Immunization Protocol for Moderna SPIKEVAX® COVID-19 Vaccine

UPDATED OCTOBER 5, 2021

Purpose

- To provide information and guidance for the COVID-19 Immunization program in Nunavut
- To summarize National Advisory Committee on Immunization (NACI) recommendations on the use of the Moderna SPIKEVAX® COVID-19 Vaccine
- To summarize key information on the handling and administering the Moderna SPIKEVAX® COVID-19 vaccine
- To review COVID Consent Form and process
- To review Government of Nunavut and Health Canada's resources for anaphylaxis and acute reactions following vaccination

New Additions to Protocol Version 3

- Age of Eligibility: Individuals age 12 years and older without contraindications to the vaccine may now receive Moderna SPIKEVAX®
- Third dose for immunocompromised individuals
- Booster dose for LTC residents and seniors (age 60 and up) living in congregate settings at a recommended interval of at least 6 months after the primary series is completed
- Co-administration with other vaccines: COVID-19 vaccines may now be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines. Tuberculin skin tests (TSTs) are an exception to this rule.

New Additions to Protocol Version 3

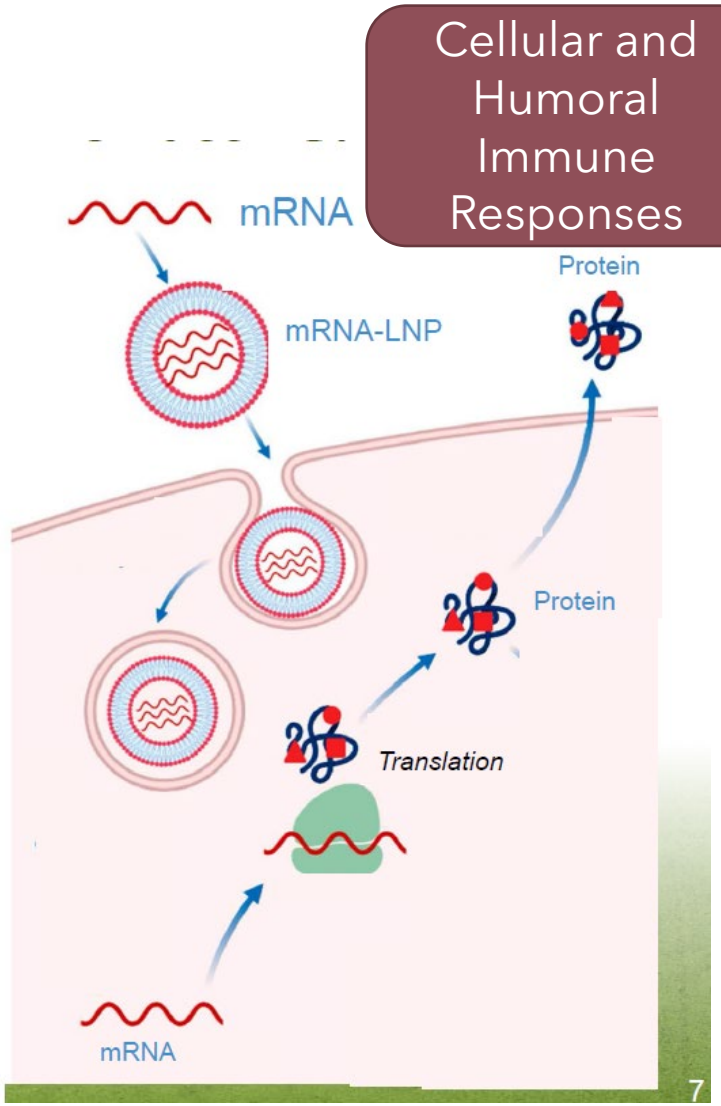
- People with SARS-CoV-2 infection may receive a complete series of a COVID-19 vaccine once they are no longer infectious and no longer have acute symptoms of COVID-19
- People who are pregnant and breastfeeding should be vaccinated with COVID-19 vaccines (unless otherwise contraindicated)
- People who are immunocompromised and people with autoimmune disease should be vaccinated with COVID-19 vaccines (unless otherwise contraindicated)
- Risk of myocarditis/pericarditis:
  - Reported in adolescents and younger adults under 30 years of age, more frequently in males compared to females, and more frequently after the second dose
- Vaccine stability at room temperature: Once a vial has been thawed to room temperature it is stable and can be used for up to 24 hours total cumulative time. This guidance remains the same whether the vial has been punctured or remains unpunctured

Product Information Moderna SPIKEVAX® COVID-19 Vaccine – mRNA-1273

- 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-dimyristol-rac-glycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection
- mRNA vaccines are not live vaccines and cannot cause infection in the host and cannot alter a person's DNA
- Multi-dose vial (10 doses), preservative-free. No dilution is required

About Vaccine

- mRNA is unstable, degrades quickly, therefore is surrounded by lipid layer to stabilize
- Lipid layer is called LNP (lipid nano particle) - forms like a balloon around the mRNA
- There are no human or animal particles in the vaccine
- IM injection → local inflammation when immune cells get to the site of the injection
- Result is that immune cells engulf the mRNA vaccine, transcribe into protein. Our own cells are used to create immune response



- Individual's aged 12 years and older without contraindications to the vaccine
- Contraindicated in:
  - Individuals who had a systemic allergic reaction, anaphylaxis, to first dose of COVID-19 vaccine
  - Individuals who were diagnosed with myocarditis or pericarditis following a previous COVID-19 vaccine
  - Individuals who had an allergy to polyethylene glycol (PEG), tromethamine or has had a severe allergic reaction to another component of the vaccine

Drawing-Up the Vaccine

1. Check for foreign particulates or discoloration (expect a white to off-white suspension; may contain white or translucent product-related particulates).
2. Use alcohol-based hand rub
3. Gently swirl the vial **(do not shake)**
4. Swab the vial stopper with the alcohol wipe and let dry
5. Ensure that the needle is tightly attached to the syringe by giving it an extra turn
6. Using aseptic technique and a new needle and syringe, draw up 0.5 ml
7. Mark the date and time of first puncture on the vial. Repeat steps 2, 3, 4, 5, and 6 to obtain 10 doses per vial
8. Discard the used needles and vial into the sharps container
9. Once the vial has been entered (needle-punctured), it should be discarded after 24 hours. Do not refreeze

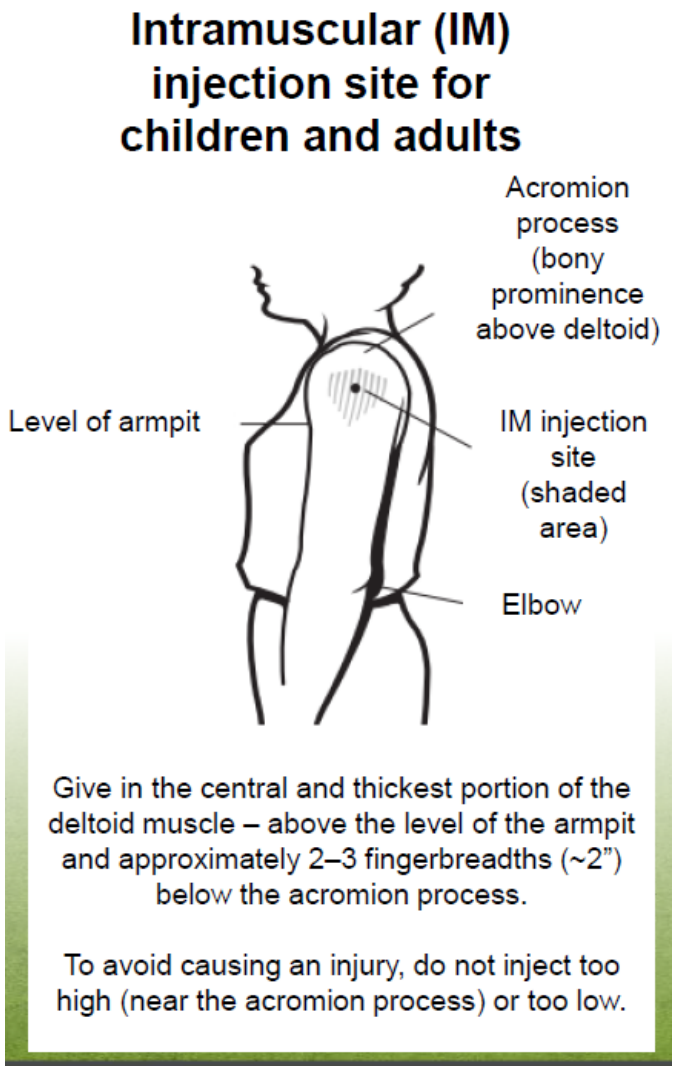
Remember not to flick the vial or needle for bubbles, and watch for wastage when drawing up

Site to use for IM Injections and Needle Length

- For most adults and adolescents, intramuscular (IM) injections should be into the deltoid muscle using a 2.5 cm (1 inch) 25-gauge needle
- For males weighing greater than 118 kg (260 pounds) and females weighing greater than 90 kg (200 pounds), the IM injection into the deltoid should use a 3.8 cm (1½ inch) 25-gauge needle.

Administering the Vaccine

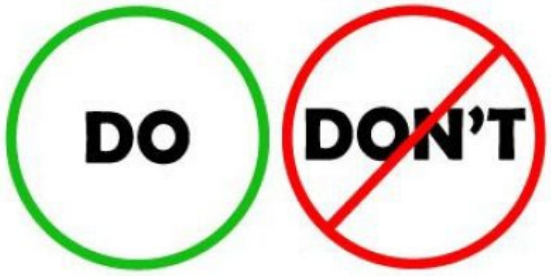
1. Use alcohol-based hand rub
2. Prepare the skin with alcohol wipe from the centre moving outwards – allow to dry
3. Give 0.5 ml dose intramuscularly in the deltoid
4. Discard needle and syringe immediately (or after activating the safety engineered device) into the sharps container
   - Do not put used needles down on the workstation
5. Use alcohol-based hand rub
6. Monitor client for 15 minutes post-vaccination for any adverse effects
7. Advise to return in 28 days for second dose
8. Client should be given the Aftercare Form, appointment card with date and time of next dose and immunization wallet card with current dose recorded



Administration Do's and Don'ts

DO

- Visually inspect the vials for foreign particulate matter and/or discoloration
- Thaw before use
- Once withdrawn from vial, administer within 5 minutes



DON'T

- **Do not** use the vial if foreign particulate and/or discoloration, discard if these conditions exist
- **Do not Shake the vial**, can make vaccine less or not effective
- **Do not** thaw too many vials at one time
- **Do not Refreeze** the vial under any circumstance
- **Do not transport immunizations** if unfrozen
- **Do not** pre-draw syringes

Dose Series

- Administered as IM in a series of 2 or 3 doses
- Each dose is 0.5 ml
- Doses are given 28 days (1 month) apart
- If administration of the second COVID-19 Moderna SPIKEVAX® vaccination is delayed, the dose should be provided as soon as possible
- The extended interval is 16 weeks (up to four months).
- If an individual is given a dose of mRNA vaccine outside of these parameters, an incident report should be filed on Meditech and the Regional Communicable Disease Coordinator (RCDC) and Territorial Communicable Disease Specialist (TCDS) are consulted for additional dosing guidance

Vaccine product	Immunization schedule	Dose volume	Minimum interval	Authorized interval	Alternate interval
Moderna COVID-19 vaccine	2-dose schedule	0.5 mL	21 days	1 month	None

Booster/Additional Dose

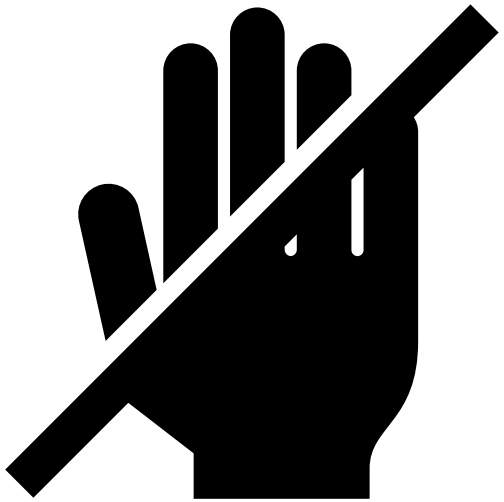
- Canada's National Advisory Committee on Immunizations (NACI) has recommended that an additional dose of an authorized mRNA COVID-19 vaccine be provided as part of the "primary series" to moderately or severely immunocompromised individuals. **This is not an authorization to administer booster dose to the general population**
- This interim authorization applies to individuals who are 12 years of age and over.
- An individual is considered moderately to severely immunocompromised if they have one of 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, Wiskott-Aldrich 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 (refer to the CIG for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.
- Meeting the minimal dosing interval requirement (at least 28 days) after receiving a 1 or 2-dose complete primary series

Vaccine Interchangeability

- NACI recommends that, 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.
- The previous dose should be counted, and the series need not be restarted.

Contraindications

- Until further studies are completed, the Moderna SPIKEVAX® vaccine is only authorized for use in people aged 12 years and older
- Contraindicated in person with proven or anaphylactic hypersensitivity to any component of the vaccine or it's packaging
- Two vaccine components have been identified as potentially resulting in a rare allergic reaction: polyethylene glycol (PEG) and tromethamine
- An authorized COVID-19 vaccine should not be offered routinely to individuals with a history of severe allergic reaction (e.g., anaphylaxis) after previous administration of a COVID-19 vaccine.
- If the patient has a history of myocarditis or pericarditis secondary to receipt of a COVID-19 vaccine, please consult the office of the CPHO for guidance before administering any COVID-19 vaccine



Precautions and additional notes

Anaphylaxis	•Appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic event following administration of this vaccine
Myocarditis/Pericarditis	•Health care professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with a COVID-19 vaccine
Acute Illness	•Consideration should be given to postpone immunization in persons with severe febrile illness or severe acute infection •Person with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved
Hematologic-Bleeding	•Should be given in caution with individuals with bleeding disorders such as haemophilia, or individuals on anticoagulant therapy to avoid the risk of haematoma following the injection, and when the potential benefit clearly outweighs the risk of administration. Control of the disorder should be optimized •Use a small gauge needle and apply pressure for 5-10 minutes after the immunization
Immune	•Immunocompromised persons, or those receiving immunosuppressant therapy may have a diminished immune response to this vaccine. •They would still need to wear a mask and practice a higher level of precautions until a significant proportion of their community has been immunized
Syncope	•Can occur before or following any vaccination as a psychogenic response to the needle injection •Precautions should be in place to prevent injury from fainting and manage syncopal reactions

Administration of Other Drugs/Biological Products

- COVID-19 vaccines may be given at the same time as, or any time before or after, other vaccines, including live, non-live, adjuvanted or unadjuvanted vaccines. Vaccines administered during the same visit should be administered at different injection sites
- There is a theoretical risk that the Moderna SPIKEVAX® COVID-19 vaccine may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results. If tuberculin skin testing or an IGRA test is required, it should be administered and read before immunization or delayed for at least 4 weeks afterwards
- However, in cases where an opportunity to perform the TST or IGRA test might be missed, the testing should not be delayed since these are theoretical considerations.

Special Populations: Pregnancy and Breastfeeding

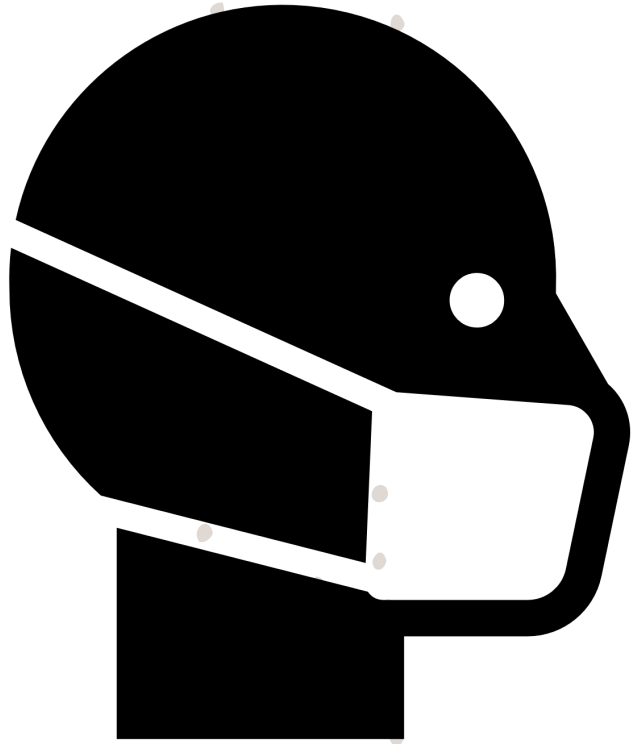
- People who are pregnant and breastfeeding should be vaccinated with COVID-19 vaccines (unless otherwise contraindicated).
- Emerging evidence suggests that COVID-19 mRNA vaccination during pregnancy is also immunogenic and results in comparable antibody titres to those generated in non-pregnant women.
- Maternal IgG humoral response to mRNA COVID-19 vaccines transfers across the placenta to the fetus, leading to a significant and potentially protective, antibody titre in the neonatal bloodstream one week after the second dose.
- Observational studies consistently show that both anti-spike IgG and IgA are present in breastmilk for at least 6 weeks after maternal vaccination with mRNA vaccines

Special Population: Previously infected with SARS-CoV-2

- People with SARS-CoV-2 infection can be vaccinated once they are no longer infectious and no longer have acute symptoms of COVID-19.
- NACI recommends previously infected individuals may receive a complete series of a COVID-19 vaccine.

Special Population: Immunocompromised

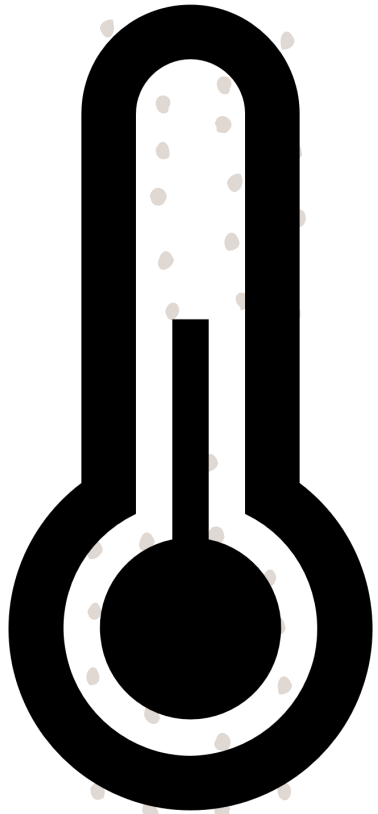
- Immunocompromised and people with autoimmune disease should be vaccinated with a 3-dose series of an mRNA COVID-19 vaccine (unless otherwise contraindicated).
- Ideally, the COVID-19 vaccine series should be completed 2 weeks before starting immunosuppressive therapy or when immunosuppressive therapy is the lowest but can be given when needed. This ensures that COVID-19 protection is provided sooner.
- These individuals should continue to follow public health recommendations on preventing infection with SARS-CoV-2 (such as wearing a mask, physical distancing, and hand hygiene) even if they have been vaccinated. Vaccination of their close contacts will also help protect them



Vaccine Handling

Storage

- The ideal way to store a vaccine is at temperatures of -25°C to -15°C
- If not punctured, the Moderna SPIKEVAX® COVID-19 vaccine can be thawed and refrigerated at +2°C to +8°C for up to 30 days, or kept at room temperature (+8°C to +25°C) for up to 24 hours
- Protect from light
- Do not store on dry ice or below -40°C
- Recommended not to be transported in liquid state
- Vials will be sent in a frozen state
- Please refer to the Transporting and Tracking Vials of Moderna SPIKEVAX® COVID-19 Vaccine from Pharmacy in Iqaluit to Client Vaccination in appendix



Thawing

Room Temperature
+8°C to +25°C

- Thaw for 1 hour, consider additional 15 minutes as giving cold immunization can be painful
- Once thawed can stay at room temp for 24 hours
- Time of puncture does not reset the time – discard after 24 hours at room temperature

OR

Refrigerator
+2°to +8°C

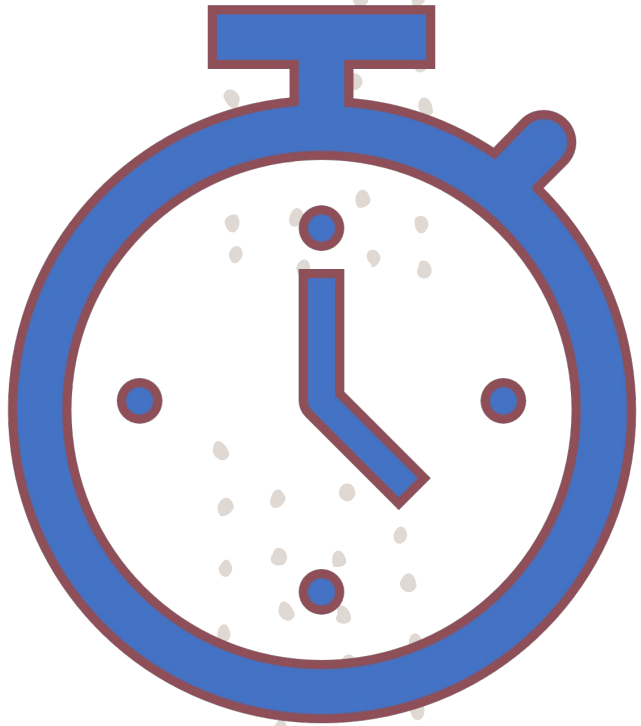
- Thaw for 2.5 hours
- If vial unpunctured can stay at fridge temp for 30 days
- Should come to room temp for 15 minutes before administering

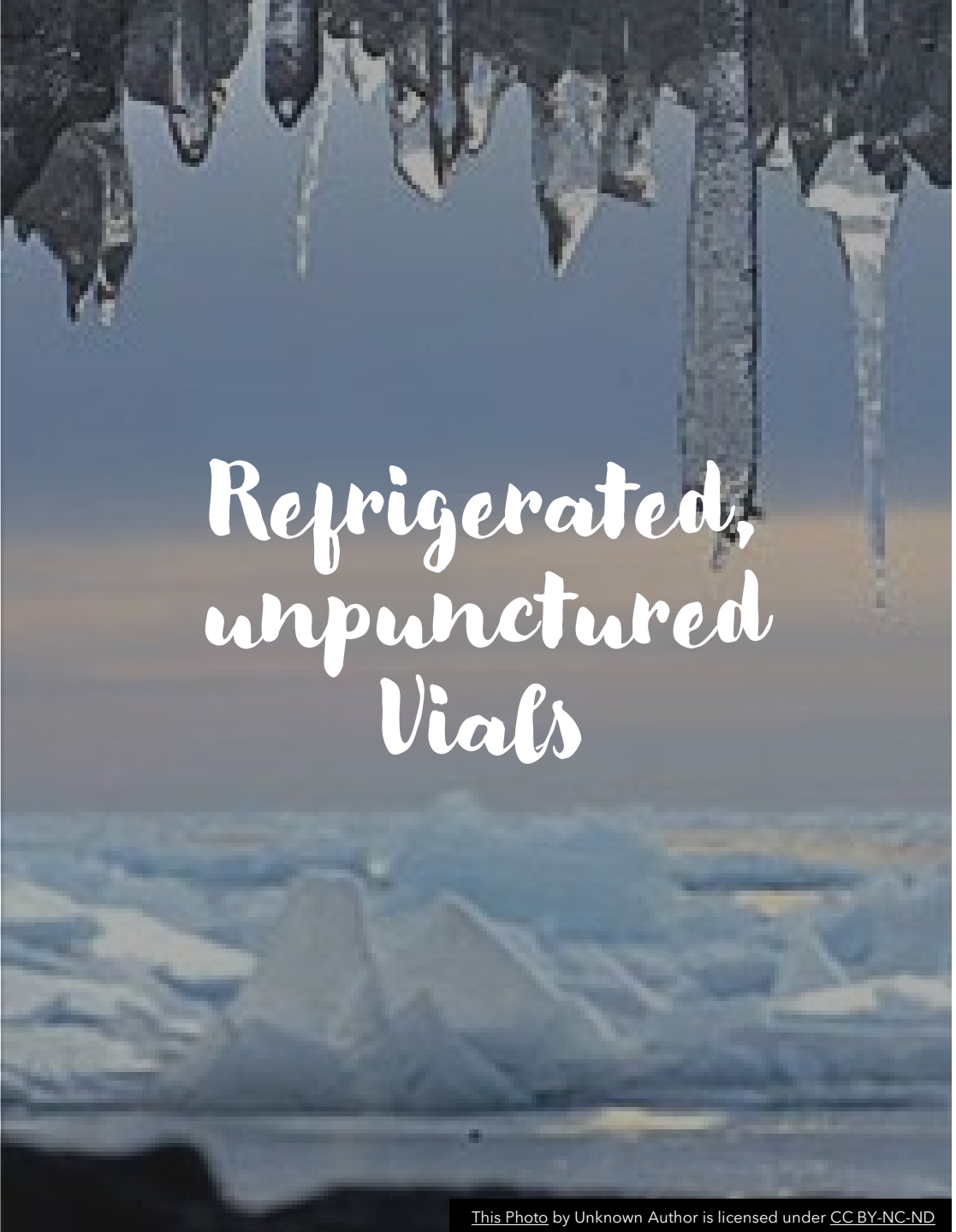
Thawing

The date and time brought into room temperature or the refrigerator should be marked so that the product is not used beyond the appropriate time

- Mark the start time and indicate clearly that it is the start time
- Also clearly indicate the end time

Once thawed, it is not to be refrozen





- Vials can be stored in the refrigerator between 2°C to 8°C (36°F to 16°F) for up to 30 days prior to first use
- Unpunctured vials may be stored between 8°C to 25°C (46°F to 77°F) for up to 24 hours
- The total time at room temperature should not exceed 24 hours. For instance, if a vial is punctured after 23 hours of being at room temperature, it is only stable for another 1 hour (cumulative total of 24 hours). The time of puncture does not reset the time. **
- After vaccine placed in refrigerator and thaws do not refreeze
- After removing from refrigerator, let the vial stand at room temperature before administering (approximately 15 minutes)

Punctured Vials

- Once the vial has been entered or needle-punctured, it can be stored at room temperature or refrigerated
- Regardless of where it is stored it **MUST** be discarded after 24 hours
- **DO NOT REFREEZE**

Consent

Immunization providers have an ethical and legal responsibility to ensure that individuals receiving immunizations, or their guardians, are fully informed when making a decision to receive or refuse any vaccine in Nunavut

- Consent forms must be reviewed and signed by the client prior to vaccination
- Typically, an 18 yr old would have the ability to make their own decisions about vaccination as a mature minor
- If this is not the case, a substitute decision-maker must sign the consent

Essential Criteria for Informed Consent

- Must be given willingly and freely without coercion
- The immunization provider must ensure the vaccine recipient is capable for consenting, or that when required, an appropriate guardian or substitute decision maker is present to give consent
- Information regarding the risks and benefits of both receiving and not receiving the vaccination should be provided
- The information should be given in a culturally sensitive way, preferably in their own language. Vaccine specific information sheets have been translated to assist in this process
- An opportunity to ask questions should be provided
- Minor side effect that occur frequently, any severe adverse (anaphylaxis), precautions and contraindications should be discussed
- Please see section 3.0 Practice Guidelines from the Government of Nunavut Immunization Manual found at https://gov.nu.ca/health/information/manuals-guidelines

Department of Health
Munaqsiliqiyikkut
Ministère de la Santé

Moderna SPIKEVAX® COVID-19 Vaccine Consent Form

Please fill in or put label:
Last Name_____
First Name_____
Community_____
DOB (dd/Month/yyyy)_____

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

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

Phone number: _____ **Email address (optional):** _____

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

For the person receiving the vaccine, please answer:

Is this your first or second dose of the Moderna SPIKEVAX® vaccine? ☐ 1st ☐ 2nd ☐ 3rd
***3rd dose only available for individuals with moderate - severe immunocompromise and individuals over 60 years of age. For eligibility criteria, please see Nunavut Moderna SPIKEVAX® protocol.
If second or third dose, on what date was your previous dose given? _____ *dd / Month / yyyy*

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

* Breastfeeding is not a contraindication to receiving the Moderna SPIKEVAX® vaccine, it can still be offered.

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

*** Tromethamine can rarely cause allergic reactions and is found in found in contrast media, oral and parenteral medications.

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

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Moderna SPIKEVAX® COVID-19 Vaccine Consent Form

Please fill in or put label:
Last Name_____
First Name_____
Community_____
DOB (dd/Month/yyyy)_____

Comments from questions above:

CONSENT FOR MODERNA SPIKEVAX® COVID-19 Vaccine:

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

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

_____ **Print Name**

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

Additional questions to help understand the populations receiving the vaccine

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

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Moderna SPIKEVAX® COVID-19 Vaccine Consent Form

Please fill in or put label:
Last Name_____
First Name_____
Community_____
DOB (dd/Month/yyyy)_____

For Administrative Use Only:

	DOSE	LOT#	SITE & ROUTE	GIVEN BY & WHEN Name and designation/Date and time
1st Dose	0.5 ml			**Name:** **Date:** *dd /Month / yyyy* **Time:**
2nd Dose	0.5 ml			**Name** **Date:** *dd /Month / yyyy* **Time:**
3rd Dose	0.5 ml			**Name:** **Date:** *dd/Month/yyyy* **Time:**

Comments:

Side Effects

Injection site reactions:

- Pain at the injection site
- Tenderness and swelling of the lymph node (underarm) on the same side of the injection
- Swelling (hardness) and/or redness

Systemic Side Effects:

- Fatigue
- Headache
- Muscle and/or joint pain
- Chills, fever
- Nausea and/or vomiting

Side Effects

- In general, side effects are more common after the second dose and among younger age group (18-64)
- Side effects have a median duration of 1-3 days
- The most frequently reported adverse reactions after any dose were pain at the injection site (92%), fatigue (70%), headache (64.7%), myalgia (61.5%) and chills (45.4%)

There is a remote chance that Moderna SPIKEVAX® COVID-19 Vaccine could cause a severe allergic reaction. It is important to have each person wait for 15-30 minutes after receiving their immunization and ensure the client knows how to contact the clinic staff if they feel unwell

Anaphylaxis

- Anaphylaxis is a serious, potentially life-threatening allergic reaction to foreign antigens. Anaphylaxis should be anticipated in every vaccine
- Pre-vaccination screening is critically important to identify potential risk factors
- Signs and symptoms have a sudden onset and progress rapidly over several minutes and involves two or more body systems
- Most frequently involved systems are skin (80-90%), respiratory (up to 70%)
- Less frequently are cardiovascular and gastrointestinal (each up to 45% of cases)
- Up to 15% of cases may also manifest CNS changes of uneasiness, altered mental status, dizziness, or confusion
- Ensure a minimum of two anaphylaxis kits are available
- If there are any concerns about a potential allergic reaction to the vaccine the client is asked to wait for 30 minutes

Anaphylaxis

- Features of severe anaphylaxis include obstructive swelling of the upper airway, marked bronchospasm and hypotension. Hypotension can progress to cause shock and collapse

System	Signs and symptoms
General/CNS	Fussiness, irritability, drowsiness, lethargy, reduced level of consciousness, somnolence
Skin	Urticaria, pruritus, angioedema, flushing
Upper airway	Stridor, hoarseness, oropharyngeal or laryngeal edema, uvular edema, swollen lips/tongue, sneezing, rhinorrhea, upper airway obstruction
Lower airway	Coughing, dyspnea, bronchospasm, tachypnea, respiratory arrest
Cardiovascular	Tachycardia, hypotension, dizziness, syncope, arrhythmias, diaphoresis, pallor, cyanosis, cardiac arrest
Gastrointestinal	Nausea, vomiting, diarrhea, abdominal pain

CNS Central nervous system

Anaphylaxis Management

- IM is the preferred route for the administration of epinephrine and the thigh is the preferred site for its administration
- When IM immunization is given and epinephrine is indicated, it should not be administered into the same muscle mass as the vaccine was administered
- Administer epinephrine IM immediately. Failure to use epinephrine promptly is more dangerous than its improper use
- DO NOT inject epinephrine into the same muscle mass (e.g., thigh) as the vaccine was administered
- When administering diphenhydramine hydrochloride IM, preferably administer at a different site to that in which epinephrine was given. However, if necessary, give diphenhydramine hydrochloride in the same thigh as that in which epinephrine was given
- Administration of epinephrine and diphenhydramine hydrochloride may be recorded on the “Anaphylaxis Assessment Guide and Record” found in section 3.7.11.
- Report the case of anaphylaxis using the Adverse Events Following Immunization (AEFI) form found in Section 3.5. The form is available here: https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html

Anaphylaxis: Initial Management in Non-Clinical Setting

IMMEDIATELY:

- call for help: _____ (phone number)
- Give epinephrine (1:1000) **IM** into an unimmunized thigh.
- If both thighs were used for immunization:
  - Give epinephrine **IM** into deltoid if client is ≥ 12 months old
  - Give epinephrine **SC** into upper outer triceps area of the arm(s) if the client is < 12 months
- If both thighs and both arms were used for IM immunizations, give epinephrine **SC** into upper outer triceps area of the arm(s) or into the fatty area of the anterolateral thigh.
- **DO NOT** give epinephrine into the same muscle mass as vaccine was given.

Epinephrine Dose: 0.01ml/kg to maximum of 0.5ml OR:	
AGE	**EPINEPHRINE**
2 – 6 months	0.07 ml
7 – 12 months	0.10 ml
13 months – 4 years	0.15 ml
5 years	0.20 ml
6 – 9 years	0.30 ml
10 – 13 years	0.40 ml
≥ 14 years	0.50 ml

- Position client in recumbent position and elevate legs, as tolerated symptomatically
- Monitor respiratory effort, pulse and level of consciousness

IF PERSON'S BREATHING IS MORE LABOURED OR LEVEL OF CONSCIOUSNESS DECREASES

- Repeat epinephrine twice at 5 minute intervals, as needed (max. 3 doses)
- Alternate right and left thigh or arm sites for repeat doses of epinephrine
- Elevate head and chest slightly
- If airway is impaired use head tilt, chin lift or jaw thrust
- If vomiting is likely, turn person to side lying position

IF SYMPTOMS ARE NOT CONTROLLED *or* TO MAINTAIN SYMPTOM CONTROL IF CLIENT CANNOT BE TRANSFERRED TO ACUTE CARE FACILITY WITHIN 30 MINUTES

- Give **one dose** of diphenhydramine hydrochloride 50mg/ml IM **preferably** at a different site to that in which epinephrine was given. If necessary, use the same thigh as the one in which epinephrine was given. Can also be given into same muscle mass as vaccine was given.
- Can give at any time interval, either after the initial or repeat doses of epinephrine.

AGE	Diphenhydramine hydrochloride
< 2 years	0.25 ml
2 – 4 years	0.50 ml
5 – 11 years	0.50 – 1.0 ml
≥ 12 years	1.0 ml

Anaphylaxis Assessment Guide and Record

DATE OF EVENT: ___ / ___ / _____ (dd/mm/yyyy)

Time of Onset of Symptoms: _____

Name: _____
(Last name, First Name)

Date of Birth: ___ / ___ / _____ (dd/mm/yyyy)

Medication Administered	Pulse (per min)	Resp (per min)	Time	Route	Dose	Site	Initials
Epinephrine #1							
Epinephrine #2							
Epinephrine #3							
Benadryl (diphenhydramine)							

Time of transfer to emergency setting: _____

Signs and symptoms (*circle pertinent findings*):

- **Skin/Mucosal:** Urticaria, angioedema, generalized itch, flushing
- **Respiratory:** Dyspnea, chest tightness, wheezing, cough, stridor
- **Cardiovascular:** Hypotension, chest discomfort, dizziness, syncope, headache
- **Gastrointestinal:** abdominal pain, nausea, emesis, diarrhea,
- **Other** (please list): _____

Vaccine Information

Vaccine(s) Given	Manufacturer	Lot #	Dose #	Route	Site	Time given

Vasovagal Syncope (fainting)

- Fainting has no adverse consequence but during, a fall or sever head injury could occur
- Usually occurs during immunization or within minutes of immunization
- If a client has fainted before during a vaccination they should be vaccinated laying down if possible; ensure to use privacy screen
- Client may complain of feeling light-headed, then become pale, lose consciousness and collapse to the ground
- May be accompanied by brief clonic seizure activity, bradycardia and faint peripheral pulses with a strong carotid pulse. Skin may be cool and clammy with some nausea and vomiting
- Place client supine, elevate lower extremities
- If vomiting occurred or is imminent, position client on one side
- Recovery usually occurs within a minute or two
- Client should be monitored for a full 30 minutes post vaccination/syncope

Clinical features	Anaphylaxis	Vasovagal syncope
Onset from time of immunization	Within minutes up to 4 hours after injection; most within 2 hours	During or within minutes of injection
Skin	Urticaria, angioedema, pruritus, erythema	Generalized pallor, cold clammy skin
Respiratory	Cough, wheeze, stridor, respiratory distress, rhinorrhea, sneezing	Normal respiration – may be shallow but not laboured
Cardiac	Tachycardia	Bradycardia
Neurologic	Sense of severe anxiety and distress; loss of consciousness – no improvement once supine or in head down position	Sense of light-headedness; loss of consciousness – improves once supine or in head down position; may be transient jerking of the limbs and eye-rolling

Reportable Adverse Events/Side effects/Administration Errors

Report all serious adverse events requiring medical attention, unusual/unexpected events, or medication errors to the RCDC Frances Digout at Fdigout@gov.nu.ca

- Rare reactions: Those that have been reported and confirmed after taking an mRNA vaccine are:
  - Myocarditis and pericarditis
  - Bell's palsy (facial paralysis)
  - Guillain- Barré syndrome
  - Anaphylaxis
- The AEFI form is available here: https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization.html
- If an inadvertent vaccine error occurs, you should:
  - Inform the client of the vaccine administration error as soon as possible. Explain the possibility for local or systemic reactions.
  - Complete an incident report on Meditech and notify the RCDC. Some examples of inadvertent administration errors include incorrect route, higher-than-authorized dose volume administered, lower-than-authorized dose volume administered, dose administered past the expiration date, etc.
  - Complete an AEFI form and submit it to the RCDC only if the inadvertent vaccine administration error results in an AEFI

Events that SHOULD be reported

- Serious events: life threatening or resulting in death; requiring hospitalization; resulting in a residual disability; associated with congenital malformation.
- Event requiring urgent medical attention.
- Unusual or unexpected events
- Clusters of events: known or new events that occur in a geographic or temporal cluster (e.g., 6 in a week) that require further assessment, even if the total number of AEFIs may not be higher than expected

Events that should NOT be reported

- Local injection site reactions and non-specific systemic reactions (e.g., headache, myalgia) should not be reported as AEFI unless these are more frequent or severe than expected based on clinical trial findings (rates and severity are typically found in the product monograph). However, always counsel clients about expected reactions following immunization and how to manage these reactions.
- Events which have another obvious cause (e.g., co-existing conditions)

Example	AEFI Report Form
Anaphylaxis	Fill out and send AEFI Report Form
Any time epinephrine given related to vaccine administration	Fill out and send AEFI Report Form
Medical care provided related to vaccine administration	Fill out and send AEFI Report Form
Mild local injection side redness/sore ness	No AEFI Report Form
Syncopal event	No AEFI Report Form
Fear of needles	No AEFI Report Form (unless medical care required)
Other co-existing morbidities such as arthritis with resulting sore joints	No AEFI Report Form

When to fill out an Adverse Event Following Immunization?

Recommendations following an adverse event

- Completed AEFI report forms should be scanned and emailed to the Regional Communicable Disease Coordinator (RCDC) as soon as possible after event
- The RCDC may determine a process for assessment and decision-making regarding reported adverse events, and which events assessed by a health care provider will require reviewing by the Chief Public Health Officer (CPOH).

Public Health Agency of Canada / Agence de santé publique du Canada

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

INSTRUCTIONS: ***For more complete instructions and definitions, refer to the user guide at:***
http://www.phac-aspc.gc.ca/im/aefi-form-eng.php

Report events which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. A causal relationship does not need to be proven, and submitting a report does not imply causality.

Of particular interest are those AEFIs which:
a. Meet one or more of the seriousness criteria
b. Are unexpected regardless of seriousness

Refer to the user guide, Background Information and for additional clarification.

NOTE:
- **The numbers below correspond to the numbered sections of the form.**
- **All dates should be captured in the following format: YYYY/MM/DD.**
- **When reporting an AEFI, check one of the boxes on the top right hand corner of the first page of the AEFI form to indicate whether it is an INITIAL or FOLLOW UP report. For all follow up reports, please specify the Unique Episode number.**

1a. The **"Unique episode number"** is assigned by the Province/Territory. Leave it blank unless authorized to assign it.
1b. The **"Region number"** is a number that corresponds to a given health unit. Leave it blank if it doesn't apply to your locale.
2. The "IMPACT LIN" is assigned by IMPACT nurse monitors (LIN: Local Inventory Number).
3. The information provided in this section is confidential and should not be sent to the Public Health Agency of Canada.
4a. Indicate the Province/Territory where the vaccine was administered, abbreviations may be used.
4c. Provide all information as requested in the table. For the "Dose #", provide the number in series (1, 2, 3, 4, or 5) if known. For the Influenza vaccine, unless a patient receives two doses in one season, the "Dose #" should be recorded as "1".
7a. Indicate the highest impact of the AEFI on the patient's daily activities as assessed by the patient or the parent/caregiver.
7c. Provide details of any investigations or treatments in section 10. If the patient was already in hospital when immunized and the immunization resulted in a longer hospital stay, indicate "Resulted in prolongation of existing hospitalization" and provide the number of days by which the patient's hospital stay was prolonged. For all hospitalizations, indicate the date of admission and discharge.
8. MOH/MHO: Medical Officer of Health, MD: Medical Doctor, RN: Registered Nurse.
9. Choose, from section 9 (AEFI details), the description that best fits the AEFI being reported. Make sure to record the time of onset and duration of signs/symptoms using the most appropriate time unit: Days, Hours or Minutes. Provide additional details of any investigation, therapy, and other information as appropriate in section 10.
11. This section is to be completed by the CMOH/DCMHO of Nunavut
12. Information in this section is not collected by all P/Ts.

Return completed form to your RCDC:

All completed forms should be faxed to RCDC at the numbers listed below:
Qikiqtaaluk: 867-975-4833; Kitikmeot 867-983-4088; Kivalliq: 867-645-8272

Date modified: NU 2014-02-20

Canada

Initial report
Follow up report (Unique episode #)

EVENTS FOLLOWING IMMUNIZATION (AEFI)

1b. Region #: 2. IMPACT LIN:

Last name: Health number:

Postal code: Phone: ( ) - (ext #:)

Last name: Relation to patient:

nunization and AEFI Onset

Age: _____

Other

4b. Medical history (up to the time of AEFI onset)
(Check all that apply and provide details in section 10)
❑ Concomitant medication(s)
❑ Known medical conditions/allergies
❑ Acute illness/injury

Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
				/		
				/		
				/		
				/		
				/		

rect immunization? ○ No ○ Unknown ○ Yes
provide details in section 10)
nded age limits ❑ Product expired
ncorrect route
nended for age ❑ Other, specify: _____

6. Previous AEFI
Did an AEFI follow a previous dose of any of the above immunizing agents (Table 4c)?
(Choose one of the following)
○ No ○ Yes *(Provide details in section 10)*
○ Unknown ○ Not applicable (no prior doses)

and Level of Care Obtained

(Choose one of the following)
ctivities
vent daily activities

7b. Outcome at time of report:
○ Death * Date: ○ Permanent disability/incapacity *
○ Not yet recovered * ○ Fully recovered ○ Unknown
*(Provide details in section 10 for items with *)*

ined: *(Choose one of the following)*
lephone advice from a health professional ○ Non-urgent visit ○ Emergency visit
__days) **OR** ○ Resulted in prolongation of existing hospitalization (by ____days)
pital admission Date of hospital discharge

○ Unknown ○ Yes *(Provide details of all treatments including self treatment, in section 10)*

○ Public health ○ Hospital ○ Other, specify: _____
Phone: ( ) - (ext #:) Fax: ( ) -

Prov/Terr: Postal code: Date reported:

_____ ○ MD ○ RN ○ IMPACT ○ Other, specify: _____

er parent/caregiver reason for reporting and confidentiality of information

Canada

IPACT LIN: Name: DOB

h, check all signs/symptoms that apply. Item(s) with asterisk (*) should be on to support the selected item(s). Use Section 10 for additional

Days from immunization to onset of 1st symptom or sign
Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Reaction crosses joint ❑ Lymphadenitis ❑ Other, specify: _____

Induration ❑ Rash ❑ Largest diameter of vaccination site reaction: ____ cm
Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound)
❑ Lymphangitic streaking ❑ Regional lymphadenopathy

Days from immunization to onset of 1st symptom or sign
Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Syndrome (ORS) ○ **Other allergic events**

❑ Prickle sensation ❑ Rash *(For these events, specify site of reaction)*
Uvula ❑ Larynx ❑ Lip EYE(S): ❑ Red bilateral
imbs ❑ Other, specify: _____ ❑ Red unilateral ❑ Itchy
se volume ❑ Capillary refill time >3 sec ❑ Tachycardia

e voice ❑ Sensation of throat closure ❑ Stridor
ezing ❑ Indrawing/retractions ❑ Grunting ❑ Cyanosis
❑ Difficulty breathing ❑ Chest tightness
usea ❑ Vomiting

Days from immunization to onset of 1st symptom or sign
Days from onset of 1st symptom/sign to resolution of all symptoms/signs

n-Barre Syndrome (GBS) ❑ * Bell's Palsy ❑ * Other Paralysis

onality change lasting ≥24hrs ❑ Focal or multifocal neurologic sign(s)
❑ EEG abnormality ❑ EMG abnormality
ic abnormality
○ No ○ Unknown
○ No ○ Unknown
onic-Clonic ○ Atonic ○ Absence ○ Myoclonic) **OR** ○ Partial
❑ Afebrile ❑ Unknown type)

ys from immunization to onset of 1st symptom or sign
s from onset of 1st symptom/sign to resolution of all symptoms/signs

veness
❑ **Rash** *(Non-allergic)* ○ Generalized ○ Localized (Site) _____
❑* **Thrombocytopenia** ❑ Platelet count <150x10⁹/L
❑ Petechial rash ❑ Other clinical evidence of bleeding
❑ **Anaesthesia/Paraesthesia** (❑ Numbness ❑ Tingling
❑ Burning ❑ Formication ❑ Other, specify: _____)
○ Generalized ○ Localized (Site) _____
❑ **Fever ≥38.0°C** *(Note: report **ONLY** if fever occurs in conjunction with a reportable event. For fever in a neurological event, use section 9c)*

❑ **Other serious or unexpected event(s) not listed in the form** *(Specify and provide details in Section 10)*

Name: DOB:
Region #: IMPACT LIN:
ate the section # when providing details. Please provide details of any investigation or treatment for

on(s) according to the Federal/Provincial/Territorial best practices.
CTION IS TO BE COMPLETED BY THE CMOH OR DCMOH

Controlled setting for next immunization
No further immunizations with: _____ *(specify)* _____
Active follow up for AEFI recurrence after next vaccine
❑ Other, specify: _____

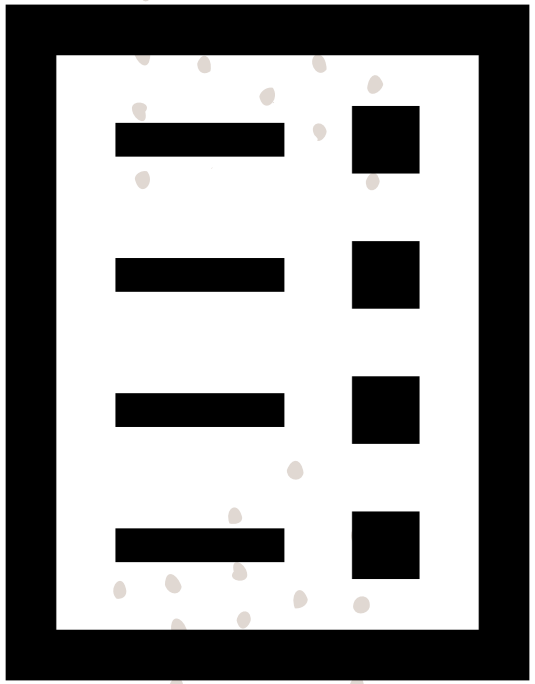
ofessional status: ○ CMOH/DCMHO ○ MD

) Date: Signature: _____

dose of same vaccine(s) *(Provide details in section 10)*

❑ Vaccine administered without AEFI ❑ Vaccine administered with recurrence of AEFI ❑ Vaccine administered, other AEFI observed
❑ Vaccine administered without information on AEFI ❑ Vaccine not administered

Documentation



- All immunizations given should be documented on Meditech and the Vaccine Vial Tracking Forms
- Update recipient's Personal Immunization Record and/or COVID-19 Vaccine wallet card as requested and provide date of next dose of vaccine.

Mandatory Vaccine Tracking (Draft)

NU COVID-19 VACCINATION - MANDATORY VACCINE VIAL TRACKING - MODERNA SPIKEVAX®

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

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

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

LOT#	
EXPIRY	

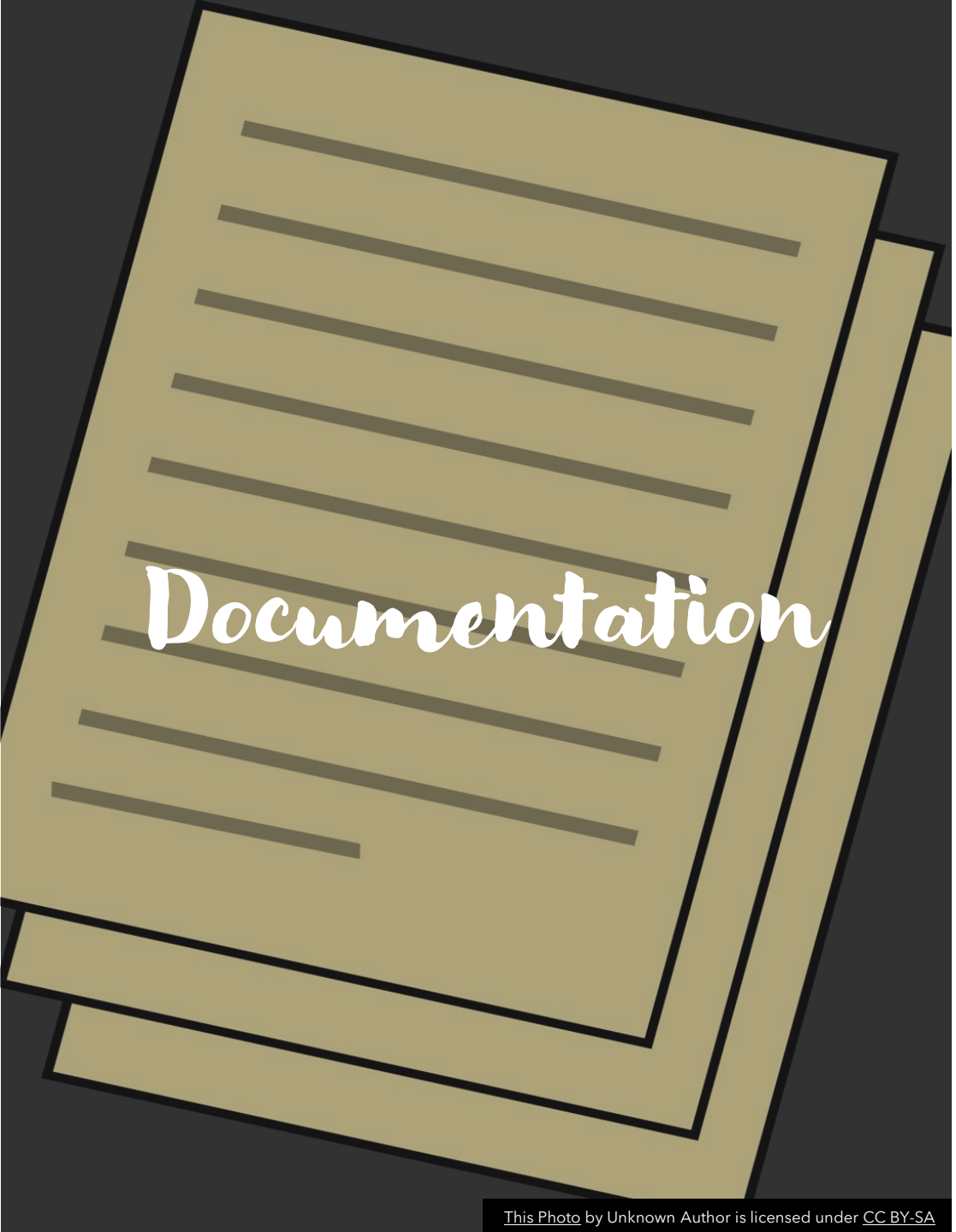
		ASSIGNED VIAL #					
		Name of Person Signed out to:					
		Name of Person Assigned to**:					
Removed from Freezer:		time (24hr)					
Thawed in refridgerator: (held at +2°C to +8°C) (takes 2.5 hours to thaw) (stable for 30 days)		Y / N					
		start time					
		end time					
		date to discard by (30days)					
Thawed at Room Temperature: (held at +8°C to +25°C) (takes 1 hour to thaw) (stable for 24 hours unpunctured)		Y / N					
		start time					
		end time					
		time to puncture by (24 hours)					
Vial Punctured (stable 24 hours ONLY)		Y / N					
		start time					
		end time (must discard)					
Initials of clients given dose from vial (optional) (to help with tracking number of doses)		1					
		2					
		3					
		4					
		5					
		6					
		7					
		8					
		9					
		10					
		11					
Doses Used from Vial: (usual 10 per vial)		Administered					
		Wasted*					
		Wastage code					
		Waste/use comments					
Vial used for home visiting		Y / N					
Signature of vaccine floater or clinical lead							

*Note: wasted or discarded refers to all unused doses (timed out, no one left to vaccinate without transporting vial, only 9 doses came out of vial means 1 wasted even if manufacturer issue). Important to capture and track accurately for program, impossible for it not to occur to some extent.
** If same person assigned to for all vials, can draw a line through to the end to indicate this
Please follow green and red sticker process as outlined by pharmacy team.
Empty vials - keep and store. Send count of empty vials at end of day. Vials can be discarded when this tracking sheet matched, signed off, and sent to RCDC and cdclabs@gov.nu.ca

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

Wastage Codes	
AA	Damaged vial/vaccine
BB	Refridgerated > 30 days
CC	Room Temp > 24 hours
DD	Punctured > 24 hours
EE	Not enough in Vial (i.e. < 0.5ml)

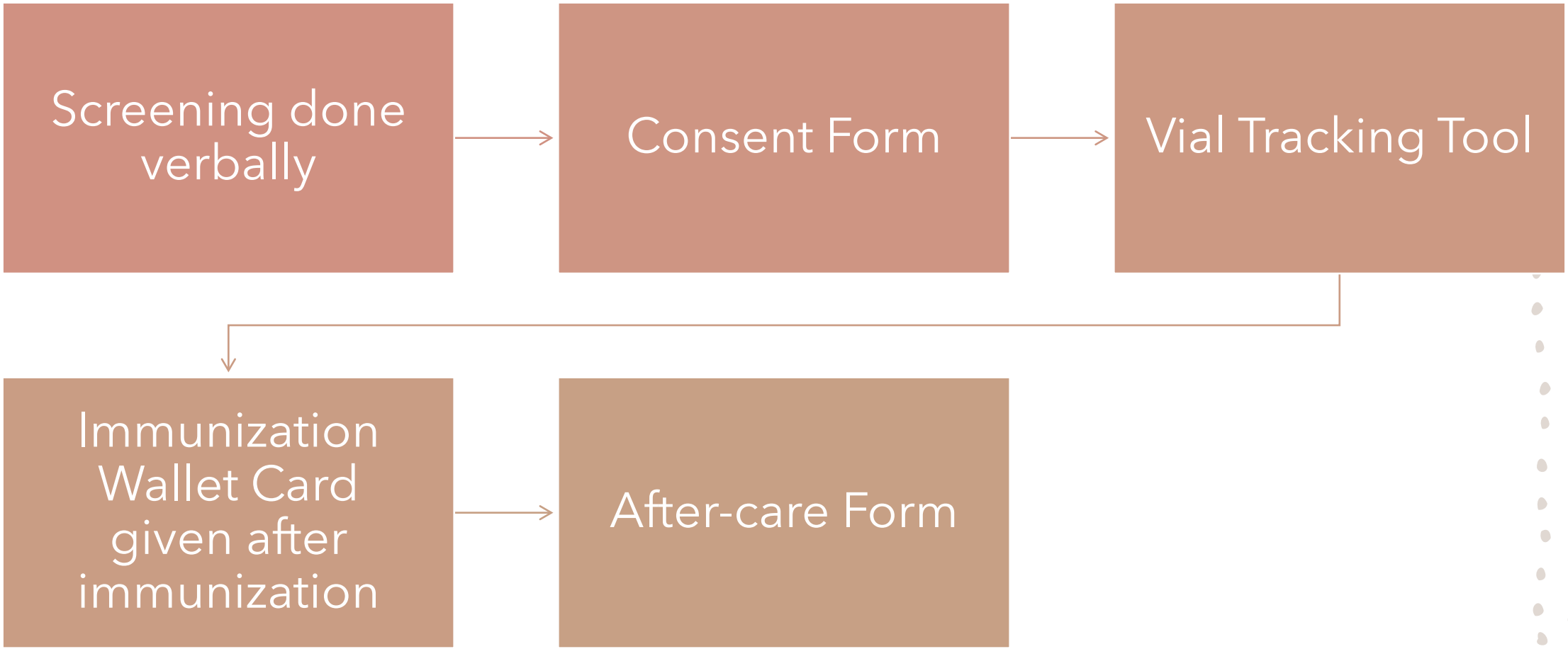
Additional Notes / Comments / Observations on storage/transport/use:



To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record :

- Time and date of administration
- Quantity of administered dose
- Anatomical site and route of administration
- Brand Name and generic name of the vaccine
- Product lot number

Documentation Workflow



Building Nunavut Together
Nunavuliuqatigiingniq
Bâtir le Nunavut ensemble

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

Last Name _____ First Name _____

Date of Birth _____

Vaccine	Date	Signature
st Dose	dd / mmm / yyyy	
nd Dose	dd / mmm / yyyy	

Please keep this card as a proof of your vaccination

Vaccination in the context of COVID-19

In the context of a pandemic, staff must abide by the infection prevention and control requirements for the immunization clinics:

- Including wearing the appropriate personal protective equipment
- Performing hand hygiene
- Remaining 2 meters apart from others where feasible and except as required to offer immunizations.

For additional information on infection prevention and control please consult: https://www.gov.nu.ca/sites/default/files/infection_prevention_and_control_resources.pdf

PPE

A point of care risk assessment is the usual practice for decisions about personal protective equipment. Immunizers should wear mask and eye shield. In communities with an ongoing outbreak of COVID-19, additional precautions maybe considered in line with current guidance and approach of health centre.

- PPE for staff working in Vaccine clinic will be a surgical mask
- PPE for staff working in Vaccine clinic who are immunizing will be a surgical mask and eye protection (face shield or goggles)
- No gloves are needed
- PPE for staff working in Vaccine clinic in an outbreak community will be surgical mask, and face shield
- Stations to be wiped down at minimum on an hourly basis, or when the staff change at the station, and/or when area is visibly soiled

Resources

- Moderna (2021). SPIKEVAX (elasomeran mRNA vaccine). Moderna: 2021. Available: covid-19-vaccine-moderna-pm-en.pdf (canada.ca) (accessed September 20, 2021).
- National Advisory Committee on Immunization (2021). An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI). Public Health Agency of Canada: 2021. Available: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html (accessed September 20, 2021).
- National Advisory Committee on Immunization (2021). National Advisory Committee on Immunization (NACI) rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2-dose primary series September 10, 2021.Public Health Agency of Canada: 2021. Available: National Advisory Committee on Immunization (NACI) rapid response: Additional dose of COVID-19 vaccine in immunocompromised individuals following 1- or 2- dose primary series-Canada.ca (accessed September 20, 2021).
- National Advisory Committee on Immunization (2021). National Advisory Committee on Immunization (NACI) rapid response: Booster dose of COVID-19 vaccine in long-term care residents and seniors living in other congregate settings September 28, 2021. Public Health Agency of Canada: 2021. Available: NACI rapid response: Booster dose in long-term care residents and seniors living in other congregate settings - Canada.ca (accessed September 28, 2021).

Questions