nunavut. Refer to the Canadian Immunization Guide (CIG) and product monograph, for specific information.
Objective	To decrease severe illness and death related to COVID-19 infection while also minimizing adverse societal impacts from COVID-19 and the pandemic response.
Indication	Active immunization against coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in individuals 6 years of age and older.
Eligibility	Individuals 18 years of age and older without contraindications to the vaccine and who have previously received a complete primary series of a mRNA COVID-19 original formulation. Individuals 12 years of age and older who are immunocompromised without contraindications to the vaccine and who have previously received a complete primary series of a mRNA COVID-19 original formulation.
Product	Moderna SPIKEVAX® Bivalent COVID-19 vaccine (mRNA SARS-CoV-2 vaccine)
Vaccine Type	Elasomeran/imelasomeran mRNA vaccine [COVID-19 mRNA vaccine, Bivalent (Original and Omicron BA.1 Variant)]
Vaccine Components	*Medicinal ingredients:* Elasomeran (mRNA) encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2), and imelasomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K983P and V984P) of the SARS-CoV-2 Spike glycoprotein (Omicronvariant B.1.1.529 [BA.1]) [1] *Non-medicinal ingredients:* acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), PEG2000-DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol), lipid SM-102, sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection. The vial stopper does not contain natural rubber latex.
Formats Available	Moderna SPIKEVAX® Bivalent multidose vial of the 0.1mg mRNA/ml formulation contains a volume of 2.5mL supplied as a frozen dispersion that does not contain preservative. Each vials contains enough vaccine for 5 doses of 0.5mL volume (50mcg of COVID-19 mRNA – 25mcg of original strain and 25mcg of Omicron BA.1 variant) each for 18years+. This product does not need to be diluted.
Manufacturer	ModernaTX, Inc. 200 Technology Square Cambridge, MA, USA, 02139
Storage & Handling	Moderna SPIKEVAX® Bivalent vials should be stored between -25° to -15° until needed.

Storage of vials prior to use	Store in the original carton to protect from light. **Unpunctured vials can be stored:** • **-25°C to -15°C (frozen) until the expiration date** • **2°C to 8°C (refrigerated) for up to 30 days** • **8°C to 25°C (room temperature) for a total of 24 hours**
Thawing vials	Thaw each vial before use: • Thaw in refrigerated conditions between 2°C and 8°C for 2.5 hours. Let each vial stand at room temperature for 15 minutes before administering. • Alternatively, thaw at room temperature between 15°C to maximum 25°C for 1 hour. • Do not re-freeze vials after thawing.
Storing and handling thawed punctured vials	Once the vial has been entered (needle-punctured), it can be stored at **room temperature or refrigerated for 24 hours**. Do not refreeze. Thawed vials and filled syringes can be handled in room light conditions. Do not puncture the vial more than 20 times.
Disposal of unused vaccine	Any unused vaccine should be placed in a biohazard sharps container and disposed of using usual regional organizational processes.
Consent	Consent forms (updated with this protocol revision) must be reviewed with the patient or parent/guardian and signed prior to vaccination. Refer to the Nunavut Immunization Manual (for routine immunizations) – Section 3.2 to review the principles of informed consent.
Administration	Review the Nunavut Immunization Manual (for routine immunizations)– Section 3.3 Administration of Biological Products for guidance on preparing and administrating immunizing agents. Moderna SPIKEVAX® Bivalent must not be reconstituted, mixed with other medicinal products, or diluted. No dilution is required prior to administration. Visually inspect the vials for foreign particulate matter and/or discolouration prior to administration. Moderna SPIKEVAX® Bivalent is a white to off-white dispersion. It may contain white or translucent product-related particulates. If either of these conditions exists, the vaccine should not be administered. Swirl the vial of Moderna SPIKEVAX® Bivalent gently after thawing and between each withdrawal. Do not shake. Shaking the vial can make the vaccine less or not effective.[1] **Administer Moderna SPIKEVAX® Bivalent intramuscularly (IM) only.** The preferred site is the deltoid muscle of the upper arm unless the muscle mass is not adequate or vaccination in that site is not possible, in which case the anterolateral thigh can be used. Do not inject the vaccine intravascularly, subcutaneously or intradermally.
Dose	A primary series with the original formulation of a mRNA vaccine must be completed before a booster dose can be given. **Moderna Spikevax (original) Administration Schedule**

<table>
<tr><td></td><td>
<table>
<tr><th>Age</th><th>Vaccination</th><th># of Doses</th><th>Interval</th><th>mRNA Dose</th><th>Dose Volume</th></tr>
<tr><td>18 years and older</td><td>Booster Doses</td><td colspan="2">6 months~ after end of primary series then every 6 months</td><td>50mcg</td><td>0.5ml</td></tr>
<tr><td>Immunocompromised Individuals*:
12 years and older</td><td>Booster Doses</td><td colspan="2">6 months~ after end of primary series then every 6 months</td><td>50mcg</td><td>0.5ml</td></tr>
</table>
*Refer to section 4.3 in Part One of the Nunavut COVID-19 Immunization Manual for the list of immunocompromising conditions.
~The recommended interval of 6 months provides a better immune response however booster doses may be offered at a shorter interval of a minimum of 3 months under special circumstances (ex. heighted epidemiologic risk or operational considerations for efficient vaccine deployment).

If Moderna Spikevax® Bivalent (50 mcg) is administered in error as part of an (mRNA) COVID-19 vaccine primary series, this dose should be considered valid as part of the primary series.
</td></tr>
<tr><td>Additional Notes
COVID-19 Vaccination & SARS-CoV-2 Infection</td><td>Refer to section 4.2 in Part One of the Nunavut COVID-19 Immunization Manual for optimal interval between SARS-CoV-2 infection and COVID-19 vaccination.</td></tr>
<tr><td>Vaccine Interchangeability</td><td>If readily available, the same mRNA COVID-19 vaccine product should be offered for the subsequent dose in a vaccine series started with an mRNA COVID-19 vaccine. However, when the same mRNA COVID-19 vaccine product is not readily available, or is unknown, another mRNA COVID-19 vaccine product recommended for use in that age group can be considered interchangeable and should be offered to complete the vaccine series.</td></tr>
<tr><td>Concurrent administration with other vaccines</td><td>COVID-19 vaccines may be given concurrently with (i.e. same day), or at any time before or after, non-COVID-19 vaccines (including live and non-live vaccines). Refer to section 6.1 in Part One of the Nunavut COVID-19 Immunization Manual for more information.</td></tr>
<tr><td>Contraindications</td><td>Moderna SPIKEVAX® Bivalent 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.</td></tr>
<tr><td>Very common and common adverse events</td><td>Some adverse events are commonly reported among 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, lymphadenopathy, fatigue, headache, muscle pain, chills, joint pain, and fever.</td></tr>
<tr><td>Uncommon, rare and very rare adverse events</td><td>Uncommon adverse events occur in 0.1% to less than 1% of vaccine recipients. Rare and very rare adverse events occur in 0.01% to less than 0.1% and less than 0.01% of vaccine recipients, respectively.

<u>Myocarditis or pericarditis following vaccination with an mRNA COVID-19 vaccine</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 COVID-19 vaccination are consistently reported to have occurred:

More often after the second dose
Usually within a week after vaccination
More often in those 12 to 29 years of age
More often in males

</td></tr>
</table>

	While long-term follow-up is ongoing, available data indicate that the majority of individuals who reported myocarditis/pericarditis after mRNA COVID-19 vaccination, though requiring hospitalization, have responded well to conservative therapy and tend to recover quickly. **Bell's palsy following vaccination with an mRNA COVID-19 vaccine** 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. Symptoms of Bell's palsy appear suddenly and generally start to improve after a few weeks. **Multisystem inflammatory syndrome in adults (MIS-A) following vaccination with an mRNA COVID-19 vaccine** Very rare cases of MIS-C or MIS-A have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. **Severe immediate allergic reactions (e.g., anaphylaxis) following vaccination with COVID-19 vaccines** Very rare cases of severe immediate allergic reactions (e.g., anaphylaxis) have been reported following vaccination with mRNA COVID-19 vaccines. 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.
Precautions	**Hypersensitivity and Allergies** **Severe immediate allergic reaction (e.g., anaphylaxis) and/or confirmed allergies to a component of a COVID-19 vaccine** In individuals with a confirmed severe, immediate (≤4h following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine or its container, consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. **Mild to moderate immediate allergic reactions to previous doses of an mRNA COVID-19 vaccine or vaccine components** A mild to moderate immediate allergic reaction is 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. In these cases, 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. Please consult with your Regional Communicable Disease Coordinator (RCDC) prior to re-immunization after an allergic reaction to a previous dose of a COVID-19 vaccine. **Acute illness** As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine. **Bleeding disorders** 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. **<u>Myocarditis and pericarditis</u>** If an individual with confirmed myocarditis (with or without pericarditis) after a dose of an mRNA vaccine would like to receive another dose of vaccine, please reach out to the Office of the Chief Public Health Officer (OCPHO) via your RCDC for instructions on how to proceed. Individuals who have a history of myocarditis unrelated to mRNA COVID-19 vaccination should consult their clinical team for individual considerations and recommendations. If the diagnosis is remote and they are no longer followed clinically for cardiac issues, they should receive the vaccine. <CIG> **<u>Guillain-Barrré syndrome (GBS)</u>** Individuals with past history of GBS unrelated to COVID-19 vaccination should receive an mRNA COVID-19 vaccine. Individuals who developed GBS after a previous dose of a COVID-19 vaccine may receive an mRNA COVID-19 vaccine, after consultation with the OCPHO (via your RCDC) if it is determined that the benefits outweigh the risk and informed consent is provided. **<u>Bell's Palsy</u>** Individuals should seek medical attention if they develop symptoms compatible with Bell's palsy following receipt of mRNA COVID-19 vaccines. Healthcare providers should consider Bell's palsy in their evaluation if the patient presents with clinically compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.<CIG> **<u>Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A)</u>** For children or adults with a previous history of MIS-C or MIS-A, vaccination or re-vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer. <CIG>
Managing Anaphylaxis	Refer to the Nunavut Immunization Manual (for routine immunizations)– Section 3.7: Management of Anaphylaxis for guidance on identifying and managing anaphylaxis that occurs post-immunization.
Pre and post vaccination counselling	Refer to section 3.4 in PART ONE of the Nunavut COVID-19 Immunization Manual for guidance on pre vaccination assessment. Vaccine recipients should wait in the clinic for 15 minutes post vaccination and be advised to report any symptoms of adverse events. 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 as described above after leaving the clinic following 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. The COVID-19 Vaccine After Care Sheet (translated in all 4 languages) should be given to clients following vaccination.

Reportable Adverse Events/ Administration Errors	Report all serious adverse events requiring medical attention, unusual/expected events, or vaccine errors to the RCDC. Refer to section 3.6 in PART ONE of the Nunavut COVID-19 Immunization Manual for procedure and forms for reporting adverse events following immunization (AEFIs) and immunization errors.
Vaccine supply and distribution	Review section on vaccine ordering in the *Policy and Procedure* section of the Nunavut Drug Formulary located here: https://www.gov.nu.ca/sites/default/files/gn_drug_formulary_binder_1_final_dec_2021.pdf Questions or concerns surrounding vaccine supply and distribution should be forwarded to the Regional Pharmacies.
Documentation	Health care professionals need to document COVID-19 vaccination in Meditech, including the time and date of administration, quantity of administered dose, anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date in Meditech. The consent form is completed and stored according to health centre processes. Update the recipient's Personal Immunization Record (i.e. immunization card) and follow operational team guidance on processes to track and call clients back for follow up doses.
References	1. National Advisory Committee on Immunization. COVID-19 vaccine: Immunization Guide. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html 2. National Advisory Committee on Immunization. COVID-19 vaccine statements. Accessed March 2023 from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html#covid-19 3. Nunavut Immunization Manual (2013). Accessed March 2023 from: https://www.gov.nu.ca/health/information/manuals-guidelines 4. Health Canada. COVID-19 Vaccines: Authorized Vaccines - Moderna Spikevax COVID-19 vaccines. Accessed March 2023 from: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html 5. ModernaTX, Inc. Product monograph - SPIKEVAX™. January 12, 2023.
Approved by the Chief Public Health Officer on XX Department of Health, Government of Nunavut	