Newfoundland and Labrador COVID-19 Immunization Program

Department of Health
and Community Services,
October 1, 2021

COVID-19 Basics

- COVID-19 is an infectious disease caused by a new coronavirus (SARS-CoV-2), recognized for the first time in December 2019 and declared a global pandemic in March 2020.
- The virus that causes COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes.
- Infected people can spread the infection even if they **do not** have symptoms.
- Some people infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe causing hospitalizations and deaths.
- Even individuals with mild symptoms may feel unwell for a long time after a COVID-19 infection.
- Variants of concern (VoCs) have been identified in NL in 2021. Research to date is showing that vaccines are effective against some of these variants.

COVID-19 Basics

Symptoms of COVID-19 Include:

- Fever (including chills/sweats);
- Cough (new or worsening);
- Shortness of breath or difficulty breathing;
- Runny, stuffy or congested nose (not related to seasonal allergies or other known causes/conditions);
- Sore throat or difficulty swallowing;
- Headache;
- acute loss of sense of smell or taste;
- Unusual fatigue, lack of energy;
- New onset of muscle aches;
- Loss of appetite;
- Vomiting or diarrhea for more than 24 hours; or
- Small red or purple spots on hands and/or feet.

Objectives

- Review Vaccines currently approved in Canada
- Contraindications and Precautions
- Storage and Handling Requirements
- Administration
- Redistribution basics
- Post Immunization Information
- Resources

COVID-19 Vaccines Authorized for Use in Canada

- **Pfizer-BioNTech Comirnaty** (approved by Health Canada on December 9, 2020)
- **Moderna Spikevax** (approved by Health Canada on December 23, 2020)
- **AstraZeneca Vaxzevria** and **COVISHIELD** (approved by Health Canada on February 26, 2021)
- **Janssen** (approved by Health Canada on March 5, 2021)

All vaccines are recommended by the National Advisory Committee on Immunization (NACI) as safe and efficacious against symptomatic lab-confirmed COVID-19 disease. This may vary by age group or risk factor.

Serologic testing for COVID-19 is not required before or after vaccination.

mRNA Vaccines-How do they work?

- COVID-19 vaccines that use messenger RNA (mRNA) platforms contain modified nucleotides that code for the SARS-CoV-2 spike protein.
- A lipid nanoparticle formulation delivers the mRNA into the recipient's cells. Once inside a cell, the mRNA provides the instructions that allow the cell to manufacture the spike protein.
- Once manufactured, the spike protein exits the cell and becomes anchored onto the cell's surface.
- The immune system is activated to recognize the spike protein as foreign and initiates an immune response. The mRNA and spike protein are then cleared by the immune system.
- mRNA vaccines teach the cells how to make a protein that will trigger an immune response without using the live virus that causes COVID-19.
- mRNA vaccines **are not live vaccines** and **cannot cause infection** in the host.
- mRNA vaccines **cannot** alter a person's DNA.
- Once triggered by an exposure to COVID-19, the body makes antibodies.
- Antibodies provide protection from infection if the virus enters the body in the future.

Viral Vector-Based Vaccines-How do they work?

- Viral vector-based vaccine technology has been used to develop many vaccines for animals. This technology has also been used in the development of human vaccines, including an Ebola vaccine.
- Viral vector-based COVID-19 vaccines use a harmless virus (such as an adenovirus) as the delivery system to help recognize and fight disease.
- Adenoviruses are viruses like the common cold. Once injected into the body, the vaccine produces the SARS-CoV-2-spike protein.
- Through this process, the body is able to develop a strong immune response against the spike protein without exposing you to the virus that causes COVID-19.
- Viral vector-based vaccines **are not live vaccines** and **cannot cause infection** in the host.
- Viral vector-based vaccines **cannot** alter a person's DNA.
- Once triggered by an exposure to COVID-19, the body makes antibodies.
- Antibodies provide protection from infection if the virus enters the body in the future.

Vaccine Efficacy against Symptomatic COVID-19

- The currently authorized COVID-19 vaccines have been shown to be highly protective in the short term against serious COVID-19 disease. New information on effectiveness of vaccine against Variants of Concern (VOCs) is evolving and early indications is that some of VOCs may impact effectiveness.
- The first dose of COVID-19 vaccines has been shown to offer at least short-term protection against confirmed COVID-19 disease, **highest efficacy is seen after the second dose is administered (if applicable).**
- Protection begins from one to two weeks after receiving the full two-dose series (if applicable).
- There is currently no available evidence on medium and long-term protection of the authorized COVID-19 vaccines, this is being studied.
- **Pfizer-BioNTech Comirnaty** 95% effective-peak immune response is seen after the second dose is administered.
- **Moderna Spikevax** 86.4% to 94% effective-peak immune response is seen after the second dose is administered.
- **AstraZeneca Vaxzevria/COVISHIELD**) 62% effective-peak immune response is seen after the second dose is administered.
- **Janssen** 66% effective-peak immune response is obtained with one dose.

Recommended COVID-19 Vaccination Schedule

Early in the immunization program an effort to maximize the number of individuals having a first dose as soon as possible, the schedule was extended for up to 4 months from 1st to 2nd dose.

In June 2021, with vaccine supply increases, the second dose schedule moved from the 4 months interval to at least 8 weeks between first and second dose.

In July, 2021 the recommendation was updated to book second dose at least 28 days and up to four months after the first dose. Research has shown that a longer dosing interval may increase and prolong the immune response to the vaccine.

If a 2nd dose is given prior to 8 weeks the series would still be considered complete as long as there was at least 28 days between the doses. The series does not need to be restarted.

The mRNA (Pfizer-BioNTech Comirnaty or Moderna Spikevax) is the ***preferential*** vaccine for 1st and 2nd dose. The viral vector should only be given if there is a contraindication to mRNA (i.e. allergy to mRNA vaccine or any components).

Additional Dose for Special Populations

NACI (September 10, 2021):

Evidence to date shows that some individuals who are moderately to severely immunocompromised may have a lower immune response to COVID- 19 vaccines compared to the general population. **NACI identifies individuals that are moderately to severely immunocompromised as those with the following conditions:**

- Active treatment for solid tumour or hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, WiskottAldrich syndrome)
- Stage 3 or advanced untreated HIV infection and those with acquired immunodeficiency syndrome
- Active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (The Canadian Immunization Guide defines high dose steroids treatment as prednisone equivalent of ≥ 2 mg/kg/day or 20 mg/day if weight > 10 kg, for ≥ 14 days), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive

Booster Doses

NACI (On September 28, 2021) recommends that:

- A booster dose of an authorized mRNA COVID-19 vaccine (Pfizer-BioNTech Comirnaty or Moderna Spikevax) should be offered to long-term care residents and seniors living in other congregate settings who have already received a primary COVID-19 vaccine series.
- This dose should be offered at a recommended interval of at least 6 months after the primary series has been completed.
- A booster dose of an authorized viral vector vaccine (AstraZeneca Vaxzevria, Janssen) should only be considered when an mRNA COVID-19 vaccine is contraindicated or inaccessible.

Simultaneous Vaccination with other Vaccine Products

Updated NACI recommendation, September 28, 2021

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

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

- Previous guidance below for reference

- If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.
- COVID-19 vaccines should not be given simultaneously with other vaccines (live or inactivated) to maximize benefits of COVID-19 vaccination.
- Wait for at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine.
- Wait for at least 28 days after the administration of a COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis).
- There may be exceptions, such as an event of infectious disease exposure.
- There is insufficient evidence on the receipt of a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.

Vaccine Schedule Delays

- If administration of the second dose of a 2-dose COVID-19 vaccine series is delayed, the second dose should be provided as soon as possible.
- Interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series.
- Every effort should be made to vaccinate with the second dose according to the recommended schedule.

Receiving a second dose is essential to provide better and longer-term protection against COVID-19 for individuals and the entire community – NACI June 17, 2021

COVID-19 Vaccine Interchangeability

- For those who received an mRNA COVID-19 vaccine (Pfizer-BioNTech Comirnaty or Moderna Spikevax), the same mRNA vaccine should be offered as the second dose if possible. If the individual presents to a clinic that does not have that vaccine available or the individual is unsure what vaccine was received as the first dose, either mRNA (Pfizer-BioNTech Comirnaty or Moderna Spikevax) vaccine can be offered as they are considered interchangeable.

Pfizer-BioNTech Comirnaty COVID-19 Vaccine Ingredient List

Medicinal Ingredients: mRNA

Non-Medicinal Ingredients:

- ALC-0315 = (4hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide
- 1,2-distearoyl-sn-glycero-3- phosphocholine cholesterol
- dibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride, sodium chloride, sucrose, water for injection

Moderna Spikevax COVID-19 Vaccine Ingredient List

Medicinal ingredients: mRNA-1273 SARS-CoV-2

Non-medicinal ingredients:

- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- acetic acid
- cholesterol
- PEG2000 DMG (1,2-dimyristoyl-rac-glycerol,methoxy-polyethyleneglycol)
- lipid SM-102
- sodium acetate
- sucrose
- tromethamine
- tromethamine hydrochloride
- water for injection

AstraZeneca Vaxzevria and COVISHIELD COVID-19 Vaccine Ingredient List

Medicinal ingredients: Recombinant, replication-deficient chimpanzee adenovirus vector SARS-CoV-2 spike glycoprotein

Non-medicinal ingredients:

- Ethanol
- Disodium edetate dihydrate (EDTA)
- L-Histidine, L-Histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80
- Sodium chloride
- Sucrose
- Water for injection (DSPC)

Janssen COVID-19 Vaccine Ingredient List

Medicinal ingredients: adenovirus type 26 (Ad26) vectored SARS-CoV-2 spike protein

Non-medicinal ingredients:

- 2-hydroxypropyl-β-cyclodextrin (HBCD)
- Citric acid monohydrate
- ethanol
- Hydrochloric acid
- Polysorbate-80
- sodium chloride
- Sodium hydroxide
- Trisodium citrate dihydrate
- water for injection

Vaccine Side Effects

Vaccine side effects are expected, can develop following vaccination, and will go away on their own. The most common side effects include:

- pain and swelling at the injection site
- tiredness, headache, muscle pain, joint pain
- chills or fever
- enlarged lymph nodes (swollen glands) that last for several days
- nausea, vomiting, diarrhea
- dizziness
- decreased appetite
- excessive sweating
- itchy skin or rash

Serious side effects after receiving the vaccine are rare but can include:

- hives (bumps on the skin that are often very itchy)
- swelling of the face, tongue or throat
- difficulty breathing

Vaccine Adverse Events

- Health Canada has communicated on its ongoing assessment of very rare adverse events reported in numerous countries of thrombosis (blood clots) with thrombocytopenia (low blood platelets) after immunization with the AstraZeneca (Vaxzevria) and COVISHIELD vaccine.

- Vaccine-induced immune thrombotic thrombocytopenia (VITT) was identified following post-licensure use of these vaccines. The exact mechanism by which the vaccine may trigger this event is still under investigation.

- Rare cases of myocarditis and pericarditis following vaccination with mRNA vaccine have been reported in Canada and other countries. While there is no clear association, this may change as more evidence emerges. Most cases have been in males under age 30.

AstraZeneca Vaxzevria/COVISHIELD Adverse Events

People experiencing any of the following symptoms in the 4-35 days after immunization, should seek immediate medical attention. Advise the attending practitioner of recently receiving an AstraZeneca Vaxzevria/COVISHEILD COVID-19 vaccination.

- Persistent and severe headache
- Seizures
- Focal neurological symptoms (Movement changes or sensation changes that affects specific functions, for example, weakness or loss of muscle control on the left or right side of the face, left or right arm, or even a small area such as the tongue. Problems with speech, vision, and hearing can also occur.)
- Blurred vision
- Shortness of breath
- Chest or abdominal pain

Myocarditis and Pericarditis

There have been very rare reports of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine product.

- Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the lining around the heart.
- Myocarditis and pericarditis has been reported more frequently in males, those under 30 years of age, and after a second dose.
- The majority of cases have been mild and individuals have recovered quickly.
- Seek immediate medical attention if you develop symptoms, which may include chest pain, shortness of breath, or the feeling of a fast, pounding or fluttering heartbeat.
- These symptoms typically occur within a week after the receipt of an mRNA vaccine dose.

As a precaution, it is recommended that individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA vaccine should wait to get their second dose until more information is available.

Vaccine Adverse Events

Websites related to this issue:

covid-19-healthcare-professionals-vaccine-toolkit.pdf (canada.ca)

Health Canada taking further action to confirm the benefit-risk profile of the AstraZeneca vaccine - Canada.ca

AstraZeneca COVID-19 Vaccine and COVISHIELD: Risk of Thrombosis with Thrombocytopenia - Recalls and safety alerts (healthycanadians.gc.ca)

Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine | CDC Online Newsroom | CDC

Contraindications

All COVID-19 vaccines currently approved for use in Canada are contraindicated in individuals with:

- a history of anaphylaxis after previous administration of **any COVID-19** vaccine.
- immediate or anaphylactic hypersensitivity to any component of the vaccine.

Summary Table of Those Who Can Receive the COVID-19 Vaccine, Those Who May Be Offered the COVID-19 Vaccine, and Those Who Should Not Receive the COVID-19 Vaccine

Table 1: Summary Table of Those Who Can Receive the COVID-19 Vaccine, Those Who May Be Offered the COVID-19 Vaccine, and Those Who Should Not Receive the COVID-19 Vaccine

	INDIVIDUALS WHO **CAN RECEIVE** the COVID-19 Vaccine	INDIVIDUALS WHO **MAY BE OFFERED** the COVID-19 Vaccine Individuals in this category who are at high risk of exposure to COVID-19 infection should consult with their health care provider to discuss vaccination.	INDIVIDUALS WHO **SHOULD NOT RECEIVE** the COVID-19 Vaccine
Age	12 years of age and over **(Pfizer-BioNTech Comirnaty)** 12 years of age and over **(Moderna Spikevax)** 18 years of age and over **(AstraZeneca Vaxzevria, COVISHIELD, Janssen)**	12 to 15 years of age **(Pfizer/BioNTech/Moderna)**	11 years of age and younger **(Pfizer-BioNTech Comirnaty)** 11 years of age and younger **(Moderna Spikevax)** 17 years of age and younger **(AstraZeneca Vaxzevria, COVISHIELD, Janssen)**
Currently experiencing symptoms that could be related to COVID-19			You should **not** be vaccinated if you have symptoms that could be due to COVID-19. If you are feeling unwell, complete the COVID-19 Self Assessment Tool or call 811 to arrange testing.
Current COVID-19 infection or past COVID-19 infection	You can be vaccinated if you are no longer infectious (10 days since first symptom or 10 days since positive test) and your symptoms have resolved.		You cannot be vaccinated while infectious (within 10 days of your first symptom or positive test). Attending a clinic while you are experiencing symptoms of COVID-19 may cause spread of infection to others.
Pregnancy	Currently pregnant or planning to become pregnant before receiving both doses of COVID-19 vaccine.		
Breastfeeding	Currently breastfeeding.		
Allergy to polyethylene glycol (Pfizer-BioNTech Comirnaty and Moderna Spikevax). Found in some cosmetics, skin care products, laxatives, cough syrups, bowel preparation products for colonoscopy, and some foods and drinks. **Allergy to polysorbate 80 (AstraZeneca Vaxzevria, COVISHIELD, and Janssen).** Found in medical preparations (e.g. vitamin oils, tablets, and anti-cancer agents), cosmetics. **Allergy to Tromethamine (Moderna Spikevax)** Found in some medications injected to do tests (contrast media) as well as other medications taken by mouth or injection, and some creams and lotions.			If you have been told you are allergic to polyethylene glycol (PEG)*, polysorbate 80, Tromethamine, or have had an allergic reaction from an unknown cause, you should not be vaccinated until it is determined to be safe by an allergist or other health care provider.
You had a severe reaction or allergic reaction to a previous dose of COVID-19 vaccine			If you had a serious or allergic reaction to your first dose of COVID-19 vaccine, you should not be vaccinated until it is determined to be safe by an allergist or other health care provider.
Medical conditions Talk with your health care provider prior to vaccination if you are unsure about your medical conditions		Problems with your immune system, history of autoimmune conditions or currently taking medications/treatments.	

** The vaccine has not been studied well enough in the **"Generally Should Not Receive**" category. Therefore it is recommended to discuss with your primary health care provider if you are at high risk of exposure to COVID-19.*

Precautions

- 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.
- Vaccination should be deferred in symptomatic individuals with confirmed or suspected COVID-19 infection, or those with respiratory symptoms.
- Vaccination should be deferred until all symptoms of an acute illness (including fever) are completely resolved before vaccinating with COVID-19 vaccine.
- AstraZeneca (Vaxzevria) COVID-19 may be offered for first or second with full informed consent related to the risk of rare blood clotting condition linked to AstraZeneca (Vaxzevria).

Vaccine Information

Pfizer-BioNTech Comirnaty COVID-19 Vaccine (6 dose per vial, 7 doses may be obtained*)

- Each dose is 0.3 mL
- Reconstitution is required
- Approved for individuals 12 years of age and older

Moderna Spikevax COVID-19 Vaccine (two formulations 10 or 14 doses per vial*)

- Each dose is 0.5 mL
- If more than the 10 or 14 doses can be obtained they should be used
- Reconstitution is not required
- Approved for individuals 12 years of age and older

*A Low Dead Space (LDS) syringe is recommended in order to obtain the maximum number of doses for the Pfizer and Moderna vaccine.

Vaccine Information

AstraZeneca Vaxzevria and COVISHIELD COVID-19 Vaccine (10 dose vial)

- Each dose is 0.5 mL
- Reconstitution is required
- Approved for individuals 18 years of age and over

Janssen COVID-19 Vaccine (5 dose vial)

- Each dose is 0.5 mL
- Reconstitution is not required
- Approved for individuals 18 years of age and older

All COVID-19 vaccines are given as an intramuscular (IM) injection into the deltoid muscle.

There is currently no evidence on the need for booster doses of COVID-19 vaccine after the vaccine series is complete.

Pfizer/BioNTech (Comirnaty) Storage Requirements

Frozen vials prior to use

The Pfizer-BioNTech Comirnaty COVID-19 vaccine must be stored at ultra-low temperatures of -90 °C to -60 °C, protected from light, in the original packaging, until ready to use. Vials can be stored at -25° C to -15° C for up to two weeks. Keep vials upright. If using Pfizer-BioNTech's Thermal Shipper for storage, replenish the dry ice when received and then every five days up to a total of 30 days. A new data logger will be required to monitor the temperature after stopping the data logger that came with the thermal shipper.

The appropriate dates and times related to storage in the thermal shipper and dry ice replenishments should be recorded. The date and time the product is moved into the refrigerator should be recorded.

Thawed, un-punctured vials (prior to dilution)

The Pfizer-BioNTech Comirnaty COVID-19 vaccine may be thawed and stored at +2°C to +8°C for up to 2 days, not diluted. Or at room temperature (up to +25°C) for up to 2 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vials can be handled in room light conditions.
Do not refreeze thawed vials.

Thawed, punctured vials (after dilution)

The Pfizer-BioNTech Comirnaty COVID-19 vaccine must be stored between +2°C to +25°C and used within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.

For more information, consult the product monograph available through Health Canada's Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the CIG, Part 1 – Key Immunization Information for additional general information.

Pfizer/BioNTech Comirnaty Vaccine Storage and Handling Requirements

- Thawing in a vaccine refrigerator may take up to 2 or 3 hours based on a tray of up to 195 vials (fewer number of vials will thaw in less time).
- Frozen vials may also be thawed at room temperature up to 25°C (may take approximately 30 minutes) but need to be protected from room light and exposure to direct sunlight.
- Once the vaccine is removed from the ultra low temperature (ULT) freezer and placed in vaccine refrigerator, the vaccine tray must be labeled with transferred date and time.
- Ensure the first thawed undiluted vials of vaccine are used first, earliest dated vaccine should be used first.

Pfizer-BioNTech Comirnaty Vaccine Storage and Handling Requirements

Vials prior to dilution:

Vaccine must be brought to room temperature before dilution.

- may take approximately 30 minutes from the ULT freezer or Thermal Shipper
- may take 5-15 minutes from vaccine refrigerator

Vials after dilution:

- vaccine must be stored between 2°C to 25°C
- vaccine must used within 6 hours from the time of dilution
- label vial with date and time diluent was added
- vials can be handled in room light conditions

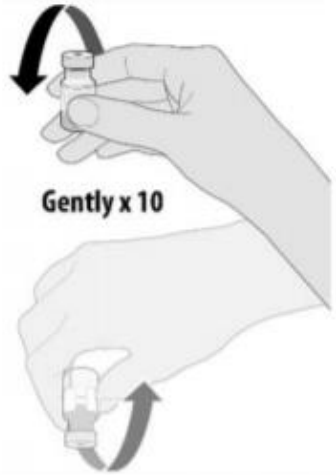
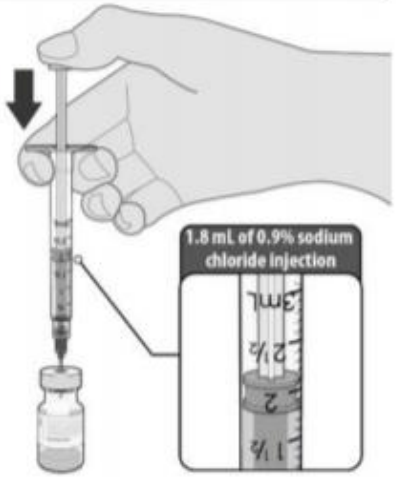
Points to Remember:

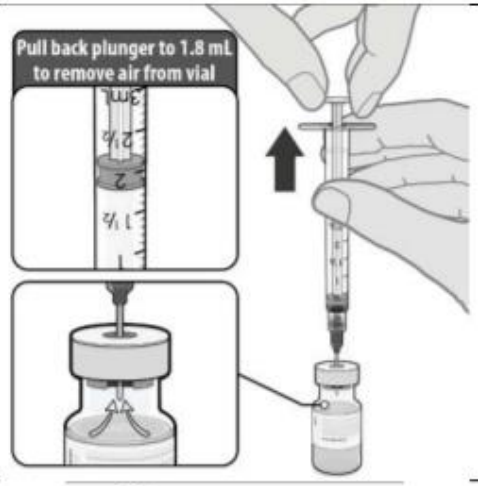
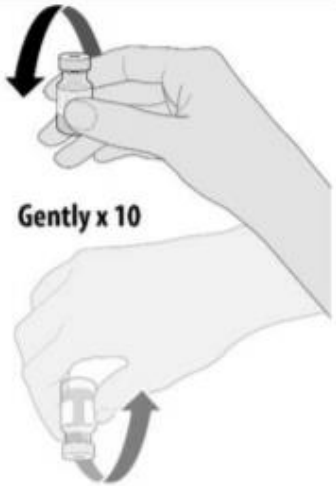
- do not preload vaccine in syringes
- discard any vaccine remaining in vials after 6 hours
- unused/wasted doses of vaccine should be captured on the COVID-19 Vaccine Clinic Worksheet and tracked in SEINET-Vaccine Management Module

Pfizer-BioNTech Comirnaty Vaccine Reconstitution

- Multiple dose vials contain a frozen preservative-free suspension and must be thawed and diluted prior to administration.
- Prior to dilution, the thawed suspension may contain a white to off-white opaque amorphous particles.
- Gently invert the **thawed** vaccine 10 times- **Do NOT shake.**
- The contents of the vaccine vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride.
- 0.9% Sodium Chloride vials are 10 ml, can only be used/punctured one time. **Discard remaining unused diluent.**
- The diluted vaccine will be an off-white suspension.
- Gently invert the **reconstituted** vaccine 10 times- **Do NOT shake.**

Never REFREEZE vaccine that has been thawed or diluted.

DILUTE BEFORE USE	
	• Remove a thawed vial of Pfizer-BioNTech COVID-19 Vaccine from the refrigerator and allow it to come to room temperature. • If using a frozen vial of Pfizer-BioNTech COVID-19 Vaccine, thaw for 30 minutes at room temperature. Vials at room temperature must be diluted within 2 hours.
	• Before dilution, invert **gently** 10 times to mix. • <u>Do not shake.</u>
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. • Cleanse the vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the Pfizer-BioNTech COVID-19 Vaccine vial using a needle 21-gauge or narrower.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• **Gently** invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • <u>Do not shake</u>.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

Moderna Spikevax COVID-19 Vaccine Storage and Handling

Frozen vials prior to use

The vaccine should be stored at temperatures of -25°C to -15°C in original carton to protect from light. Do not store on dry ice or below -40°C.

Thawed, un-punctured vials

The vaccine can be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to **24** hours.

Thawed, punctured vials

The vaccine should be stored between +2°C to +25°C and used within **24** hours from the time of first puncture. During storage, vials should be protected from light.

Do not refreeze thawed vials.

For more information, consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the CIG, Part 1 – Key Immunization Information for additional general information.

Moderna Spikevax COVID-19 Vaccine Storage and Handling

Thawing Vials Prior To Use

- Multiple-dose vial contains a frozen preservative-free suspension and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes.
- Thaw at room temperature between 15°C to 25°C for 1 hour.
- After thawing, let vial stand at room temperature for 15 minutes before administering.

After thawing, do not refreeze.

Punctured vials

- Once the vial has been punctured by a needle it can be stored at room temperature or refrigerated, but must be discarded after 24 hours.

After puncturing vial, do not refreeze.

Moderna Spikevax COVID-19 Administration

- Moderna Spikevax COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates.
- After thawing, let each vial stand at room temperature for 15 minutes before administering.
- Swirl the vial gently after thawing and between each withdrawal.
- **Do not shake.**
- Inspect vials for non-product related particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Administer intramuscular (IM) in the deltoid muscle of the upper arm.
- A needle length of ≥1 inch should be used.
- Using aseptic technique, cleanse the vial stopper with an alcohol swab.
- Withdraw each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection.
- Once a dose is withdrawn from the vial, it should be administered immediately.
- Once the vial has been punctured by a needle. it should be discarded after **24** hours. **It is important to date and time all vials.**

Unused/wasted doses of vaccine should be captured on the COVID-19 Vaccine Clinic Worksheet and tracked in SEINET-Vaccine Management Module.

Prefilled syringes for home bound clients- Moderna Spikevax Only

Preparing prefilled syringes of Moderna Spikevax vaccine (ONLY) for transport to home bound clients:

- Remove the appropriate number of vials to cover the number of doses required from storage unit.
- If vaccine is in frozen form, allow 2.5 hours at +2° C to +8° C or 1 hour at room temperature for time to thaw.
- Withdraw the number of doses needed to complete arranged home visits for vaccination. If an entire vial is not utilized, date and time of puncture must be clearly marked on the vial and it should be stored immediately in a regulated vaccine fridge and used within 24 hours.
- Using a cooler large enough to store the vaccine or prefilled syringes and 4-5 chill packs, pack items for transport and cover appropriately.
- Prefilled syringes should be cushioned into place to limit the amount of jostling during transit. Inserting paper among the prefilled syringes would be the best action.
- Add a thermometer inside the container next to the prefilled syringes. If a thermometer is not available, a cold mark and warm mark can be used. Refer to manufacturing guidelines to ensure warm and cold marks are appropriately prepared for transport. Temperatures must be maintained at +2° C to +25° C.
- Place cover on vaccine cooler. If it is recognized that not all the prefilled syringes or vaccine arranged to be administered that shift will be used every effort should be made to use any vaccine remaining in pre-filled syringe. Prefilled syringes must be utilized within **24** hours of when source vial was punctured.

THERE IS NO GUIDANCE AT THIS TIME FOR PREFILLED SYRINGES FOR OTHER COVID-19 VACCINES

AstraZeneca Vaxzevria and COVISHIELD COVID-19 Vaccine Storage and Handling

Unopened vial

AstraZeneca Vaxzevria and COVISHIELD vaccine are stable in a vaccine regulated refrigerator at +2° C to +8° C until its expiry date.

Opened vial

After the vial has been punctured, AstraZeneca Vaxzevria and COVISHIELD vaccine is stable for:

- 6 hours at room temperature (up to +25° C).
- 48 hours in a refrigerator at +2° C to +8° C.
- An opened vial can be re-refrigerated, but the cumulative storage time at rom temperature must not exceed 6 hours, and the total cumulative storage time must not exceed 48 hours.

Janssen COVID-19 Vaccine Storage and Handling

Unopened vial

Janssen vaccine is stable in a vaccine regulated refrigerator at 2 to 8 degrees Celsius until its expiry date.

Opened vial

After the vial has been punctured, Janssen vaccine is stable for:

- 3 hours at room temperature (up to +25° C)
- 6 hours in a refrigerator at +2°C to +8°C.

AstraZeneca Vaxzevria, COVISHIELD and Janssen Vaccine Administration

- AstraZeneca Vaxzevria vaccine is a colorless to slightly brown/opaque suspension. COVISHIELD and Janssen vaccines are colorless to slightly clear/opaque solutions.
- Swirl the vial prior to each withdrawal.
- **Do not shake.**
- Inspect vials for particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- Administer intramuscular (IM) in the deltoid muscle of the upper arm.
- A needle length of ≥1 inch should be used.
- Using aseptic technique, cleanse the vial stopper with an alcohol swab.
- Withdraw each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection.

Unused/wasted doses of vaccine should be captured on the COVID-19 Vaccine Clinic Worksheet and tracked in SEINET-Vaccine Management Module.

COVID-19 Vaccine Redistribution

Potential redistribution example scenarios:

- Transport to long term care facilities (LTC)
- Transport to an off-site or satellite clinic
- Transport to remote communities with lower population density
- Transport to another site to avoid wastage

Sites must use their own shipping containers, temperature monitors, and insulated carriers for redistribution.

For more information on Vaccine re-distribution guidelines, refer to the provincial document:

COVID-19-Vaccine-Shipping-and-Receiving-Guidelines.pdf (gov.nl.ca)

General Guidelines

- Individual vials or full trays of frozen Pfizer BioNTech Comirnaty vaccine must be redistributed undiluted in the **thawed state. DO NOT TRANSPORT VACCINE AFTER IT HAS BEEN RECONSTITUTED**
- Thawed vaccine must be securely packaged and transported in an insulated container at 2°C to 8°C.
- Vials should be stored upright whenever possible however, vials may roll around in the trays when being moved in and out of storage.
- Transportation time for Pfizer-BioNTech Comirnaty and Moderna Spikevax vaccine cannot exceed 12 hours.
- Avoid leaving containers in areas where they are exposed to direct sunlight.
- Track time vaccine is at room temperature.

DO NOT TRANSPORT VACCINE AFTER IT HAS BEEN RECONSTITUTED

Storage Guidelines for Point Of Use

- Check vaccine temperature upon arrival at the receiving site and store vaccines at recommended temperatures (2°C to 8°C) immediately.
- If vaccines cannot be stored in an on-site storage unit (i.e. vaccine refrigerator), they should be kept in a portable vaccine storage unit (i.e. insulated container).
- If using an insulated container, place a temperature monitoring device (preferably with a probe in a thermal buffer) as close as possible to the vaccines, check and record temperatures hourly, and keep the container closed as much as possible.

If there is a temperature excursion, please contact the regional CDC department for guidance.

Post-COVID-19 Vaccination Counselling

Advise individuals to:

- wait 15 minutes as with any vaccine administration.
- continue to practice recommended public health measures for prevention and control and transmission regardless of vaccination with COVID-19 vaccine.
- use oral analgesics or antipyretics for the management of side effects (e.g., pain or fever), if they occur after vaccination.
- return for second dose of the COVID-19 vaccine (if applicable).
- wait 28 days after a dose of COVID-19 vaccine before receiving any other vaccines.
- there are no contraindications related to pregnancy, COVID-19 vaccine can be given at any time during pregnancy and while breastfeeding.

Adverse Events Following Immunization (AEFI)

- It is important to stress to vaccine recipients the importance of notifying Public Health at _____of any adverse reactions.
- AEFI fillable forms should be completed right away on any reported adverse events.
- Completed AEFIs are to be submitted to:

_____

Medical Exemptions

A client with the following contraindication to receiving the COVID-19 vaccine as outlined by NACI can obtain a Medical Exemption from their primary health care practitioner.

- Severe allergic reaction or anaphylaxis after a previous dose of an mRNA vaccine.
- Severe allergic reaction to anaphylaxis to any of the components (including polyethylene glycol [PEG], tromethamine, and polysorbates) of the vaccine.
- A diagnosed episode of myocarditis or pericarditis after receiving a dose of a mRNA vaccine

Documentation

- Vaccine documentation is done through the Electronic Medical Record (EMR) with the exception of Long Term Care where Meditech will be used.
- Approved abbreviation for **Pfizer-BioNTech Comirnaty COVID-19 Vaccine** (COVID-19 mRNA vaccine).
- Approved abbreviation for **Moderna Spikevax COVID-19 Vaccine** (mRNA-1273 SARS-CoV-2 vaccine).
- Approved abbreviation for **AstraZeneca Vaxzevria/COVISHIELD Vaccine**
  (ChAdOx1-S [recombinant])
- Approved abbreviation for **Janssen Vaccine**
  (Ad26.COV2.S, recombinant)

NL COVID-19 Immunization Plan and Resources

https://www.gov.nl.ca/covid-19/vaccine/

References

1. Moderna Product Monograph:
https://pdf.hres.ca/dpd_pm/00059305.PDF

2. National Advisory Committee on Immunizations(NACI) Statement:
https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html

3. Pfizer/BioNTech Product Monograph:
https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf

4. Covishield / Astrazeneca Product Monograph
https://covid-vaccine.canada.ca/info/pdf/astrazeneca-covid-19-vaccine-pm-en.pdf

5. Janssen Product Monograph
https://covid-vaccine.canada.ca/info/pdf/janssen-covid-19-vaccine-pm-en.pdf

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