



Appendix B COVID-19 Vaccine Protocol

Guidance for Vaccination with COVID-19 Vaccines During a Home Visit

Background:

There are several reasons a small number of individuals may not be able to come to the health centre or clinic to be vaccinated and may need to receive the COVID-19 vaccine at home. While every effort should be made for clients to travel to the clinic for their immunization, there will be circumstances where this is just not feasible. The purpose of this document is to outline a procedure to bring the vaccine to these clients in a home visit in a way which ensures:

- The vaccine is transported in a way which maintains its effectiveness when administered.
- Wastage of the vaccine resulting from the home visit is as limited as possible.

Note that COVID-19 vaccines are more unstable than most other vaccines currently in use and there is concern that jarring or shaking the vaccine would make the vaccine less effective or ineffective. Frozen transport is preferred to any liquid/thawed transport. **Do not transport pre-filled syringes or punctured/diluted vials.**

Preparing for a home visit:

Please note that COVID-19 vaccines are less stable than most other vaccines currently in use and they are recommended to be transported in a frozen state and then thawed (please see appropriate thawing guidance in the SPIKEVAX® and COMIRNATY® COVID-19 immunization protocols as they are unique for both vaccines).

The risk of transporting the vaccine in a liquid, thawed state is that any jarring or shaking, even from going over a gravel road in a car, would render the vaccine ineffective and not protect the vaccinated client from COVID-19 infection so frozen is the preferred option.

The following steps should take place at least a day before the home visit is planned:

Identifying Health Care Providers:

- Two healthcare staff are to attend the home visit, including an interpreter if required. If only one nurse is available to attend, a second attendant must accompany in case any urgent situations arise.



Identifying clients:

- Home care clients should be carefully screened to identify individuals who cannot access the clinic. All options to assist the client to attend the clinic should be explored before making plans for a home visit. This could include doing a radio call out for volunteers to drive clients who require assistance to the clinic.
- Once a client has been identified for home visit - explore with the client and family if anyone else in the house is eligible to receive the vaccine. Consideration should be given to vaccinating anyone in the household who is eligible to reduce wastage of vaccine by using all doses in the vial. Please review eligibility requirements in the appropriate COVID-19 immunization protocol.
- If the community has an Elder's apartment complex (these are self-contained / separate apartments) and there is one Elder who cannot reasonably travel to the clinic, consider offering vaccination to all Elders living in those apartments at the same time to minimize wastage / doses discarded.

Obtaining consent:

- When clients are identified, make arrangements to conduct a home visit, with an interpreter if required, to obtain their informed consent for the vaccine. You will need to take both the consent forms and information sheets to this visit. The consent forms are brought back to the health centre and the information sheet left with the client.
- If possible, obtain consent, in advance, from other eligible family members, other household contacts or others in the apartment building at the same time. This helps to confirm there will be 10 people willing to be vaccinated during the same visit. While this is a time-consuming process, it will reduce vaccine wastage.
- Note that this step may be combined with the visit itself in some circumstances. At minimum, verbal consent should be obtained prior to the home visit.

Making appointments:

- At the visit to obtain consent, provide an appointment card. Alternatively, advise the client that they will be contacted by the health centre to confirm the appointment date and time.
- Inform the client and family in advance that the healthcare team may be at the home for longer than one hour, to allow required thawing time. Reminder: thawed vials cannot be moved between households.

Securing vaccine:

- Notify the person in charge of ordering the vaccine that a vial will be required for vaccinations during a home visit so that a vial will be available on that day.



- Refrigeration packs for transporting the vaccine are to be assembled with the cooling packs placed in the freezer or fridge. For any inquiries related to vaccine transport, please contact your regional pharmacy or the COVID-19 Special Operations Division.

On the day of the home visit:

- The morning of the home visit, the clerk is to contact the client to:
 - Confirm the time for the home visit.
 - Confirm that the client and household members are still wanting to receive vaccine.
 - Screen for any symptoms of acute or febrile illness using the COVID-19 Vaccine Clinic Screening Questionnaire.
 - Confirm all individuals eligible for the vaccine are booked and registered on Meditech.
- The clerk should notify the nurse of any concerns prior to the visit.
- Gather supplies (see list below) and assemble the transportation refrigeration pack (see Appendix A for details on assembling pack).
- The frozen or fridge temperature vial will be signed out to indicate it is being used for a home visit. A Vaccine Vial Tracking Log will need to accompany the vaccine. The vial should not be taken out of the freezer or fridge and put into the refrigeration pack until the health care team are ready to leave the health centre. **Do not transport pre-filled syringes or punctured/diluted vials.**
- **The refrigeration cooler with the vial should be held in the hands or on the lap of one of the immunizers during transport. The cooler is not to be put on the floor or in the trunk of a car. Every attempt should be made to carry the cooler without jostling.**
- The vial is transported back to the clinic in the cooler to be discarded; any wastage is recorded on the Vaccine Vial Tracking Log. NOTE: Any remaining doses in a punctured vial should not be used after transport.

Documentation:

- Once the team returns from the home visit, it is the nurse's responsibility to document the encounter on 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.



Materials Needed to Administer the Vaccine (non-outbreak community):

Patient's file and immunization record cannot leave the health centre but should be reviewed prior to the home visit.

<input type="checkbox"/> Cell phone	<input type="checkbox"/> Vaccination record wallet card
<input type="checkbox"/> Anaphylaxis kit – (Appendix B)	<input type="checkbox"/> Completed Consent Forms
<input type="checkbox"/> Cooler with frozen packs and vaccine (Appendix A).	<input type="checkbox"/> Spare Consent Forms and Information Sheets in appropriate languages
<input type="checkbox"/> Surgical masks (for providers, client and household members)	<input type="checkbox"/> 10 - After Care sheets in appropriate languages
<input type="checkbox"/> Disposable face shield or goggles	<input type="checkbox"/> Reporting Adverse Event Forms
<input type="checkbox"/> Hand sanitizer	<input type="checkbox"/> Vaccine Log
<input type="checkbox"/> Cotton balls or gauze pads	<input type="checkbox"/> Blue pad
<input type="checkbox"/> Sterile syringes and needles	<input type="checkbox"/> Sharps container
<input type="checkbox"/> Antiseptic swabs	<input type="checkbox"/> Bag(s) for used materials

Materials Needed to Administer the Vaccine (outbreak community):

- In addition to above materials, the following additional PPE is required:
 - Disposable gown, gloves, booties.



During the home visit (non-outbreak community):

1. Just before leaving the clinic, the clerk to call the client and notify them the team is en-route.
2. Don mask before leaving the car; bring masks for household members.
3. Remove outerwear and don face shield (or goggles) immediately upon entering the home.
4. Ask the clients and others in the home to also don a mask.
5. Sanitize hands, put a blue pad down on a surface to create a clean field and remove the frozen vial from the refrigerated container, marking the time the vaccine is removed on the Vaccine Vial Tracking Log. Record the time the vaccine will be thawed (1 hour later), diluted (if applicable) and when it should be discarded. For patient comfort, the vaccine can be left at room temperature for a further 15 minutes to ensure room temperature and minimize discomfort.
6. While vaccine is thawing, review informed consent a final time in case client has any questions. At this time, also review consents of other household members receiving the vaccine.
7. Place remaining vaccine administration supplies on the clean field. The sharps container and anaphylaxis kit placed nearby and easily accessible.
8. Prepare and administer as per the appropriate COVID-19 Immunization Protocol.
9. Put syringe directly into the sharps container and document vaccine administration on the back of the consent form. Give client the After Care sheet.
10. Stay with the client for at least 15 minutes to ensure there are no adverse reactions; 30 minutes if there are concerns about allergies. Ensure client has a means to contact health centre if having a reaction beyond the 15 minute wait.
11. Give client their vaccination record wallet card as well as an Appointment Card with a date for the second dose according to the appropriate vaccine protocol. Inform the client the health centre will contact them prior to the next appointment.
12. Collect used materials and take with you in a bag.
13. Perform hand hygiene with hand sanitizer.



During the home visit (outbreak community):

- As above with additional measures to prevent transmission of infection - droplet and contact precautions when visiting the home of a client with suspected COVID-19. This includes gown, gloves, booties, surgical mask and face shield.
- Additional resources are available in the Infection Prevention and Control Manual and Housekeeping Manual including posters on donning and doffing PPE.
- In an outbreak community it would be safer to vaccinate household contacts rather than those who live in other households in the same building to reduce the spread of infection. This may mean some vaccine wastage occurs.

Additional Infection Prevention and Control Strategies:

1. Explain to client that you will be using disposable PPE and ask if your disposable PPE can be left in the home for the client to discard. Explain to client that they should maintain at least 2 metres physical distancing while removing PPE.
2. Only carry supplies required to administer vaccine and disposable PPE. Avoid using your cell phone or accessing anything that may be in your pockets.
3. Bring vaccine supplies into the house as described above – in outbreak communities, may wish to wait outside of home for part of the time while vaccine is thawing.

References

Ontario Ministry of Health. (2020). Novel Coronavirus (COVID-19) Guidance for Home and Community Care Providers Retrieved from: http://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/2019_home_community_care_guidance.pdf

Government of Nunavut, Department of Health. Immunization Manual. Retrieved from: <https://www.gov.nu.ca/health/information/manuals-guidelines>



Appendix A: 3.1.7 Maintaining Cold Chain during Transport

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

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



Hard-sided plastic insulated container

Refrigerator-conditioned cold packs

Newer Styrofoam cooler with walls at least 2 inches thick

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

Container for transport

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



Cooling Packs

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



Frozen Packs





Insulating Barrier/Filler Materials and the Vaccine

Packing peanuts

Bubble wrap

Blue pads



Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from individual boxes – if multiple vials are in a single box the vial required for the home visit will need to be removed. Be sure to fill any spaces between vaccine boxes with crumpled paper or other filler to prevent shifting of contents in the insulated container.



Temperature Monitor

Warm/cold markers Min/max thermometer

Use a properly placed min/max thermometer or cold chain

monitor near the vaccine. The temperature- monitoring device should be placed in the middle of the vaccines and should not come in contact with the refrigerated or frozen packs.



References:

1. Adapted from Nova Scotia Immunization Manual, by the Government of Nova Scotia, 2008. Adapted with permission.
2. Public Health Agency of Canada (2007). National Vaccine Storage and Handling Guidelines for Immunization Providers [PDF version]. Retrieved from <http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/pdf/nvshglp-ldemv-eng.pdf>.



Appendix B: 3.7.6 Anaphylaxis Management in the Community

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

This section is intended as a guide for the initial management of patients in a mass immunization clinic, public health clinic, or similar non-emergency setting. For severe life-threatening anaphylaxis, advanced care should be managed in the health centre or hospital setting following the protocol outlined in Section D-09 and D-10 of the Government of Nunavut Drug Formulary.

Action of Epinephrine

IM is the preferred route for the administration of epinephrine and the thigh is the preferred site for its administration.

When epinephrine is administered intramuscularly, it acts on beta adrenergic receptors found in the skeletal muscle vasculature causing vasodilation. Thus, when IM immunization is given and epinephrine is indicated, it should not be administered into the same muscle mass as the vaccine was administered. The epinephrine will produce vasodilation locally at the site, increase vascular permeability, and may increase absorption of the offending antigen.

Side effects of excessive doses of epinephrine pose little danger but can add to the person's distress by causing palpitations, tachycardia, flushing, and headache. Cardiac dysrhythmias can occur in older adults but are rare in otherwise healthy children.

Administration of Epinephrine

Call emergency response as per community guidelines.

Administer epinephrine IM immediately. The most important step in the management of anaphylaxis is the immediate administration of aqueous epinephrine 1:1,000. Failure to use epinephrine promptly is more dangerous than its improper use. Use the epinephrine dosing chart outlined in "Anaphylaxis: Initial Management in Non-hospital Setting" in Section 3.7.10.

IM injection of epinephrine into the thigh is the preferred route for administration.

DO NOT inject epinephrine into the same muscle mass (e.g., thigh) as the vaccine was administered.



If the thigh cannot be used in a child \geq 12 months of age or an adult (e.g., client has received IM injections in both thighs), give epinephrine IM into the deltoid muscle(s).

If both arms and both legs have been used for IM immunizations, administer epinephrine SC into the upper outer triceps area of the arm(s), or into the fatty area of the anterolateral thigh.

Injection of epinephrine can be made through clothing, if necessary. Repeat epinephrine at 5-minute intervals twice as needed (i.e., if breathing becomes more laboured or level of consciousness decreases). Note: Administer a maximum of three doses of epinephrine.

Alternate between right and left thigh or arm sites for repeat doses of epinephrine (to maximize absorption of epinephrine).

Note: An epinephrine self-injector (Epipen or Twinject) can also be used in the situation when the immunization provider is not present and if the layperson who administers the self-injector is knowledgeable about proper use. The regular preparations contain 0.3 mL of epinephrine 1:1000 and can be used for individuals over 6 years of age. If a vaccinee or their parent/guardian refuses the administration of epinephrine when it is indicated, inform them of the risk and immediately call for help to arrange for transfer to an acute care facility. The administration of diphenhydramine hydrochloride (Benadryl) is not appropriate in this situation. Diphenhydramine hydrochloride is considered second-line therapy to epinephrine and should never be administered alone in the treatment of anaphylaxis.

Diphenhydramine Hydrochloride (Benadryl)

Give one dose of diphenhydramine hydrochloride (Benadryl) IM as an adjunct to epinephrine when the person is not responding well to epinephrine, or to maintain symptom control in those who have responded (as epinephrine is a short-acting agent). Its use is recommended when transfer to an acute care facility cannot be done within 30 minutes. Its use is considered second-line therapy to epinephrine and should never be administered alone in the treatment of anaphylaxis.

The approximate doses for injection (50 mg/ml solution) are outlined in “Anaphylaxis: Initial Management in Non-hospital Setting” in 3.7.10. NOTE: BENADRYL IS PAINFUL WHEN GIVEN IM.

When administering diphenhydramine hydrochloride IM, preferably administer at a different site to that in which epinephrine was given. However, if necessary, give diphenhydramine hydrochloride in the same thigh as that in which epinephrine was given.

Diphenhydramine hydrochloride can be given into the same muscle mass as the vaccine was given.



Diphenhydramine hydrochloride can be given at any time interval either after the initial or repeat doses of epinephrine, as indicated by the person's condition.

3.7.7 Other Considerations

Position client in the recumbent position and elevate legs, as tolerated symptomatically. This slows progression of circulatory compromise, if present, by preventing orthostatic hypotension and helping to shunt effective circulation from the periphery to the head, heart, and kidneys.

Monitor pulse, respiratory effort, and level of consciousness to guide medication use: • If person experiences respiratory difficulty: elevate head and chest slightly.

- If airway is impaired: improve position by using head tilt, chin lift, or jaw thrust.
- If vomiting is likely, turn person to side lying position.

Arrange for rapid transport by vehicle to the health center or emergency room (depending on community). Since 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2 – 9 hour asymptomatic period, hospitalization or a long period of observation is recommended for monitoring.

3.7.8 Recording of the Anaphylactic Event

Administration of epinephrine and diphenhydramine hydrochloride may be recorded on the "Anaphylaxis Assessment Guide and Record" found in section 3.7.11.

Report the case of anaphylaxis using the Adverse Events Following Immunization (AEFI) form found in Section 3.5.

Document the vaccine reaction on Immunization Record under the comments section.

Await the CPHO review and recommendation regarding subsequent immunization with the associated biological product(s).

If the reaction is deemed to have been anaphylactic, the associated biological product(s) cannot be administered in the future. Except in the case of rabies post-exposure vaccine, the history of anaphylaxis is a contraindication to the administration of the associated biological product(s).

Record this contraindication in the client's personal and electronic immunization record. Discuss with the client/guardian the CPHO recommendation regarding subsequent immunization.



References

- British Columbia Centre for Disease Control Section V –Management of Anaphylaxis in a Non-clinical Setting, by the British Columbia Centre for Disease Control. The materials in this section were adapted and are being used with permission of British Columbia Centre for Disease Control.
- Government of Nunavut, Department of Health. Immunization Manual. Retrieved from: The Immunization Manual (<https://gov.nu.ca/health/information/manuals-guidelines>)