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3.0 Practice Guidelines

3.1 Management of Biological Products

3.1.1 General Guidelines

- Assign one nurse in each health center to be the Vaccine Coordinator. The Vaccine Coordinator is responsible for the management of all immunizing agents. An additional nurse must be trained to be the replacement when required.
- All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to **immediately notify** the designated Vaccine Coordinator of the arrival of the vaccine shipment so that it can be handled and stored appropriately.
- Always arrange immunizing agents the same way inside the refrigerator by expiry date.
- To assist in maintaining cold chain in a power outage it is recommended to place water bottles in the refrigerator.
- Protect immunizing agents from light at all times by keeping them in the manufacturer-supplied box.
- Remove immunizing agents from the refrigerator only when they are to be used immediately and put them back in the refrigerator immediately after each use.
- Reconstitute vaccines immediately prior to use and ONLY with the diluent provided by the manufacturer. For multi-dose vials, print the date opened on the label after opening.
- For reconstituted products, refer to the manufacturers' package insert for stability information following reconstitution. For example, opened multi-dose vials of Fluviral must be discarded if not used within 28 days.
- Do not use any immunizing agents that have not been stored according to standards until an assessment has been made by pharmacy.
- Do not use any immunizing agents that are beyond their expiration date. The expiration date of immunizing agents must be checked each time they are used. When the expiry date is marked as a month and year, the vaccine or diluent may be used up to and including the last day of the month.
- The Vaccine Coordinator must also check the expiration dates each month when completing an inventory of the agents stored in the refrigerator. If an agent is past its expiration date, it must be removed from the refrigerator immediately, marked "**DO**

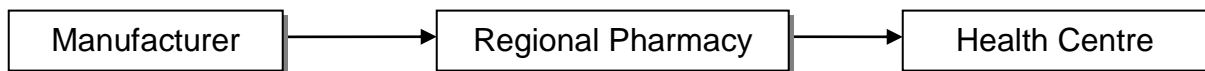
NOT USE,” and returned to the Regional Pharmacy for destruction or credit where applicable.

- Adhere to strict aseptic technique when handling vaccines.

3.1.2 Management of Cold Chain

Cold chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with administration of the vaccine. The optimum temperature for refrigerated vaccines is between 2°C and 8°C. For frozen vaccines the optimum temperature is –15°C or lower. In addition, protection from light is a necessary condition for some vaccines.

Proper storage temperatures must be maintained at every link in the chain.



Vaccines are sensitive biological products that may be less effective, or even destroyed, when exposed to temperatures outside the recommended range. Vaccines exposed to temperatures above or below the recommended temperature range can experience some loss of potency with each episode of exposure.

Maintaining the potency of vaccines is important for several reasons:

- There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine-preventable disease.
- Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccine may result in the cancellation of immunization clinics, resulting in lost opportunities to immunize.
- Revaccination of clients who received an ineffective vaccine is professionally uncomfortable and may cause loss of public confidence in vaccines and/or the healthcare system.

An estimated 17-37 percent of health-care providers expose vaccines to improper storage temperatures. Refrigeration temperatures are more commonly kept too cold rather than too warm.

When a cold chain break has been identified after a vaccine has been administered, the type of vaccine and the duration and temperature of the exposure will be taken into account when assessing the situation. Serological testing or revaccination may be suggested.

Three main elements combine to ensure proper vaccine transport, storage, and handling:

- trained personnel

- transportation and storage equipment
- efficient management procedures

3.1.3 Roles and Responsibilities of Health Care Providers Handling Biological Products (Vaccines)

Each health centre/public health unit should have a Vaccine Coordinator, typically a nurse, who is responsible for routine handling of vaccines.

The responsibilities of the Vaccine Coordinator include:

- ordering vaccines
- maintenance and monitoring of vaccine fridge
- reporting of cold chain events and handling of vaccines with cold chain breaks
- training and education of other staff in health centre on cold chain practices
- reporting of the monthly temperature log to the pharmacy technician
- mail the cold chain markers and log monthly to the pharmacy technician

The responsibilities of the Regional Communicable Disease Coordinator (RCDC) include:

- advising on cold chain best practices and supporting the vaccine coordinator
- connecting with community for any issues related to cold chain breaks or abnormal temperature logs as reported by pharmacy technicians and provide education/support as needed

The responsibilities of the Territorial Communicable Disease Specialist (TCDS) include:

- reviewing cold chain breaks and reporting issues to CMOH and Territorial Director of Pharmacy
- developing guidelines and education materials to support best practices in vaccine ordering and storage
- staying current on best practices
- representing Nunavut in F/P/T committees

The responsibilities of the Regional Pharmacy Technician include:

- packaging and shipping of vaccines using cold chain best practices

- reviewing monthly temperature logs from the communities and reporting any issues to RCDC and Director of Pharmacy
- reviewing cold chain marker reports monthly and reporting any issues to RCDC

3.1.4 Ordering Vaccines

The designated Vaccine Coordinator for each health centre/public health unit is responsible for ordering vaccines.

Once the vaccine order form (section 3.1.12) is completed it is faxed to the Regional Pharmacy. The Regional Pharmacy will prepare and ship the required vaccines.

Nunavut experiences extreme cold temperatures, which can cause challenges in maintaining cold chain during transport. It is recommended that all health centres order vaccines for the year in the summer months between June and August, to reduce the risk of a cold chain event.

Annually each community will be required to submit vaccine estimates and inventory for the upcoming year as per regional practice and coordinated by RCDC & TCDS. TCDS will review quantities and assist with appropriate ordering.

3.1.5 Maintenance and Monitoring of Vaccine Fridge and Cold Chain Markers

Vaccine storage units must be selected carefully and used properly. A purpose-built (lab or pharmacy grade) refrigerator is the standard for storing vaccines as listed on the Territorial Procurement guide. At minimum, any refrigerator or freezer used for vaccine must:

- be able to maintain the required vaccine storage temperatures through all seasons
- be large enough to hold the year's highest monthly inventory, including influenza vaccine
- have a calibrated thermometer and a data logger inside each storage compartment
- be dedicated to the storage of vaccine only
- be placed in a secure location away from unauthorized and public access

Any style of small single-door fridge is unpredictable in terms of maintaining temperatures and should **NOT** be used. With combined refrigerator and freezer units, the freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store freezer-stable vaccine.

No piece of equipment is infallible. At some point equipment failure will happen as a result of a power outage, breakdown, or normal wear and tear. Vaccine security requires that these failures be anticipated and that backup equipment and backup plans be available. Regular maintenance of all equipment is recommended to maintain optimal functioning.

A minimum/maximum thermometer should be placed in the center of each fridge. The temperature log (see section 3.1.10) should be filled in twice daily, recording the minimum and maximum temperatures in the fridge.

Biological products, such as vaccines, are incredibly sensitive to temperature fluctuations and can be rendered ineffective if exposed to temperatures outside the recommended 2°C and 8°C.

Nunavut experiences significant challenges in the shipment of vaccines, as temperatures are regularly below freezing for most of the year. A coordinated effort between health centres/public health, regional pharmacy, and the regional communicable disease coordinators (RCDC) is essential in ensuring these expensive biological products remain viable for administration.

In an effort to improve the safety of shipping vaccines, this system of monitoring vaccines during the transport between regional pharmacy to the health centre/public health has been developed.

Cold chain markers are sent out with all vaccine shipments in Nunavut. The following are 3 different types of cold chain markers that are used:

- 3M Monitor Mark™
- 3M Freeze Watch™
- ColdMark Freeze Indicator®

When a shipment is received, fill out cold chain marker log (found in section 3.1.13). This log should be faxed monthly or with each new vaccine shipment to the regional Pharmacy Technician and cold chain markers should be mailed/shipped back to Pharmacy Technicians

3.1.6 Cold Chain Breaks

The optimum temperature for refrigerated vaccines is between 2°C and 8°C. The stability of various immunizing agents can vary considerably. For example, some can tolerate long periods of exposure to heat without exhibiting a serious lack of activity. But for others, exposure to a higher temperature translates into degradation in their activity, and each

exposure produces a cumulative effect. Most immunizing agents are unstable when exposed to freezing.

When immunizing agents are exposed to temperatures of less than 2°C or more than 8°C, the result is a break in the cold chain. Immunizing agents affected by a break in the cold chain must be placed in cold quarantine, that is, packaged separately, identified with a sticker reading "DO NOT USE," and stored in a refrigerator at between 2°C and 8°C separately from immunizing agents in current use, until a decision is made whether or not they can be used.

If you become aware of inappropriate vaccine storage conditions, the following steps should be taken immediately:

1. Notify the Regional Pharmacy (copying the Regional Communicable Disease Coordinator) of the cold chain break.
2. Complete and fax the report titled *Incident Report: Vaccine Cold Chain Failure* (see section 3.1.9) to the regional pharmacy, (copying the Regional Communicable Disease Coordinator if possible). Please include the following information:
 - date and time of incident
 - the issue, e.g., inappropriate temperature and/or exposure to light
 - length of time the vaccine may have been exposed to inappropriate conditions
 - the room temperature where the vaccine storage unit is located (if available)
 - current temperature inside the vaccine storage unit and freezer if applicable
 - minimum and maximum temperature readings inside the vaccine storage unit
 - presence of water bottles in the refrigerator
 - action that has been taken to protect the vaccines
 - the product's appearance (e.g., freezing may change the appearance of adsorbed vaccines, causing the formation of granules or flakes, or provide evidence of ice formation)
 - the inventory of the vaccines affected by the event. Include vaccine name, lot number, expiry date, and quantity.
3. Vaccines must be bagged, dated, and labeled "DO NOT USE - under investigation for cold chain break."
4. Isolate and quarantine the affected vaccines under cold chain conditions between 2°C to 8°C until the integrity of the vaccine is determined.
5. If your vaccine storage unit is not maintaining the appropriate storage conditions, discuss with your supervisor or manager.

6. Await recommendations from pharmacy. Their final recommendations will detail which vaccines are safe for use or which ones are to be returned to the pharmacy for destruction.

7. Vaccines determined to be safe for use should be marked with a permanent marker indicating the cumulative length of time exposed to cold chain breaks.



Remember:

1. All multi-dose vials that have been previously opened and are involved in a cold chain incident **MUST** be discarded.
2. Clearly identify vials that have had an initial breach to the cold chain.
3. Vaccines safe for use should be marked with a permanent marker indicating the cumulative length of time exposed to cold chain breaks.
4. Most products involved in a second cold chain break must be assessed on a case-by-case basis.
5. In the absence of temperature monitoring, room temperature is assumed to be +25°C unless circumstances warrant consideration of higher temperature, such as direct sunlight or an additional heat source.
6. Consult with your RCDC in the event that an unstable vaccine was inadvertently administered.

3.1.7 Maintaining Cold Chain during Transport

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

Container for transport



Hard-sided plastic insulated container



Newer Styrofoam cooler with walls at least 2 inches thick

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



Refrigerator-conditioned cold packs



Frozen 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.

Insulating Barrier/Filler Materials

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.



Packing peanuts



Bubble wrap



Blue pads

The Vaccine

Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes. 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

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.



Warm/cold markers



Min/max thermometer

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>.

Keep Vaccines Safe

Ordering Vaccine

- Order vaccine for your patient population only.
- Order vaccines in the summer months to reduce the risk of freezing during transport in the winter.
- Complete a refrigerator inventory once a month.

Storing Vaccine

- Store all vaccine between 2°C and 8 °C.
- Keep a digital high-low thermometer in the refrigerator and record temperature twice daily.
- Contact regional pharmacy for advice when vaccine has been exposed to temperatures outside of 2°C and 8°C – i.e. power outage or refrigerator failure. Keep vaccine in refrigerator until you receive guidance from pharmacy.
- Develop a back-up plan for power outage/ refrigerator failure.
- Protect refrigerator plug – secure it so it will not accidentally become unplugged.
- Do not store vaccine in the door of a refrigerator.
- Store full bottles of water on empty shelves and on the door of the refrigerator to maintain consistency in temperature.
- Do not use a “Bar” or half-size refrigerator.
- Use products with the earliest expiry dates first; place vaccine with the longest expiry dates behind those with the earliest expiry dates.
- Do not use your vaccine refrigerator for specimen storage and non-medical purposes such as staff lunches to limit opening your refrigerator door and for biological safety.
- Leave space between products in the refrigerator to allow air to circulate.
- Make sure to close the vaccine refrigerator properly after each use.

Handling Vaccine

- Never leave vaccine outside of the refrigerator.
- Remove vaccine from the refrigerator only for the

withdrawal of the required dose(s).

- Mark the date on all multi-dose vials of vaccine when first opened – use opened vials before opening a new multi-dose vial and use within the timeframe specified by the manufacturer.

Transporting Vaccine

- Use insulated coolers with tight fitting lids and ice packs when transporting vaccine.
- Keep ice trays and ice packs in your freezer for use during transport of vaccine.
- Do not put vaccine directly on ice pack.
- Keep vaccine in original package.
- Wrap vaccine in bubble wrap or other insulating material before placing on ice packs.
- For long distance travel, wrap bubble-wrapped vaccine in newspaper for extra insulation and place a thermometer in the cooler.

Recording Vaccine

Document on patient chart and immunization record vaccine given, dose, site, date, lot #, expiry and signature of person who administered the vaccine.

Pharmacy Contact Information

Qikiqtani General Hospital Pharmacy

Tel: 867-975-8600 ext 2306

Fax: 867-975-8606

Kitikmeot Regional Pharmacy

Tel: 867-983-4526

Fax: 867-983-4201

Kivalliq Regional Pharmacy

Tel: 867-645-8334

Fax: 867-645-8348



Incident Report – Vaccine Cold Chain Failure

Health Centre: _____	Date of Incident: _____
Phone Number: _____	Date reported to Pharmacy: _____
Fax Number: _____	Contact Person: _____

STEP 1: CHECK THE BOX THAT BEST DESCRIBES THE INCIDENT

A. Power Interruption:	<input type="checkbox"/> Power Outage	<input type="checkbox"/> Power Interruption to Equipment
B. Equipment Problem:	<input type="checkbox"/> Equipment Breakdown	<input type="checkbox"/> Other Equipment Problem
C. Handling Error:	<input type="checkbox"/> Vaccine Left Out	<input type="checkbox"/> Refrigerator Door Left Open
D. Shipment Problem:	<input type="checkbox"/> Temperature Reading	<input type="checkbox"/> Product Damaged in Transit

Exposed Temperature	Highest: _____ °C	Duration: _____ hours _____ minutes
	Lowest: _____ °C	Duration: _____ hours _____ minutes

PLEASE DESCRIBE EVENT:	PLEASE IDENTIFY WHICH ACTIONS HAVE BEEN TAKEN:
	<input type="checkbox"/> Vaccine in question isolated in bag/container and placed in refrigerator between 2° - 8°C
	<input type="checkbox"/> The bag/container clearly marked with "Do Not Use: Quarantined"
	<input type="checkbox"/> Mark exposed vaccines with a permanent marker indicating the cumulative length of time exposed to a cold chain break

PLEASE ANSWER EACH QUESTION LISTED BELOW:

1. Was there a min/max thermometer in the fridge? Yes No
2. Were water bottles in the fridge at the time of this event? Yes No
3. Was there a temperature log maintained for this fridge? Yes No
4. What was the air temperature of the room where the vaccines were stored? _____ °C
5. What actions have been taken to correct the problem?

Please complete the table on page 2 with the names and quantity of vaccine exposed in the cold chain break event and fax along with this completed form to pharmacy. Await recommendations on which vaccines are safe for use, and which vaccines should be returned to Regional Pharmacy for destruction.

Completed by: _____ **Date:** _____

Temperature Log

1. Record the current temperature and the minimum/maximum fridge temperature twice daily: when you first open the office and before closing.
2. Remember to reset your min/max fridge thermometer after recording the temperatures.

Month: _____	Room Temp	REFRIGERATOR TEMPERATURE									
Year 20 _____		AM					PM				
Day of the Month		Time	Current C°	Min C°	Max C°	Initial	Time	Current C°	Min C°	Max C°	Initial
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
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29											
30											
31											
Signatures											

3.0 Practice Guidelines

3.1 Management of Biological Products

3.1.11 Packing a Cooler for School-Based or Mass Immunization Clinics

Avoid transporting vaccines as much as possible. The more often they are moved, the more likely it is that they might become spoiled. It is very important to maintain the cold chain when moving vaccines.

When transporting vaccines using a personal vehicle, do not place vaccines inside the trunk of the vehicle. Avoid placing the vaccine in direct sunlight or directly in line with air from the vehicle's heater and air conditioner.

Never leave vaccine unattended.

Protecting Vaccines during Immunization Clinics

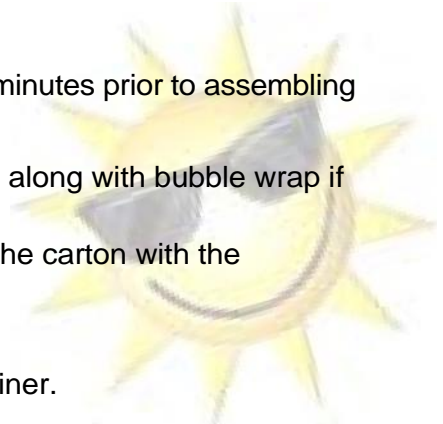
1. Maintain the vaccines at the required temperature (between 2°C and 8°C) during the immunization clinic. It is important to ensure that the administered vaccine retains its potency.
2. Minimize the number of times that the cooler is opened during the immunization.
3. Record temperature readings in the insulated cooler:
 - before leaving the office with the cooler
 - upon arrival at the clinic location, but prior to the immunization clinic
 - every 3 hours during the clinic
 - upon completion of the clinic, but before transport back to the office
 - after return to the office, but before the vaccines are placed back in the refrigerator

Following these steps will ensure that the vaccines are maintained at the required temperature throughout the process and that the vaccines that are returned to the refrigerator have not been exposed to temperatures below 2°C or above 8°C.

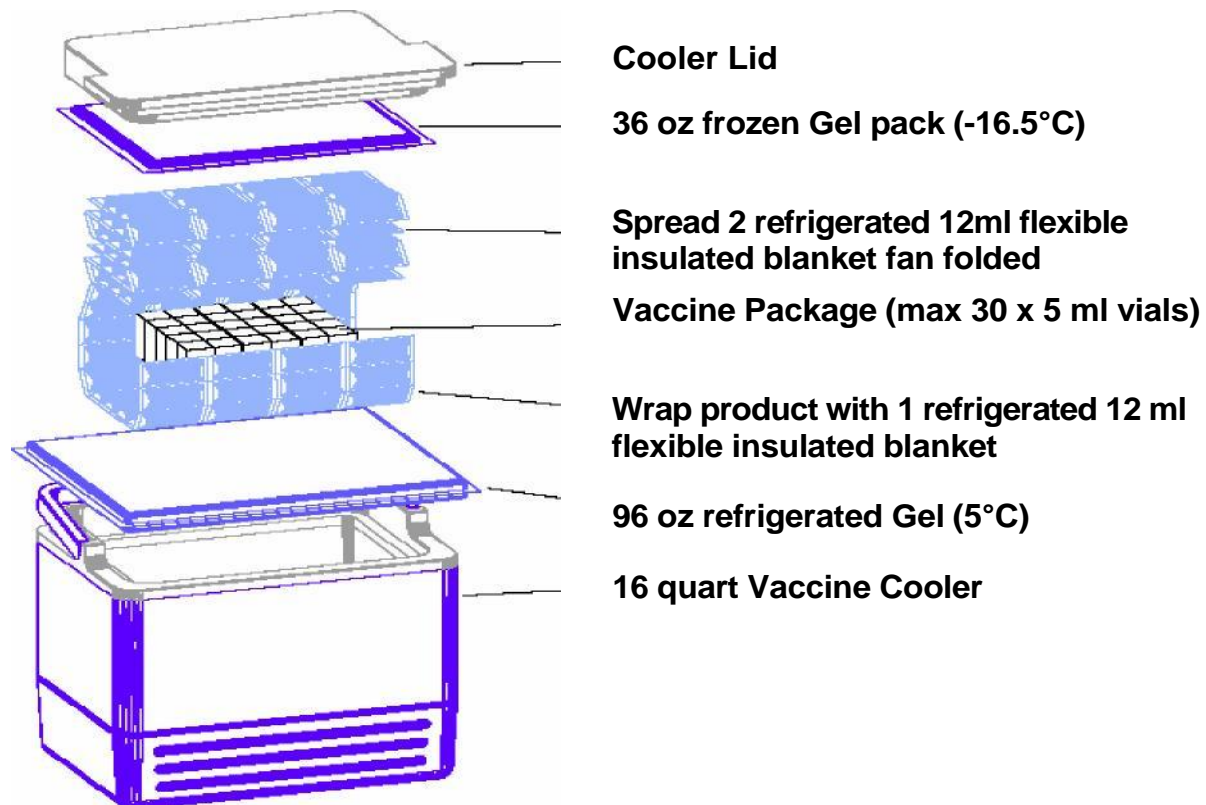
Vaccine Cooler Packing for School-Based & Community Mass Immunization Clinics

16 Quart Igloo Vaccine Cooler (Summer Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated temperature monitoring device(s) inside the carton with the Product(s).
4. Obtain one 16 quart vaccine cooler.
5. Spread one 96 oz refrigerated gel on the bottom of the container.
7. Wrap product carton with one layer of refrigerated flexible insulating blankets on top of the refrigerated Gel.
7. Fan fold two layers of refrigerated flexible insulating blankets on top of the product carton.
8. Place one 36 oz frozen Gel on top.



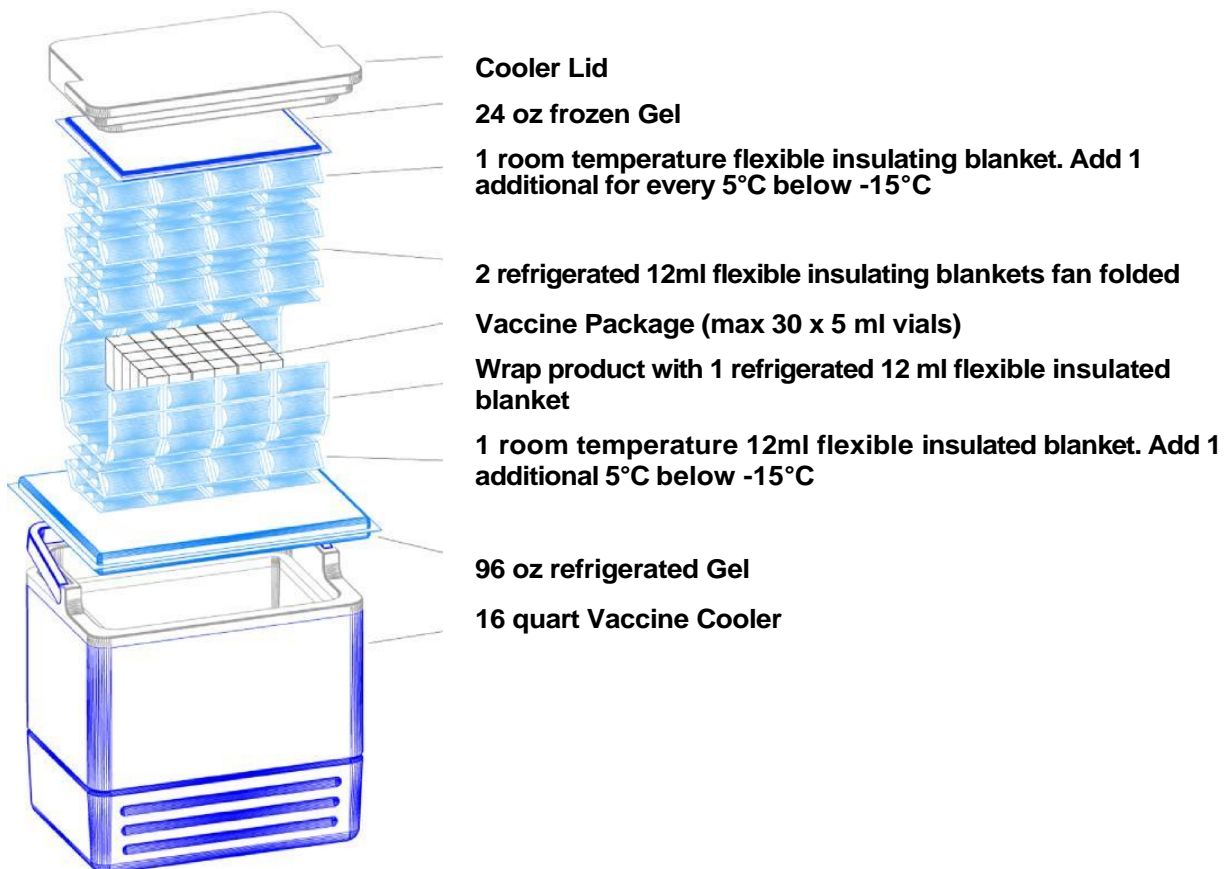
Packing Diagram for Vaccine Shipment – 16 Quart Cooler (Summer – June 1 to Sept 30)



16 Quart Igloo Vaccine Cooler (Winter Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated temperature monitoring device(s) inside the carton with the Product(s).
4. Obtain one 16 quart vaccine cooler.
5. Spread one 96 oz refrigerated (5°C) gel on the bottom of the container.
6. Place one layer of room temperature (22°C) flexible insulating blanket on top of the refrigerated gel. Add one additional blanket for every 5°C below -15°C
7. Wrap product carton with one layer of refrigerated flexible insulating blanket.
8. Fan fold two layers of refrigerated (5°C) flexible insulating blankets on top of the product carton.
9. Place one layer of room temperature (22°C) flexible insulating blanket on top of the product carton. Add one additional blanket for every 5°C below -15°C.
10. Place one 24 oz frozen Gel on top.

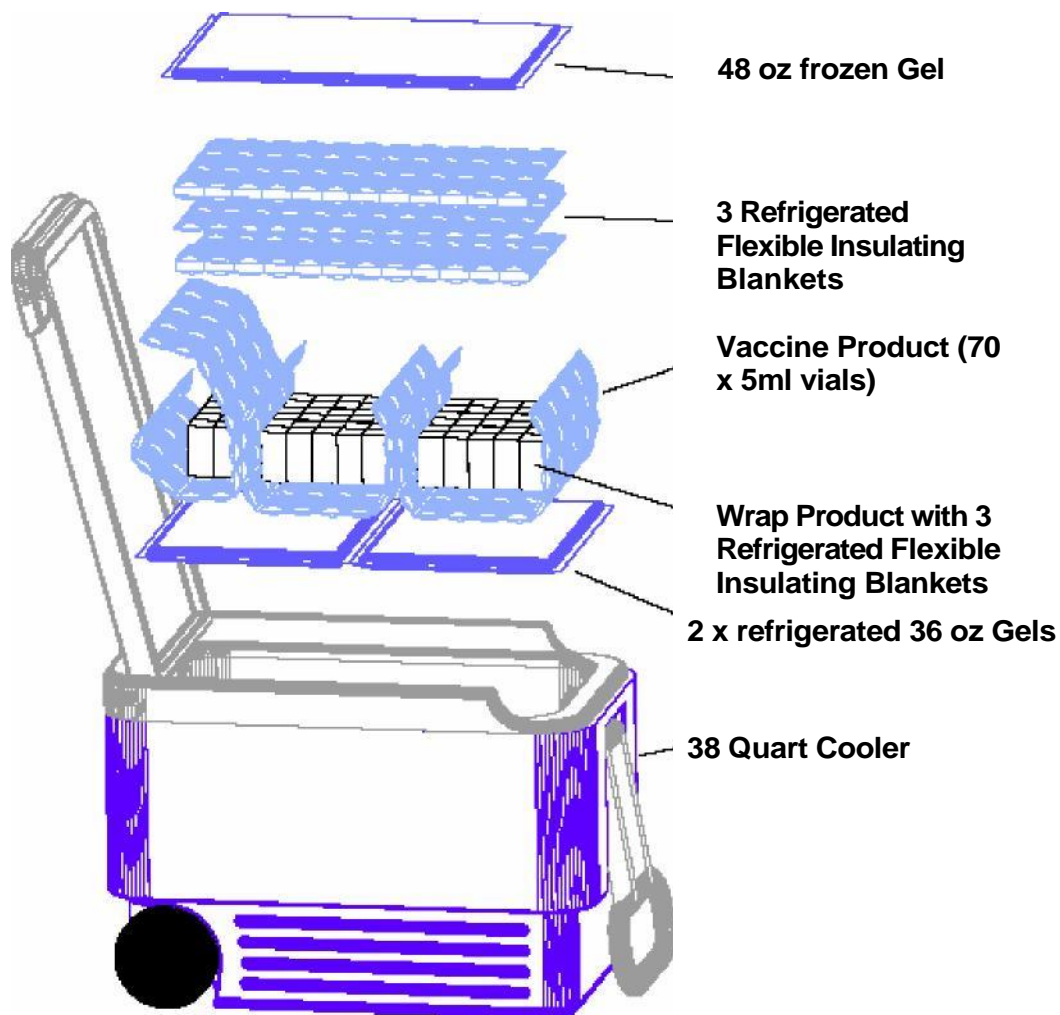
Packing Diagram for Vaccine Shipment – 16 Quart Cooler (Winter – Oct 1 to May 31)



Quart Igloo Vaccine Cooler (Summer Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated temperature monitoring device(s) inside the carton with the Product(s).
4. Obtain one 38 quart vaccine cooler.
5. Spread two 36 oz refrigerated gel on the bottom of the container.
6. Wrap product carton with three refrigerated flexible insulating blankets.
7. Fan fold three layers of refrigerated flexible insulating blankets on top of the product carton.
8. Place one 48 oz frozen Gel on top.

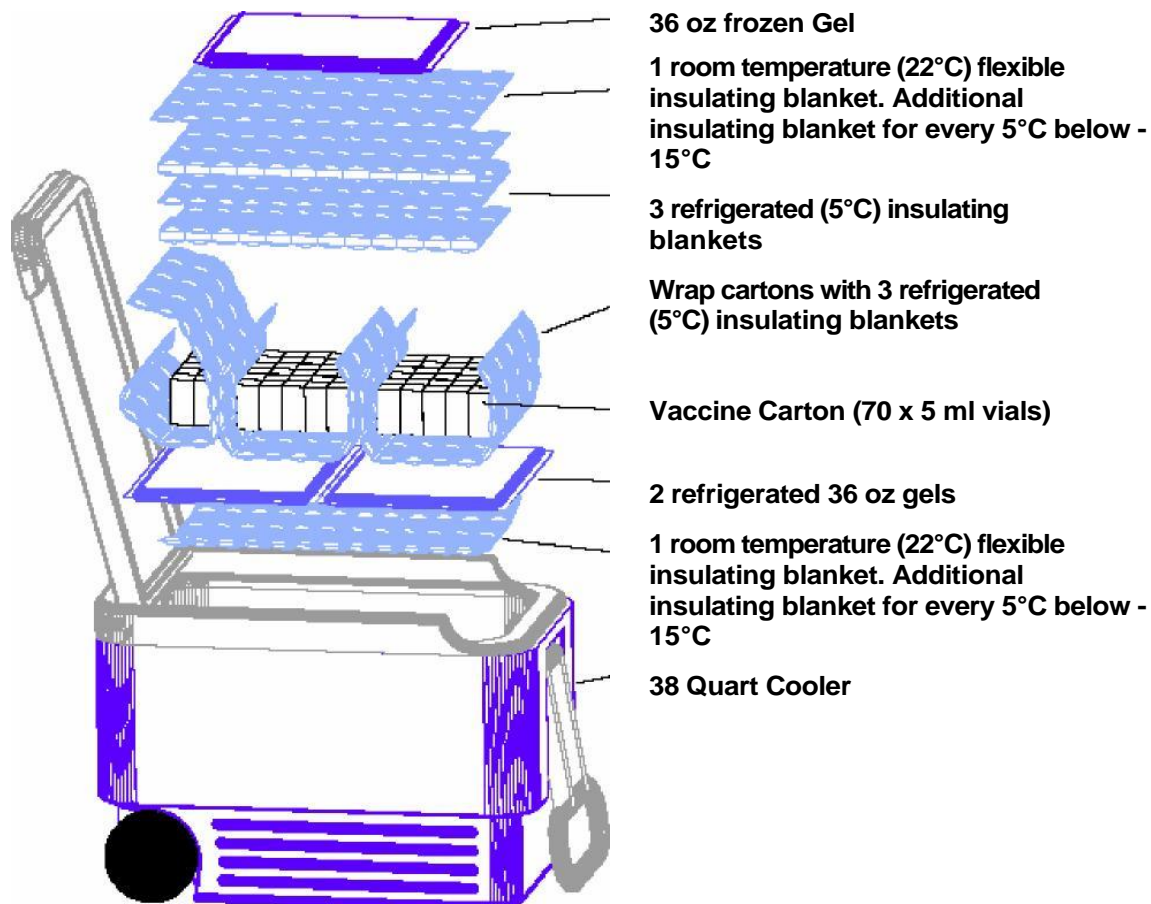
Packing Diagram for Vaccine – 38 Quart Cooler (Summer – June 1 – Sept 30)



38 Quart Igloo Vaccine Cooler (Winter Configuration)

1. Condition cooler with frozen gel from freezer storage for 5-30 minutes prior to assembling packages.
2. Pack the product(s) into the appropriate sized product carton along with bubble wrap if required.
3. Place the activated temperature monitoring device(s) inside the carton with the Product(s).
4. Obtain one 38 quart vaccine cooler.
5. Spread one room temperature (22°C) flexible insulating blanket on bottom of container. Add one additional blanket for every 5°C below -15°C.
6. Place two 36 oz refrigerated (5°C) gel on top of the flexible insulating blanket.
7. Wrap product carton with three refrigerated (5°C) flexible insulating blankets.
8. Fan fold three layers of refrigerated (5°C) blankets on top of the product carton.
9. Spread one room temperature (22°C) flexible insulating blanket on bottom of container. Add additional layer for every 5°C below -15°C.
10. Place one 36 oz frozen Gel on top.

Packing Diagram for Vaccine Shipment – 38 Quart Cooler (Winter – Oct 1 to May 31)



Vaccine Order Form

Community: _____ **Ordered By:** _____

Date: _____

MT #	REFRIGERATED VACCINES	BRAND NAMES	ABBR.	ORDERING UNIT	ORDER QTY
071	Bacille Calmette-Guérin Vaccine		BCG	10 dose vial	
085	Botulism Anti-toxin (Types A, B & E)		BAtx	250 mL vial	
615	Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio (Pediatric)	Quadracel® Infanrix®-IPV Adacel®-Polio Boostrix®-Polio	DTaP-IPV DTaP-IPV Tdap-IPV Tdap-IPV	0.5 mL vial	
532	Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio, <i>Haemophilus Influenza</i> type b (Pediatric)	Infanrix®-IPV/Hib Pediaceal® Pentacel®	DTaP-IPV-Hib	0.5 mL vial	
938	Hepatitis B Vaccine (Pediatric)	Engerix®-B Recombivax HB®	HB	0.5 mL vial	
321	Hepatitis B Vaccine (Adult)	Engerix®-B Recombivax HB®	HB	1 mL vial	
1270	Human Papillomavirus Vaccine	Gardasil®9	HPV9	0.5 mL vial	
361	Influenza (Seasonal) Virus Vaccine 0.5 mL	Fluzone QIV®	Inf	5 mL vial	
461	Measles, Mumps and Rubella Vaccine	M-M-R® II Priorix®	MMR	0.5 mL vial	
1269	Measles, Mumps, Rubella and Varicella Vaccine	Priorix-Tetra®	MMRV	0.5 mL vial	
429	Meningococcal C Conjugate Vaccine	Menjugate® NeisVac-C®	Men-C	0.5 mL vial	
1271	Meningococcal Quadrivalent Vaccine (A, C, Y and W-135) (for Grade 9 students)	Nimenrix® Menactra®	Men-C-ACYW	0.5 mL vial	
524	Palivizumab Vaccine 50 mg	Synagis®	RSVAb	0.5 mL vial	
523	Palivizumab Vaccine 100 mg	Synagis®	RSVAb	1.0 mL vial	
568	Pneumococcal Conjugate Vaccine, 13-valent	Prevnar® 13	Pneu-C-13	0.5 mL vial	
569	Pneumococcal Polysaccharide Vaccine, 23-valent	Pneumovax® 23	Pneu-P-23	0.5 mL vial	
571	Poliomyelitis Vaccine, Inactivated	Imovax Polio	IPV	0.5 mL syr	
620	Rabies Immune Globulin 150 units/mL inj	HyperRab® S/D Imogam®	Rablg	2 mL vial	
621 622	Rabies Vaccine 2.5 units/vial inj	Imovax® Rabies RabAvert®	Rab	1 mL syr	
1272	Rotavirus Oral Vaccine	Rotateq®	Rot-1	1.5 mL oral applicator	
223	Tetanus, Diphtheria, Acellular Pertussis (for use in Adolescents and some Adults)	Adacel® Boostrix®	Tdap	0.5 mL vial/syr	
672	Tetanus, Diphtheria (Adult)	Td Adsorbed	Td	0.5 mL vial	
678	Tetanus Immune Globulin	HyperTet® S/D	Tlg	250 unit syr	
704	Tuberculin PPD Skin Test	Tubersol®	TST	1 mL vial	
713	Varicella Vaccine	Varivax® III Varilrix®	Var	0.5 mL vial	
	Other				

**** Refer to the Nunavut Immunization Manual for details on immunization schedules ****

Note: Nunavut does not always stock the same brand name for each vaccine. Vaccines under the same MT # code are interchangeable. Please use up products according to expiry date to minimize wastage.

Fax Completed Form to: Baffin: 867-975-8606 Kivalliq: 867-645-8348 Kitikmeot: 867-983-4201



A checklist for safeguarding the storage and handling of your vaccine supply

	Yes	No
1. We have a designated person in charge of ordering vaccines, inventory management and refrigerator monitoring		
2. Our staff have been provided with training about the importance of good vaccine management		
3. All our vaccines are unpacked and refrigerated IMMEDIATELY upon delivery		
4. If there is a break in the cold chain, any exposed vaccines are labeled as “ DO NOT USE ” in the refrigerator		
5. We contact Regional Pharmacy and RCDC to report cold chain incidents and determine if vaccines are useable		
6. We use a laboratory or industrial fridge.		
7. We DO NOT store any food or beverages in the refrigerator		
8. Our vaccines are rotated on the “ FIRST TO EXPIRE, FIRST OUT ” principle		
9. Vaccines that will expire soonest are used first		
10. Our vaccines are checked for EXPIRY dates at the beginning or end of every month		
11. Expired vaccines are removed from the refrigerator		
12. We return damaged/expired vaccines to Regional Pharmacy		
13. We order vaccines based on clinic needs		
14. The temperature of the refrigerator is maintained between +2°C to +8°C		
15. Our vaccines are stored in the MIDDLE shelves of the refrigerator and NOT on the shelves in the door of the refrigerator		
16. Our refrigerator is equipped with a Data logger.		
17. A “ TEMPERATURE LOG ” is posted on the refrigerator and the temperature of the refrigerator, the ambient (room) temperature, and the dial settings of the refrigerator is recorded and initialed TWICE daily (morning and evening)		
18. Sealed water bottles or flexible insulating blankets are stored (if space allows) on the upper and lower shelves and in the door of the refrigerator. Ice packs are stored in the freezer		
19. A “ DO NOT UNPLUG ” sign has been placed next to our refrigerator’s electrical outlet		
20. A hard-sided or soft-sided insulated cooler with a tight-fitting lid along with icepacks and insulating material is always used in transporting vaccines for short periods of time and at clinic workstations		
21. An EMERGENCY PLAN for power outages and refrigerator malfunctions has been established		
22. We have a copy of Nunavut Immunizations Manual- Management of Biologicals as a detailed reference for storage and handling of vaccines		
If all of the above answers are “YES”, we are doing a great job of safeguarding our vaccines, If not we have assigned someone to implement changes.		

Protect the vaccines. Protect your patients

Vaccine Cold Chain Management

Temperature

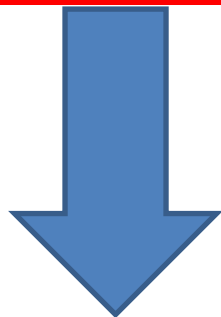
- keep vaccines refrigerated between 2 to 8 degrees

Checks

- Check and record temperature twice daily AM and PM
- Record internal and ambient temperature
- Use the Temperature Log sheet for recording

Cold Chain Breach

- **What action should you take?**
- (If the temperature went below and or above 8 degrees at any length of time.)



Quarantine Vaccines

- Package vaccines separately in a bag or box and label **"DO NOT USE"**
- Keep quarantined vaccines refrigerated in a fridge that is able to maintain temperature

Notify

- Notify Regional Pharmacy of the Cold Chain Breach (copying the RCDC)
- Use the Incident Report: Vaccine Cold Chain Failure for reporting
- Notify nursing staff not to use the quarantined vaccines

"DO NOT USE"

- **WAIT** for the Regional Pharmacist recommendations as to the viability of the vaccines.



3.1.14 Cold Chain Marker Log

Community Name	
Date of Biologicals Shipment Received	
Type of Cold-chain Marker Received	
Interpretation of Cold-chain marker	
Additional comments or actions required	
Name and Designation of Reporter	

Fax this completed form to Regional Pharmacy Technician at:

Qikiqtaaluk Region: 867-975-8606

Kitikmeot Region: 1-867-983-4201

Kivalliq Region: 1-867-645-8348

3.0 Practice Guidelines

3.2 Principles of Informed Consent

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Purpose

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3.0 Practice Guidelines

3.2 Principles of Informed Consent

Purpose:

- To provide immunization providers in Nunavut with all necessary information in order to obtain informed consent when providing immunizations.
- To ensure that all Nunavummiut are informed when making decisions regarding immunizations in Nunavut.
- To define the process of documentation of the consent for immunizations in Nunavut.

Introduction:

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 vaccines in Nunavut. This section will define informed consent, identify criteria necessary for ensuring informed consent, and provide a consent form for the documentation of informed consent.

3.2.1 Essential Criteria for Informed Consent

- Consent must be given willingly and freely without coercion.
- The immunization provider must ensure the vaccine recipient is capable of 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 effects that occur frequently, any severe adverse effects (such as anaphylaxis), precautions, and contraindications should be discussed.

3.2.2 Age of Consent

In Nunavut, all adults (over the age of majority, which in Nunavut is 19 years) are presumed to be capable of consenting or withholding consent unless the practitioner has reason to believe the adult lacks capacity.

Unlike adults, most minors (under 19 years of age) are presumed to be incapable of consenting on their own behalf. Instead, the child's parent or legal guardian consents on their behalf:

- If the child lives with both parents, either parent can consent to treatment;
- If the child lives with one parent, only the custodial parent can consent;

- If the child is in the care of the Director of Child Welfare, only the Director or a designate can consent to treatment;
- If the child lives with a legal guardian with full parental rights, the legal guardian can consent.
- If a parent/guardian signs consent for a series and then they are no longer the guardian (ie. Child apprehended), the original signed consent is still valid and the consent remains binding until it is withdrawn.

3.2.3 Mature Minors and Informed Consent

The common law also recognizes a category of minor called the “mature minor”. A mature minor is typically between the ages of 15-18 years and has the necessary capacity to fully understand the consequences of treatment or refusing treatment.

Mature minor status is always decided on a case-by-case basis and requires a judgment call by the immunization provider. A mature minor can override the medical decisions made by his/her parents and can either give consent or refuse immunizations.

Minors can also apply to the Court to receive a declaration under the *Children’s Law Act* that they are capable of managing their own lives, including their medical treatment. This is sometimes referred to as being an “emancipated minor”.

3.2.4 Documentation of Consent

- All immunizations given in Nunavut require a signed consent by the individual or their parent/legal guardian using the vaccine consent form.
- For each routine series of vaccines, consent needs to be given only once at the beginning of the series. This consent must be signed and dated.
- A witness is not required to sign the consent form, unless there is any doubt that the person signing actually is whom he/she says he/she is.
- On occasion, written consent may not be feasible, for example:
 - The parent/guardian is not present
 - in school based immunization programs where the child did not bring back the signed consent form
 - when a child is in one community and the parent/guardian is in a different community.

In these situations, the immunization provider can receive verbal or telephone consent. This is an exception to the rule, and the expectation is that, if possible, the consent form should be signed. Verbal/telephone consent must be documented by the immunization provider in the client’s chart or on the consent form.

- The vaccine recipient, parent or guardian cannot read

If the parent/guardian cannot write, someone can sign their name for them and the parent/guardian can sign with an X or some other mark. It remains the responsibility of the immunization provider to ensure that consent has met all the criteria to be considered informed.



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Department of Health
Munaqhiqiyitkut
Ministère de la Santé

General Immunization and Screening Consent Form

Please fill in OR addressograph/affix label:

Last Name: _____
 First Name: _____
 Sex (M/F): _____
 DOB (dd/mm/yyyy): _____
 Chart #: _____
 HCP #: _____
 Community of Residence: _____

It is recommended you or your child/ward receive vaccine(s) to protect against the following disease(s):

PRIMARY SERIES

- Bacille Calmette-Guérin (BCG)
 - Hepatitis B
 - Rotavirus
 - Diphtheria, Tetanus, Acellular Pertussis, Inactivated Polio, Haemophilus Influenza Type B
 - Pneumococcal Conjugate
 - Measles, Mumps, Rubella, Varicella
 - Meningococcal C
 - Other _____
- Other _____

BOOSTERS and OTHER VACCINES (i.e. travel immunizations, botulism, specific immune globulins)

- Pneumococcal Polysaccharide
- Human Papilloma Virus (HPV)
- Tetanus, Diphtheria, Acellular Pertussis, Polio or Diphtheria, Tetanus, Acellular Pertussis, Polio
- Tetanus, Diphtheria, Acellular Pertussis
- Tetanus, Diphtheria

- Other _____ Other _____
- Other _____ Other _____

Note: For Influenza, Synagis and Rabies please refer to individual consent forms.

Tuberculin Skin Test (TST) – Mantoux Test

The following standard information will be discussed with you before receiving any vaccine:

- **Benefits** of vaccination (personal, community)
- **Risk** of not getting vaccinated (possibility of getting the disease)
- **Eligibility** for the vaccine(s)
- **Possible** common or serious **adverse events**
- **Assessment** of health status and possible reasons to delay or not give vaccine(s)
- **Disease(s)** being prevented

CONSENT:

I understand the information in the Vaccine Fact Sheets for the vaccines listed. I understand the benefits and possible reactions for each vaccine and the risk of not getting immunized. I have had the opportunity to ask questions that were answered to my satisfaction. I understand this consent is valid for the vaccine(s) listed, unless the consent is cancelled.

I consent I do not consent

to receiving the vaccine(s) for : My Child My Dependat/Ward or Myself

Print Name

Signature of Client or Parent/Legal Guardian *(if applicable)*

Date (dd/mm/yyyy)



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 Department of Health
 Munaqhiiliqiyitkut
 Ministère de la Santé

Formulaire général de consentement à l'immunisation et au dépistage

Veillez remplir **OU** utiliser un adressographe/apposer l'étiquette.

Nom de famille : _____
 Prénom : _____
 Sexe (H/F) : _____
 Date de naissance (jj/mm/aaaa) : _____
 N° de dossier : _____
 N° du FS : _____
 Communauté de résidence : _____

Il est recommandé que vous ou votre enfant/enfant sous tutelle receviez le(s) vaccin(s) à des fins de protection contre la (les) maladie(s) suivante(s) :

SÉRIES PRIMAIRES

- Bacille de Calmette et Guérin (BCG)
- Hépatite B
- Rotavirus
- Diphtérie, tétanos, vaccin antioquelucheux acellulaire, vaccin antipoliomyélitique inactivé, Haemophilus influenza de type B
- Vaccin conjugué contre le pneumocoque
- Rougeole, oreillons, rubéole, varicelle
- Vaccin méningococcique du groupe C
- Autre _____
- Autre _____

VACCINS DE RAPPEL ET AUTRES VACCINS (p. ex. immunisation du voyageur, botulisme, immunoglobuline spécifique)

- Vaccin antipneumococcique
- Papillomavirus
- Tétanos, diphtérie, vaccin antioquelucheux acellulaire, polio ou diphtérie, tétanos, vaccin antioquelucheux acellulaire, polio
- Tétanos, diphtérie, vaccin antioquelucheux acellulaire
- Tétanos, diphtérie

- Autre _____
- Autre _____
- Autre _____
- Autre _____

Remarque : Pour les vaccins contre la grippe et la rage, et le vaccin Synagis, veuillez vous référer aux formulaires de consentement individuels.

Test cutané à la tuberculine (TCT) – Test de Mantoux

Les renseignements courants suivants seront discutés avec vous avant de recevoir tout vaccin :

- **Avantages** de la vaccination (personnels, communautaires)
- **Risque** associé au fait de ne pas recevoir le vaccin (possibilité d'attraper la maladie)
- **Admissibilité** au(x) vaccin(s)
- **Possibilité d'événements indésirables** communs ou sérieux
- **Évaluation** de l'état de santé et des raisons potentielles pour retarder ou ne pas donner le(s) vaccin(s)
- **Maladie(s)** étant empêchée(s)

CONSETEMENT :

Je comprends les renseignements contenus dans les fiches de renseignements sur les vaccins pour les vaccins énumérés. Je comprends les avantages et les réactions possibles pour chaque vaccin ainsi que les risques associés au fait de ne pas être immunisé. J'ai eu l'occasion de poser des questions auxquelles on a répondu à ma satisfaction. Je comprends que ce consentement est valide pour le(s) vaccin(s) énuméré(s), à moins que le consentement ne soit annulé.

Je consens Je ne consens pas

à recevoir le(s) vaccin(s) pour : Mon enfant Ma personne à charge/mon enfant en tutelle ou Moi-même

Nom en lettres moulées _____ Signature du client ou parent/tuteur légal (*le cas échéant*) _____ Date (jj/mm/aaaa) _____

Formulaire de consentement à l'immunisation et au dépistage en milieu scolaire

Nom _____ Date de naissance _____
 École (le cas échéant) _____ Année/Classe _____

La section suivante doit être remplie par le parent ou le tuteur légal :

Parent/Tuteur _____	Adresse _____
Tél. du parent : Domicile () - _____	Travail () - _____

Cher parent,

Il est recommandé que tous les enfants soient complètement immunisés conformément au calendrier actuel du ministère de la Santé du gouvernement du Nunavut. Veuillez lire les feuillets de renseignements sur les vaccins ci-joints et indiquer votre consentement ou votre refus au bas de cette page, puis **remettre ce formulaire à l'école**. Pour toute question, veuillez appeler l'infirmier au numéro de téléphone indiqué ci-dessous. Nous vous remercions de l'attention que vous accordez à cette question importante.

Nom de l'infirmier _____ Tél. de l'infirmier _____

VEUILLEZ RÉPONDRE AUX 3 QUESTIONS ET SIGNER LE CONSENTEMENT OU LE REFUS AU BAS DE CE FORMULAIRE.

Votre enfant doit recevoir le(s) immunisation(s) cochée(s) dans les cases ci-dessous. Si vous signez le consentement, votre enfant recevra le(s) vaccin(s) à l'école.

- | | |
|--|--|
| <input type="checkbox"/> Diphtérie, Coqueluche acellulaire, Tétanos (dcaT) | <input type="checkbox"/> Papillomavirus humain (PVM) |
| <input type="checkbox"/> Rougeole, Oreillons, Rubéole (ROR) | <input type="checkbox"/> Méningococcie ACYW-135 |
| <input type="checkbox"/> Varicelle | <input type="checkbox"/> Autre : _____ |

- | | | |
|--|------------------------------|------------------------------|
| 1. Votre enfant a-t-il des allergies?
Le cas échéant, veuillez préciser. | Oui <input type="checkbox"/> | Non <input type="checkbox"/> |
| 2. Votre enfant a-t-il des problèmes médicaux?
Le cas échéant, veuillez préciser. | Oui <input type="checkbox"/> | Non <input type="checkbox"/> |
| 3. Votre enfant a-t-il déjà eu des réactions à des vaccins précédents?
Le cas échéant, veuillez préciser. | Oui <input type="checkbox"/> | Non <input type="checkbox"/> |

Test cutané à la tuberculine (TCT) – Test de Mantoux

CONSENTEMENT À L'IMMUNISATION OU REFUS

J'ai lu les feuillets de renseignements sur les vaccins et je comprends les informations fournies concernant les risques et les avantages du programme d'immunisation du Nunavut, et **JE CONSENS** ou **JE NE CONSENS PAS**

à ce que _____ soit immunisé(e) avec le(s) vaccin(s) requi(s).
Nom complet (l'enfant ou vous-même)

_____ conformément au calendrier actuel.

Je comprends pleinement que ce consentement est valide à moins que je ne le retire, par écrit, auprès d'un infirmier de la santé publique ou d'un infirmier en santé communautaire.

Signature (vous-même ou parent/tuteur)

Relation à l'enfant (le cas échéant)

Date

Une fois rempli, veuillez remettre ce formulaire à l'école.

Iliharvikmi Tunnganiqaqtuq Aanniaqtailinahuarutighanik Kapuutighanik Naunaiyainikkullu Angirutit Titiraq

Atia _____ Annivia _____

Iliharvik (piyaaqqat) _____ Puqtunia/Iliharvia _____

Hamna iniqtiqtauyughaq angayuqqaamit maligakkut munaqtianinluunniit:

Angayuqqaq/Munaqti _____	Humiiuuq _____
Angayuqqaap Hivayautait: Aihimavik () - _____	Havavik () - _____

Haluu Angayuqqaq,

Pitquyahimayug tamaita tamaat aanniaqtailinahuarutighanik kapuqtauhimayughat maliklugu tatja pitjutaani Nunavut Kavamatkut Munarhiliqinikkut Havavianin. Taiguqlugu atatjutihimayug Kapuutitigut Naunaiyautit Titiqqat iniqtiqlugulu angirut qinngitjutiluunniit ataani uumani titiraqmi **utiqtillugulu una titiraq iliharvikmun**. Apirhuutiqaaruvit hivayatjavat munarhi hivayautaa titiraqtauhimayug ataani. Quanaqutit pigavit uumani anginiqaqtumi ihumaginirmi:

Munarhip _____ Munarhip _____
 Atia _____ Hivayautaa _____

INIQTILUGIT PINGAHUT APIQUUTIT SAINIQLUGULU ANGIROUTIT QINNGITJUTILLUUNNIIT ATAANI UUMANI TITIRAQMI.

Nutarat piyughaliqtuq ukuninga aanniaqtailinahuarutighanik kapuutimik/nik naunaiyaqtauhimayut qiuqutinnuat ataani. Sainirungni angirutit nutarat kapuqtauniaqtuq iliharvikmi.

- | | |
|--|--|
| <input type="checkbox"/> Tetanus, diphtheria, acellular pertussis (Tdap) | <input type="checkbox"/> Human papilloma virus (HPV) |
| <input type="checkbox"/> Measles, mumps unalu rubella (MMR) | <input type="checkbox"/> Meningococcal ACYW-135 |
| <input type="checkbox"/> Varicella | <input type="checkbox"/> Aallat: _____ |

- | | | | |
|--|------------------------------|--|----------------------------------|
| 1. Nutarat hunanit nakuungiqpakpa timikkut (allergies)?
Angiruvit, ilitturipkaqluta | Hii <input type="checkbox"/> | | Imannaq <input type="checkbox"/> |
| 2. Nutarat aanniarutiqaqqa?
Angiruvit, ilitturipkaqluta | Hii <input type="checkbox"/> | | Imannaq <input type="checkbox"/> |
| 3. Nutarat hulaqutihimavakpa hivuagut kaputimit(nit)?
Angiruvit, ilitturipkaqluta | Hii <input type="checkbox"/> | | Imannaq <input type="checkbox"/> |

Tuberculin Uvinikkut Uuktuuti (TST) – Mantoux uuktuuti

ANGIRUTIT QINNGITJUTILLUUNNIIT AANNIAQTAILINAHUARUTIGHANIK KAPUUTINIK

Taiguqhimayatka kapuutitigut naunaiyautit titiqaq kangirhimayaralu ilitturipkaitjutit tuniyahimayut mighaagut qayangarniinni ikayurutiinnilu uvani aanniaqtailinahuarutighanik kapuutini pinahuarutimi Nunavunmi, taimaalu

ANGIQHIMAYARA imaaluunniit **QINNGIHIMAYARA**

una _____ aanniaqtailinahuarutighanik kapuqtauluni ukuninga pitquyahimayuni kapputighami(ni)
 Tamaat Atia (nutaraq ilvilluunniit)

_____, maliklugu tatja pitjutaani.

Kangiqhittiarhimayunga una angirutit atuqniqaqtuq kihiani nutqaqtittinganin uvamnit, titiraqhimanikkut, uumunga Nunallaani Munarhimun.

Sainiutaa (ilvit unaluunniit angayuqqaq/munaqti)	Ilagiigutikkut Nutaraqmun (pitjutitqaqqaq)	Uplua
Iniqhimakpat utiqtilugulu una titiraq iliharvikmun		

School Based Immunization and Screening Consent Form

Name _____ Date of Birth _____

School (if applicable) _____ Grade/Classroom _____

The following section to be filled out by the parent or legal guardian:

Parent/Guardian _____	Address _____
Parent Phone Numbers: Home () - _____	Work () - _____

Dear Parent,

It is recommended that all children be fully immunized in accordance with the current schedule of the Government of Nunavut Department of Health. Please read the attached Vaccine Fact Sheets and complete the consent or refusal at the bottom of this page and **return this form to the school**. If you have questions please call the nurse at the phone number listed below. Thank you for your attention to this important matter:

Nurse's Name _____ Nurse's phone # _____

PLEASE COMPLETE THE 3 QUESTIONS AND SIGN THE CONSENT OR REFUSAL AT THE BOTTOM OF THIS FORM.

Your child is due for the immunization(s) checked in the boxes below. If you sign the consent your child will then receive the vaccine/s at school.

- | | |
|--|--|
| <input type="checkbox"/> Tetanus, diphtheria, acellular pertussis (Tdap) | <input type="checkbox"/> Human papilloma virus (HPV) |
| <input type="checkbox"/> Measles, mumps and rubella (MMR) | <input type="checkbox"/> Meningococcal ACYW-135 |
| <input type="checkbox"/> Varicella | <input type="checkbox"/> Other: _____ |

- | | | | |
|---|------------------------------|--|-----------------------------|
| 1. Does your child have allergies?
If yes, tell us about it | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |
| 2. Does your child have medical problems?
If yes, tell us about it | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |
| 3. Has your child had reaction(s) to previous vaccine(s)?
If yes, tell us about it | Yes <input type="checkbox"/> | | No <input type="checkbox"/> |

Tuberculin Skin Test (TST) – Mantoux test

CONSENT OR REFUSAL FOR IMMUNIZATION

I have read the vaccine fact sheets and understand the information provided regarding the risks and benefits of the immunization program in Nunavut, and **I CONSENT** or **I DO NOT CONSENT**

for _____ to be immunized with the required vaccine(s)
Full name (child or self)

_____, in accordance with the current schedule.

I fully understand that this consent is valid unless withdrawn by me, in writing, to a Public Health Nurse or a Community Health Nurse.

Signature (self or parent/guardian)	Relationship to Child (if applicable)	Date
--	--	-------------

When complete return this form to the school



Naunaiyautighaq Kapuutini Aanniaqtailinahuarutikhani

Una naunaiyautit atuqtauyughaq tamainnun kappuutini aanniaqtailinahuaqnikkut upautitjutini.

1. Kapuqtaunahuaqtut aanniaqqa uplumi?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
2. Kapuqtaunahuaqtuq aallanik aanniarutiqaqqa?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
3. Kapuqtaunahuaqtuq havautituqqa?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
4. Kapuqtaunahuaqtuq timikkut ihuiqpakpa hivuagut kapuutinin aanniaqtailinahuarutinin?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
5. Kapuqtaunahuaqtuq hunanit timikkut nakuungiqaqpa?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
6. Qaangiqlhimayumi ukiumi, kapuqtaunahuaqtuq auliqhiqpakpa ukuningaluunniit aukkut pitjutainnik, tuniyauhimavakpaluunniit uuminga immune (gamma) globulin?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
7. Kapuqtaunahuaqtuq hingaihimava hingainiarungnarhiyuq luunniit tikiliqtughami tatqirhiutimi?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq
8. Kapuqtaunahuaqtuq pivakpa kapuutinin aanniaqtailinahuarutinin qaangiqlhimaliqtuni hitamani havainirni?	<input type="checkbox"/> Hii	<input type="checkbox"/> Imannaq

If yes is answered to any of the above questions, please discuss before giving the vaccine.

Questionnaire de dépistage prévacination

Ce questionnaire doit être utilisé lors de chaque séance de vaccination.

1. La personne qui reçoit le vaccin est-elle malade aujourd'hui?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
2. La personne qui reçoit le vaccin a-t-elle des problèmes de santé?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
3. La personne qui reçoit le vaccin prend-elle des médicaments?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
4. La personne qui reçoit le vaccin a-t-elle déjà eu des réactions allergiques après une vaccination?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
5. La personne qui reçoit le vaccin souffre-t-elle d'allergies?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
6. Au cours de la dernière année, la personne qui reçoit le vaccin a-t-elle reçu une transfusion de sang ou de produits du sang ou une injection de gammaglobuline?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
7. La personne qui reçoit le vaccin est-elle enceinte ou pourrait-elle tomber enceinte au cours du prochain mois?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non
8. La personne qui reçoit le vaccin a-t-elle eu d'autres vaccins au cours des quatre dernières semaines?	<input type="checkbox"/> Oui	<input type="checkbox"/> Non

If yes is answered to any of the above questions, please discuss before giving the vaccine.

3.0 Practice Guidelines

3.3 Administration of Biological Products

Contents

Introduction

3.3.1 General Information

3.3.2 Preparation Phase

3.3.3 Materials Needed to Administer the Vaccine

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3.3.7 Methods for Reducing Anxiety and Pain During Immunization

3.3.8 Intramuscular (IM) Injection

3.3.9 Subcutaneous (SC) Injection

3.3.10 Intradermal (ID) Injection

3.3.11 Injection Technique for Rabies Immune Globulin (Rablg)

Material for this section was adapted with permission from the Immunization Manual from Quebec, as it is indicated below.

The original French version of Chapter 6 of the Protocole d'immunisation du Québec (Quebec Immunization Protocol) entitled Techniques d'administration was edited by the Ministère de la Santé et des Services sociaux. The Ministère accepts no responsibility for the present English translation or any resulting damage, loss or injury. In the event of any contradiction between the English version and the French version, the latter shall prevail. The Government of Quebec remains the sole owner of the work's copyright. The agency translating the document agrees to respect and protect the Government of Quebec's copyright. In addition, the copyright held by the Government of Quebec also applies to any reproduction of the text in whole or in part, and all electronic, computer or web-based form of said text.

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3.0 Practice Guidelines

3.3 Administration of Biological Products

Introduction

Every immunizing agent must be administered as recommended to achieve optimal immune response and to limit adverse local reactions.

This standard of practice for administering injections applies for all vaccines, with exceptions. This chapter presents the details of administering immunizing agents.

3.3.1 General information

Wash your hands before preparing the vaccines and prior to administration.

Wearing gloves is not required for immunizations, except if the vaccinator thinks he or she will come into contact with potentially infectious body fluids or has broken skin on the hands.

Use a different sterile syringe for each injection.

Do not mix different vaccines in the same syringe, unless otherwise indicated by the manufacturer.

Reconstitute the products according to the manufacturer's instructions.

Administer the vaccines as soon as possible after reconstitution.

Do not prepare drawn up vaccine in syringes in advance.

Administer the immunizing agent according to the recommended schedule (age, route of administration, dose and interval between doses).

Check the expiration date:

- If the expiration date is in month/year format, the product may be used until the end of the month indicated;
- If the expiration date is in day/month/year format (ex.: 31/03/12), the product may be used no later than by the end of the day indicated;
- If the expiration date has passed, the product must not be used.

3.3.2 Preparation phase

Check the patient's file and immunization record.

Identify the vaccines to be administered.

Review the vaccines to be administered.

Prepare the materials needed to administer the vaccine.

3.3.3 Materials Needed to Administer the Vaccine

Patient's file and immunization record

Sterile syringes and needles

Antiseptic swabs

Cotton balls or gauze pads

Immunizing agents

Anaphylaxis kit

Sharps container

3.3.4 Preparing Immunizing Agents

Vial

Gently shake or swirl the vial immediately before drawing the immunizing agent from it.

Clean the surface of the rubber stopper with an antiseptic swab.

You do not need to change the needle used to draw the product from the vial before the injection.

Multi-dose vial

Write the date or time the vial was opened on the vial's label.

Put the vial back in the refrigerator immediately after drawing the vaccine from it.

At the end of an immunization session, discard opened multi-dose vials that do not contain a preservative.

During an immunization session, what remains in a multi-dose vial can be drawn into a syringe and topped up with the contents of another vial under the following conditions:

- The product contains a preservative;
- The product has not expired;
- The vials are kept between 2°C and 8°C, and the cold chain has been maintained between withdrawals from the two vials;
- Aseptic technique is strictly adhered to;
- The vials are from the same lot number.

Ampoule

Gently shake the ampoule to achieve a homogenous consistency immediately before drawing the product from it.

Clean the neck of the ampoule with an antiseptic swab.

3.3.5 Administration

Where possible, do not inject an immunizing agent in a site:

- That is inflamed or itchy;
- Where there is a scar, a nodule, sensitivity, induration or pain;
- If the limb is paralyzed or inactive;
- If the limb is affected by a problem in the lymphatic system, such as in lymphangioma or mastectomy;
- If there is a dialysis access or peripherally inserted central catheter.

Vaccines can be injected in tattoos, except intradermally (ID).

Aspiration is not advised because it is painful and unnecessary as no large blood vessels are near the injection site.

3.3.6 Administration of several injections during the same visit

If a patient needs several injections administered during the same visit:

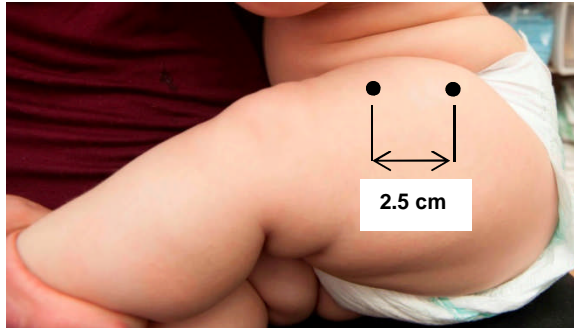
- All vaccines should be prepared immediately before their injection and labelled correctly;
- The least painful vaccines should be administered first;
- Two injections can be administered in the same site (deltoid region or vastus lateralis region) as follows: two intramuscular (IM) injections; one IM injection and one subcutaneous (SC) injection; or two SC injections. Injections should be spaced at least 2.5 cm (1 in.) apart to identify the cause of any local reactions and to prevent immune interference.

For example:

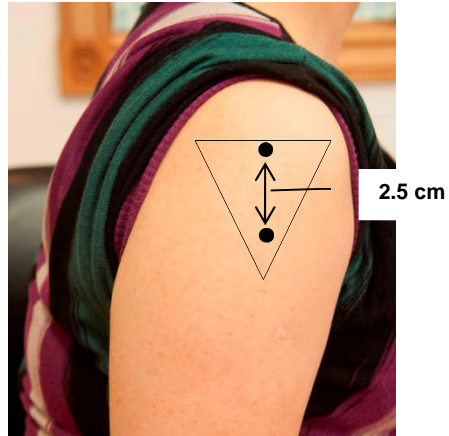
- Vastus lateralis: two IM injections—DTaP-IPV-Hib and pneumococcal conjugate;
- Deltoid: two IM injections—Tdap and HB—or one IM injection and one SC injection (MMR).

Multiple Injection Sites

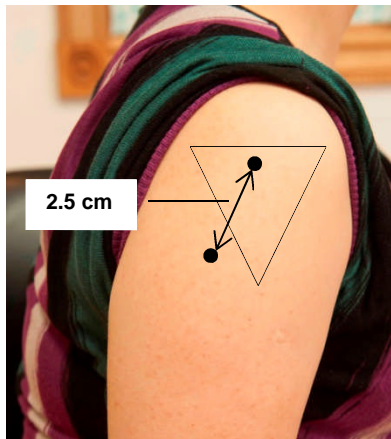
Spacing for Multiple IM Injections in the Vastus Lateralis



Spacing for Multiple IM Injections in the Deltoid Muscle



Spacing for IM Injection in the Deltoid Muscle and SC Injection in the Arm



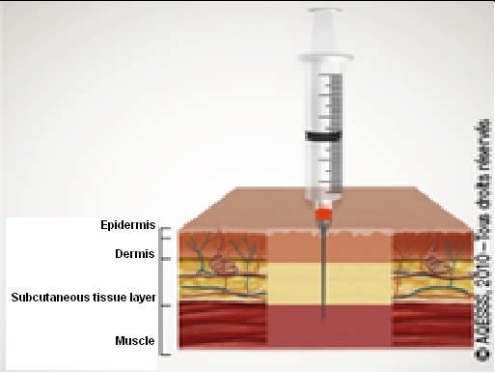
3.3.7 Methods for Reducing Anxiety and Pain During Immunization

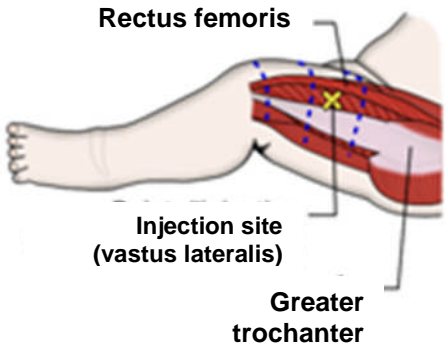
Immunization	Cognitive strategies	Pharmaceutical intervention	Other
Before	Behaviour of parents and vaccinators ¹	Topical analgesics ²	Administration of a slightly sweet liquid (not honey) for children ≤ 12 months ³
During	Behaviour of parents ⁴ and vaccinators	—	Interventions by the vaccinator ⁵ Interventions by the parent ⁶
After	—	Oral analgesics ⁷	Breastfeeding Comforting


Adapted from MINISTÈRE DE LA SANTÉ ET DES SERVICES SOCIAUX, *Les injections multiples dans le cadre de la pratique vaccinale au Québec : Formation* (multiple injections in Quebec's immunization practices: training), p. 52.

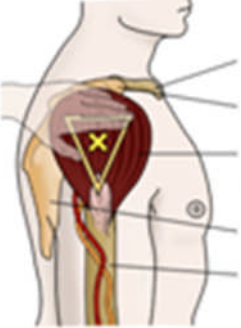
- (1) Vaccinators: talk about the benefits of vaccines and include the parents in comforting the child; parents: prepare the child for the experience at home, never use immunization as a punishment.
- (2) Can be used with any IM or SC vaccines. Effective, but not recommended for regular use. The EMLA cream and patch (2.5% lidocaine and 2.5% prilocaine) and Ametop gel (4% amethocaine) have been proven effective.
- (3) Dissolve one packet of sugar in 15–30 ml of water. Regional pharmacy also carries a sucrose solution that can be given prior to vaccination.
- (4) Directed or undirected distraction. For example, have children exhale through the mouth during the immunization, tell them a story, rock them or cuddle them.
- (5) Apply pressure on the injection site for 10 seconds or lightly tap the site just before the injection. Ensure the child is positioned correctly. Use an appropriate injection technique.
- (6) Breastfeeding, skin-to-skin contact, use of a soother. Comforting, for older children.


3.3.8 Intramuscular (IM) Injection

Procedure	
	<p>Use a needle that is long enough to reach the muscle.</p> <p>Stretch the skin tight between the thumb and forefinger.</p> <p>Insert the needle in a sure, quick movement.</p> <p>Do not aspirate the needle.</p> <p>Quickly inject the product.</p>

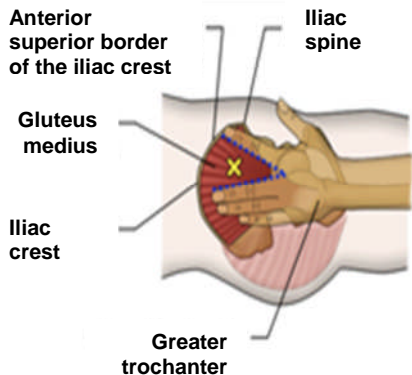
Injection Site for Vastus Lateralis Muscle	
	<p>The injection site can be found by dividing the upper leg into 3 sections, and injections can be given into the middle outer aspect of the thigh.</p> <p>This is the preferred site for IM injection in infants less than 1 year of age.</p>
<p>Maximum quantity:</p> <p>1 ml in children 5 ml in adults</p>	<p>Needle:</p> <p>25 gauge 7/8 – 1” in <1 year of age 1 – 1.5” in >1 year of age</p>

Positioning of an Infant (< 1 year) for IM Injection in the Vastus Lateralis	
	<p>Have the parent securely hold the infant close to their body. Both arms should be secured in one of the parent's hands and the legs should be held by the parent's other hand.</p>

Injection Site for Deltoid Muscle (preferred site for all > 1 year)		
	<p>Clavicle</p> <p>Acromion</p> <p>Deltoid</p> <p>Scapula</p> <p>Humerus</p>	<p>Locate the site by imagining a triangle whose base is at the inferior border of the acromion and whose point sits over the deltoid insertion.</p> <p>In adults, the area created should be about 5 cm x 5 cm and be located four finger widths below the acromion process, on the lateral side of the arm.</p>
	<p>Maximum quantity: 1 ml in children 2 ml in adults</p>	<p>Needle: 25 gauge 7/8 – 1.5”</p>

Positioning of a child > 1 year for IM Injection in the Deltoid (preferred site)	
	<p>Have the parent securely hold the child close to their body. Legs should be placed between the parent's legs and firmly held in place. The arm not being vaccinated should be tucked under the parent's arm and the arm to be used should be securely held with the parent's hand.</p>

**Injection Site for Ventrogluteal Muscle
(for giving immune globulin only)**



Place the person on their side or stomach.
Place the palm of your hand on the hip at the level of the greater trochanter, with your fingers pointed toward the person's head.
Point your index finger to the anterior superior iliac spine and extend your middle finger back along the iliac crest. Your index and middle fingers should make a V.
Make the injection in the middle of the V.

Maximum quantity:
1 ml in children
2 ml in adults

Needle:
25 gauge
7/8 – 1" in < 1 year of age
1 – 1.5" in > 1 year of age

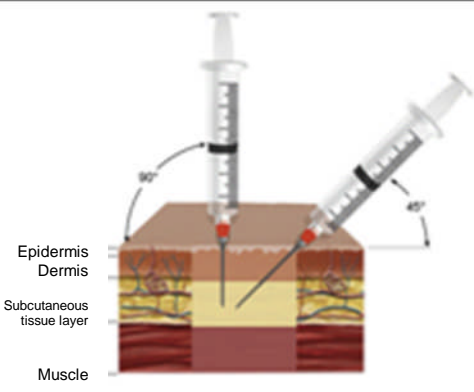
**Positioning for IM Injection into the Ventrogluteal Muscle
(for giving immune globulin only)**

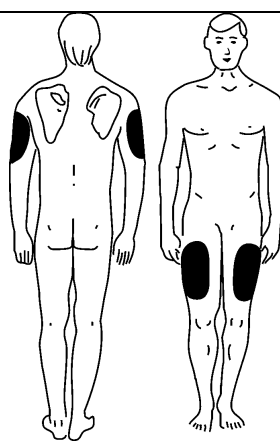


Have the patient lie on the side opposite the injection site, with the knee of the upper leg flexed toward the chest.

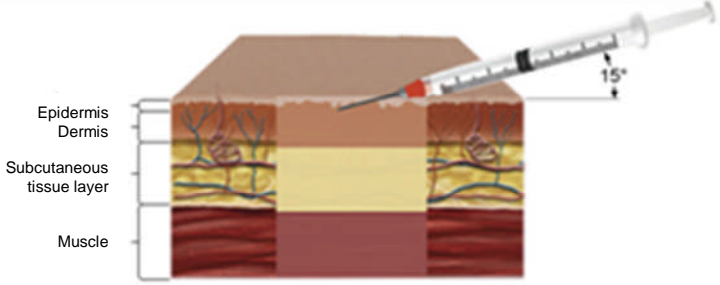
If the left hip is exposed, place your right hand on it with the fingers pointed toward the patient's head. If the right hip is exposed, use your left hand.


3.3.9 Subcutaneous (SC) Injection


Procedure	
	<p>Pinch the skin between the thumb and forefinger to raise the subcutaneous tissue.</p> <p>Insert the needle quickly and firmly.</p> <p>Release the tissue.</p> <p>Do not aspirate the needle.</p> <p>Quickly inject the product.</p> <p>5/8" 25 gauge needle is recommended.</p>

Injection Site for Subcutaneous (SC) Injection		
<p>For all ≥ 1 year: Posterolateral surface of the arm is the preferred site.</p>		<p>For infants < 1 year: Anterolateral surface of the thigh is the preferred site.</p>

3.3.10 Intradermal (ID) Injection

Procedure	
	<p>Stretch the skin between the thumb and forefinger.</p> <p>Gently insert the needle with the bevel of the needle turned upward. The point of the needle will be visible just under the skin.</p> <p>Release the skin.</p> <p>Slowly inject the product.</p> <p>Wait a few seconds after the injection before removing the needle.</p>

Injection Site for the Tuberculin Skin Test (TST)	
	<p>The TST should be given in the middle of the anterior surface of the forearm.</p> <p>It is administered in a syringe with a 27-gauge ½ inch needle, the bevel facing upwards.</p> <p>A blister will appear during the injection. It will have the texture of an orange peel and be lighter than the surrounding skin.</p> <p>If the blister does not appear immediately, start the injection over in the other arm or 2" below the botched site.</p>

Injection Site for the Bacille Calmette-Guérin (BCG) Vaccine	
	<p>The BCG should be given over the outer lower aspect of the deltoid region on the right arm.</p> <p>It is administered in a syringe with a 27-gauge ½ inch needle, the bevel facing upwards.</p> <p>A blister will appear during the injection. It will have the texture of an orange peel and be lighter than the surrounding skin.</p> <p>If the blister does not appear immediately, reposition the needle before administering the rest of the dose. If the entire dose has been injected and the blister has not appeared, the person is considered immunized, and the injection should not be redone.</p>

Positioning of an Infant for the BCG Vaccine



Wrap the infant tightly with only the right arm exposed.



Lay the infant on her left side.

Have one health care provider holding the infant firmly in place.

The parent or guardian can assist by holding the legs.

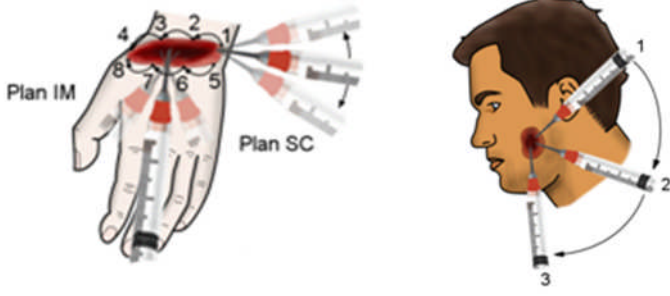
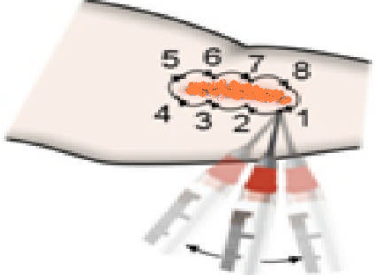
Both health care providers must wear eye protection and ensure that the infant's and parents eyes are protected as well.

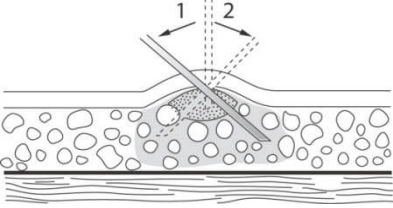
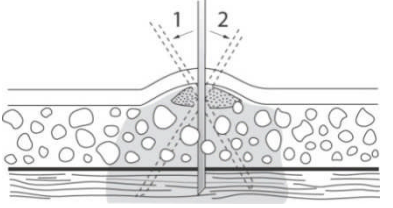
3.3.11 Injection Technique for Rabies Immune Globulin (Rablg)

Injection Site	Needle	Procedure
In and around a wound caused by a rabid or potentially rabid animal (including the face)	<ul style="list-style-type: none"> • 23–25 gauge • Length of the needle is dependent on the depth of the wound 	<p>Before injection:</p> <ul style="list-style-type: none"> • Take several minutes to clean the wound with soapy water (4 parts water to 1 part soap), even if the wound occurred several hours before. • Apply a virucidal agent (i.e. povidine-iodine solution, also known as Betadine) as soon as possible after washing. • Prepare the immunizing agent according to the number and size of the wounds. • If needed, dissolve the Rablg in two or three parts 0.9% NaCl, being sure to divide this solution equally among the sites. • Use a new needle and syringe for each new wound site (ex.: face, thigh). • Use non-sterile gloves.

Remember

- The quantity of Rablg to use is proportional to the size and depth of the wounds.
- The rest of the Rablg must be administered intramuscularly in the ventrogluteal or vastus lateralis muscle.
- For open wounds, inserting the needle in subcutaneous tissue is less painful than inserting it through healthy skin.
- If a little blood fills the syringe, reposition the needle and continue. If a lot of blood fills the syringe, discard the materials and start over.
- The first dose of the rabies vaccine must be administered intramuscularly in a different site than where the Rablg will be injected (preferably in the deltoid in individuals > 1 year of age).

Injection in an Open Wound	Injection in a Closed Wound
	
<p>Choose the angle based on the depth of the wound and the tissues affected.</p> <p>Insert the needle in the edges of the wound at a 30° to 90° angle, with the bevel of the needle turned upward.</p>	<p>Choose the angle based on the depth of the wound and the tissues affected.</p> <p>Insert the needle through healthy skin at a 30° to 90° angle, with the bevel of the needle turned upward and pointed toward the wound.</p>

Subcutaneous	Intramuscular
	
<ul style="list-style-type: none"> • Lightly aspirate the needle to be sure it is not inside a blood vessel. • Slowly inject some of the product until the tissue swells slightly or goes pale. • Withdraw the needle a few millimetres. Change the angle of the needle—imagine the needle making the shape of a fan. Then, reinsert the needle into the tissue and continue with the injection. • Remove the needle entirely and reinsert it nearby. • Repeat these steps along the entire edge of the wound. • Cover the wound with a sterile bandage. 	

References

1. Adapted from: Quebec Immunization Manual, by the Government of Quebec, 2013. Adapted with permission.

3.0 Practice Guidelines

3.4 Documentation of Immunizations

Personal Immunization records should be provided to each vaccine recipient. The recipient is responsible to bring this record to appointments. Appointment cards are recommended to encourage the recipient to return at the appropriate time.

Nunavut Immunization Records

Immunizations may be provided by Birthing Centers and Hospitals, both within and outside the Territory. These records should be forwarded to the appropriate Public Health Office or the Health Center in the community where the client resides. Please review these immunization records carefully on an individual basis, as practices may not be standardized.

If someone relocates from outside of NU, a new immunization card should be created from existing records. These immunization records should be kept at the local Public Health Office or Health Center.

Nunavut immunization cards should be kept in an easily retrievable manner that permits regular checking and updating of the individual's immunization status. The immunization record should not be archived in a patient's chart. During audits, outbreaks, times of disaster, or pandemic mass clinics, these cards are then readily available. They are filed in alphabetical order by year of birth.

The nurse or midwife is responsible to give immunizations that are due based on reviewing vaccine inserts and protocols, the most current Nunavut Immunization schedule, the recipient's Nunavut Immunization card, and the Nunavut catch-up schedule. Don't rely solely on appointment cards, penciled directions or sticky notes. Use black ink and do not write in pencil. Please ensure that all fields are correctly filled in including: date, name of vaccine and manufacturer, lot number, route, site, name and designation of vaccinator. Document the diluents in the same manner as a vaccine.

In addition to information about vaccinations given, documentation should include all relevant serologic data and should document adverse events following immunization as well as contraindications, exemptions or reasons for deferring vaccination.

While electronic immunization registries are recommended nationally, only some Health Centers in Nunavut have them. Most rely on paper or hard copy records to document immunizations. A Nunavut wide electronic immunization registry is under development.



IMMUNIZATION RECORD

Allergies : _____

Name (Last/First): _____ DOB: dd-mm-yyyy: _____ (M/F): _____ HCP: _____ Community of Residence: _____	Chart #: _____ House: _____ Phone: (H) _____ (C) _____ Parent/Guardian: _____
--	---

Date dd-mm-yyyy	Vaccine	Product Trade Name	Lot#	Dose	Route	Site	Signature and designation
	BCG						
	#1 Hep B						
	#2 Hep B						
	#1DTaP-IPV/Hib						
	#1 Pneu-C						
	#1 Rotavirus						
	#2 DTaP-IPV/Hib						
	#2 Pneu-C						
	#2 Rotavirus						
	#3 DTaP-IPV/Hib						
	#3 Pneu-C						
	#3 Hep B						
	#1 MMRV						
	Diluent						
	Men-C-C						
	#4 Pneu-C						
	#4 DTaP-IPV/Hib						
	#2 MMRV						
	Diluent						
	Pneu-P						
	#5 DTaP-IPV/Hib						
	#1 HPV						
	#2 HPV						
	Tdap						
	Men-C-ACYW 135						

Routes: SC = Subcutaneous IM = Intramuscular PO = By mouth ID = Intradermal

Anatomical sites: LA = Left Arm RA = Right Arm LL = Left Leg RL = Right Leg

Diseases vaccinated against:

- | | |
|---|---|
| BCG = Tuberculosis
Hep B = Hepatitis B
DTaP-IPV/Hib = Diphtheria, tetanus, pertussis, polio,
Haemophilus influenza type B
MMRV = Measles, mumps, rubella, varicella
Men-C-C = Meningococcal C
Men-C-ACYW 135 = Meningococcal A, C, Y, W 135 | Rotavirus = Rotavirus
Pneu-Conjugate = Streptococcus pneumoniae
Pneu-Polysaccharide = Streptococcus pneumoniae
HPV = Human Papillomavirus
Tdap = Tetanus, diphtheria, pertussis |
|---|---|

Date dd-mm-yyyy	Comments (documented vaccine preventable diseases, reactions, unusual events related to any immunization)

3.0 Practice Guidelines

3.5 Management and Reporting of Adverse Events

Introduction

3.5.1 Reporting Averse Events

3.5.2 Recommendations Following an Adverse Event

3.5.3 Documentation

3.5.4 Summary of Reporting Criteria

3.5.5 Adverse Events Following Immunization Form

3.0 Practice Guidelines

3.5 Management and Reporting of Adverse Events

Introduction

An adverse event following immunization (AEFI) is any untoward medical occurrence in a vaccinee that follows immunization and may not have a causal relationship with the vaccine or the immunization process.

The purpose of this document is to provide criteria for the reporting of adverse events, and to assist health practitioners who administer vaccines with the interpretation of adverse events following immunization and their implications for subsequent immunization.

3.5.1 Reporting Adverse Events

Vaccine safety is a focus of pre-licensure studies. An acceptable safety profile must be observed in order for vaccines to progress to phase III (clinical) trials in humans. These studies provide frequency data on the occurrence of common adverse events such as local reactions at the injection site or systemic events, and grading of the severity of these events. Uncommon and rare adverse events are usually not identified in pre-licensure studies and reliance is placed on phase IV studies or post-marketing surveillance; this is especially important in the first year or so following introduction of a vaccine.

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)

Events that **should be** reported include the following (full details in the Summary of Reporting Criteria table below):

- 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:
 - the event that has either not been identified previously (for example, Oculo-Respiratory Syndrome (ORS) was first identified during the 2000/2001 influenza season), or
 - the event has been identified before but is occurring with greater frequency in the population (e.g., extensive local reactions)
- 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.

Temporal association alone (i.e., onset of an event following receipt of vaccine) is not proof of causation.

When an adverse event follows the administration of a passive immunizing agent (e.g. immune globulin) an AEFI report should not be completed. Instead, please follow the established procedures for reporting an adverse drug reaction to the Canadian Adverse Drug Reaction Monitoring Program at Health Canada and contact RCDC.

When an adverse event follows the administration of an active immunizing agent (e.g. vaccine) that is administered *simultaneously* with a passive immunizing agent (e.g., immune globulin) and/or a diagnostic agent (e.g., tuberculin skin test), complete the Adverse Events Following Immunization (AEFI) Report Form found in Appendix A of this section.

3.5.2 Recommendations Following an Adverse Event

Completed AEFI report forms should be faxed 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 Medical Officer for Health (CMOH).

The following are **recommended** criteria for events to be reviewed by the Medical Health Officer:

- events which the client's health care provider considers to confer precautions, contraindications or a reason to postpone a future immunization
- all events managed as anaphylaxis
- all neurological events including febrile and afebrile convulsions
- allergic events
- all events where medical attention is required, and
- all events that are serious (resulting in hospitalization, residual disability, death, or congenital malformation)

Recommendations following adverse event review should be discussed with the client and provided to the client's primary health care provider.

3.5.3 Documentation

Documentation of the AEFI and CMOH recommendations should be made in the client's chart, on the immunization record, and on the electronic chart (when applicable).

3.5.4 Summary of Reporting Criteria

Adverse event Following Immunization	Reporting Criteria	Temporal Criteria ¹	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reaction at Injection Site			
Abscess, Infected	<ul style="list-style-type: none"> Material from abscess known to be purulent (positive gram stain or culture) OR There are one or more signs of localized inflammation (erythema, pain to light touch, warmth) AND Evidence of improvement on antimicrobial therapy OR Physician-diagnosed 	0 – 7 days	
Abscess, Sterile	<ul style="list-style-type: none"> Physician diagnosed AND any of the following: Material from mass is known to be non-purulent Absence of localized inflammation Failure to improve on antimicrobial therapy 	0 – 7 days	
Cellulitis	<ul style="list-style-type: none"> Physician-diagnosed AND characterized by at least 3 of the following: pain or tenderness to touch, erythema, induration or swelling, warmth 	0 – 7 days	
Nodule	<ul style="list-style-type: none"> Is more than 2.5 cm in diameter AND Persists for more than 1 month 	0 – 7 days	
Pain or Redness or Swelling	<ul style="list-style-type: none"> Pain or redness or swelling that extends past the nearest joint AND/OR Pain or redness or swelling that persists for 10 days or more 	0 – 48 hours	

1. The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

Adverse event Following Immunization	Reporting Criteria	Temporal Criteria ¹	
		Inactivated Vaccines	Live Attenuated Vaccines
Systemic Reactions			
Adenopathy/ Lymphadenopathy	<ul style="list-style-type: none"> Enlargement of one or more lymph nodes, ≥ 1.5 cm in diameter AND/OR Draining sinus over a lymph node 	0 – 7 days	MMR: 5 – 30 days Varicella: 5 – 42 days
Fever	<ul style="list-style-type: none"> Fever $\geq 38^{\circ}\text{C}$ that occurs in conjunction with another reportable adverse event 	Timing in conjunction with the other reportable adverse event(s)	
Hypotonic- Hyporesponsive Episode (HHE)	<ul style="list-style-type: none"> Physician-diagnosed AND Reduced muscle tone AND Hyporesponsiveness or unconsciousness AND Child < 2 years of age 	0 -48 hours	
Parotitis	<ul style="list-style-type: none"> Physician-diagnosed parotitis following immunization with a mumps-containing vaccine 	Not applicable	MMR: 5 – 30 days
Orchitis	<ul style="list-style-type: none"> Physician-diagnosed orchitis following immunization with a mumps-containing vaccine 	Not applicable	MMR: 5 – 30 days
Rash	<ul style="list-style-type: none"> Inactivated vaccines: Generalized rash for which medical attention is sought, when the rash is believed to be caused by the vaccine, and for which no alternative cause has been identified OR Live vaccines: an expected rash following a live vaccine that requires hospitalization 	0 – 7 days	MMR: 0 – 30 days Varicella: 0 – 42 days
Screaming/ persistent crying	<ul style="list-style-type: none"> Crying is continuous/ unaltered AND Lasting for 3 or more hours 	0 – 72 hours	
Severe Vomiting/ Diarrhea	<ul style="list-style-type: none"> 3 or more episodes of vomiting or diarrhea in a 24 hour period AND Symptoms are severe, i.e., projectile vomiting or explosive, watery diarrhea 	0 – 72 hours	0 – 72 hours

1. The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

Adverse event Following Immunization	Reporting Criteria	Temporal Criteria ¹	
		Inactivated Vaccines	Live Attenuated Vaccines
Allergic Reactions			
Anaphylaxis	<ul style="list-style-type: none"> Any event managed as anaphylaxis following immunization 	0 – 24 hours	
Oculo-respiratory syndrome (ORS)	<ul style="list-style-type: none"> Bilateral red eyes AND Respiratory symptoms Following influenza vaccine 	0 – 24 hours	
Other Allergic reactions	<ul style="list-style-type: none"> Skin OR Respiratory OR Gastrointestinal manifestations 	0 – 48 hours	
Neurological Events			
Anaesthesia/ paraesthesia	<ul style="list-style-type: none"> Physician-diagnosed anaesthesia or paraesthesia lasting 24 hours or more 	0 – 15 days	MMR: 0 – 30 days Varicella: 0 – 42 days
Bell's Palsy	<ul style="list-style-type: none"> Physician-diagnosed Bell's Palsy 	0 – 3 months	
Convulsion/ seizure	<ul style="list-style-type: none"> Seizures (febrile or afebrile) Include temperature if febrile seizure reported 	0 – 72 hours	MMR: 5 – 30 days Varicella: 5 – 42 days
Encephalopathy or Encephalitis or Acute Disseminated Encephalomyelitis (ADEM)	<ul style="list-style-type: none"> Physician-diagnosed encephalopathy or encephalitis or ADEM 	0 – 42 days	MMR: 5 – 30 days Varicella: 5 – 42 days
Guillain-Barré syndrome (GBS)	<ul style="list-style-type: none"> Physician-diagnosed GBS 	0 – 56 days	
Meningitis	<ul style="list-style-type: none"> Physician-diagnosed meningitis for which no other cause has been identified 	Not applicable	MMR: 5 – 30 days Varicella: 5 – 42 days
Subacute sclerosing panencephalitis (SSPE)	<ul style="list-style-type: none"> Physician-diagnosed SSPE 	Not applicable	Up to 10 years following immunization with a measles-containing vaccine

1. The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

Adverse event Following Immunization	Reporting Criteria	Temporal Criteria ¹	
		Inactivated Vaccines	Live Attenuated Vaccines
Other Events of Interest			
Arthritis	<ul style="list-style-type: none"> Physician-diagnosed arthritis AND Lasting 24 hours or more 	0 – 30 days	MMR: 5 – 30 days Varicella: 0 – 42 days
Intussusception or hematochezia	<ul style="list-style-type: none"> Physician-diagnosed intussusception or hematochezia 	Not applicable	Rotavirus vaccine: 0 – 42 days
Syncope with injury	<ul style="list-style-type: none"> Syncope with injury following immunization 	0 – 30 minutes	
Thrombocytopenia	<ul style="list-style-type: none"> Physician-diagnosed thrombocytopenia 	0 – 30 days	
Other severe or unusual events ²		Variable based on event	

- The length of time between vaccine administration and onset of events is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.
- Other serious or unusual events may include those events which:
 - are life threatening or result in death; require hospitalization
 - result in a residual disability; are associated with a congenital malformation
 - require urgent medical attention
 - have:
 - not been identified previously (e.g. Oculo-Respiratory Syndrome (ORS) was first identified during the 2000/2001 influenza season), or
 - been identified before but is occurring with greater frequency in the population (e.g., extensive local reactions)
 - are 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.

References:

- British Columbia Centre for Disease Control Section IX – Adverse Events Following Immunization, by the British Columbia Centre for Disease Control. The materials in this section were developed and are being used with permission of British Columbia Centre for Disease Control.



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

REPORT OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

1a. Unique episode #: _____ **1b. Region #:** _____ **2. IMPACT LIN:** _____

3. Patient Identification

First name: _____ Last name: _____ Health number: _____
 Address of usual residence: _____
 Province/Territory: _____ Postal code: _____ Phone: () - (ext #:)
Information Source: First name: _____ Last name: _____ Relation to patient: _____
 Contact info, if different: _____

4. Information at Time of Immunization and AEFI Onset

4a. At time of immunization
Province/Territory of immunization: _____
Date vaccine administered: YYYY / MM / DD (hr: am/pm)
Date of birth: YYYY / MM / DD **Age:** _____
Sex: Male Female 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

4c. Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site
					/		
					/		
					/		
					/		
					/		

5. Immunization Errors
Did this AEFI follow an incorrect immunization? No Unknown Yes
(If Yes, choose all that apply and provide details in section 10)
 Given outside the recommended age limits Product expired
 Wrong vaccine given Incorrect route
 Dose exceeded that recommended 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)

7. Impact of AEFI, Outcome, and Level of Care Obtained

7a. Highest impact of AEFI: *(Choose one of the following)*
 Did not interfere with daily activities
 Interfered with but did not prevent daily activities
 Prevented daily activities

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

7c. Highest level of care obtained: *(Choose one of the following)*
 Unknown None Telephone advice from a health professional Non-urgent visit Emergency visit
 Required hospitalization (___days) **OR** Resulted in prolongation of existing hospitalization (by ___days)
 Date of hospital admission YYYY / MM / DD Date of hospital discharge YYYY / MM / DD

7d. Treatment received: No Unknown Yes *(Provide details of all treatments including self treatment, in section 10)*

8. Reporter Information

Setting : Physician office Public health Hospital Other, specify: _____
 Name: _____ Phone: () - (ext #:) Fax: () -
 Address: _____
 City: _____ Prov/Terr: _____ Postal code: _____ Date reported: YYYY / MM / DD
 Signature: _____ MD RN IMPACT Other, specify: _____

Note: Discuss with patient or his/her parent/caregiver reason for reporting and confidentiality of information

Unique episode #:

Region #:

IMPACT LIN:

Name:

DOB

9. AEFI Details: Complete all sections as appropriate; for each, check all signs/symptoms that apply. Item(s) with asterisk (*) should be diagnosed by a physician. If not, provide sufficient information to support the selected item(s). Use Section 10 for additional information including, clinical details and test results.

9a. Local reaction at or near vaccination site Interval: -> __Min __Hrs __Days from immunization to onset of 1st symptom or sign Duration: -> __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Infected abscess Sterile abscess Cellulitis Nodule Reaction crosses joint Lymphadenitis Other, specify: _____

For any vaccination site reaction indicated above, check all that apply:

Swelling Pain Tenderness Erythema Warmth Induration Rash Largest diameter of vaccination site reaction: ___ cm Site(s) of reaction (e.g. LA, RA) Palpable fluctuance Fluid collection shown by imaging technique (e.g. MRI, CT, ultrasound) Spontaneous/surgical drainage Microbial results Lymphangitic streaking Regional lymphadenopathy

9b. Allergic and Allergic-like events Interval: -> __Min __Hrs __Days from immunization to onset of 1st symptom or sign Duration: -> __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Chose one of the following: Anaphylaxis Oculo-Respiratory Syndrome (ORS) Other allergic events

Skin /mucosal: Urticaria, Erythema, Pruritus, Prickle sensation, Rash, ANGIOEDEMA: Tongue, Throat, Uvula, Larynx, Lip, EYE(S): Red bilateral, Red unilateral, Itchy. Cardio-vascular: Measured hypotension, central pulse volume, Capillary refill time >3 sec, Tachycardia, or loss of consciousness. Respiratory: Sneezing, Rhinorrhea, Hoarse voice, Sensation of throat closure, Stridor, Dry cough, Tachypnea, Wheezing, Indrawing/retractions, Grunting, Cyanosis, Sore throat, Difficulty swallowing, Difficulty breathing, Chest tightness. Gastrointestinal: Diarrhea, Abdominal pain, Nausea, Vomiting.

9c. Neurologic events Interval: -> __Min __Hrs __Days from immunization to onset of 1st symptom or sign Duration: -> __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

* Meningitis * Encephalopathy/Encephalitis * Guillain-Barre Syndrome (GBS) * Bell's Palsy * Other Paralysis Seizure * Other neurologic diagnosis, specify: _____

Depressed/alterd level of consciousness Lethargy Personality change lasting >=24hrs Focal or multifocal neurologic sign(s) Fever (>=38.0 C) CSF abnormality EEG abnormality EMG abnormality Neuroimaging abnormality Brain/spinal cord histopathologic abnormality

Seizure details: Witnessed by healthcare professional Yes No Unknown Sudden loss of consciousness Yes No Unknown Generalized (Specify: Tonic Clonic Tonic-Clonic Atonic Absence Myoclonic) OR Partial Previous history of seizures (Specify: Febrile Afebrile Unknown type)

9d. Other events Interval: -> __Min __Hrs __Days from immunization to onset of 1st symptom or sign Duration: -> __Min __Hrs __Days from onset of 1st symptom/sign to resolution of all symptoms/signs

Hypotonic-Hyporesponsive Episode (age <2 years) Limpness Pallor/cyanosis responsiveness/unresponsiveness Persistent crying (Continuous and unaltered crying for >=3 hours) * Intussusception Arthritis Joint redness Joint warm to touch Joint swelling Inflammatory changes in synovial fluid Parotitis (Parotid gland swelling with pain and/or tenderness) Rash (Non-allergic) Generalized Localized (Site) *Thrombocytopenia Platelet count <150x10^9/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:

Unique episode #:

Region #:

IMPACT LIN:

10. Supplementary information (Please indicate the section # when providing details. Please provide details of any investigation or treatment for the recorded AEFI).

Large dashed-line area for supplementary information.

11. Recommendations for future immunization(s) according to the Federal/Provincial/Territorial best practices.

THIS SECTION IS TO BE COMPLETED BY THE CMOH OR DCMOH

- Checkboxes for immunization recommendations: No change to immunization schedule, Expert referral, Determine protective antibody level, Controlled setting for next immunization, No further immunizations with, Active follow up for AEFI recurrence after next vaccine, Other, specify.

Name: Professional status: O CMOH/DCMHO O MD

Comments: Phone: () - (ext #:) Date: YYYY / MM / DD Signature: _____

12) Follow up information for a subsequent dose of same vaccine(s) (Provide details in section 10)

- Checkboxes for follow-up information: Vaccine administered without AEFI, Vaccine administered with recurrence of AEFI, Vaccine administered, other AEFI observed, Vaccine administered without information on AEFI, Vaccine not administered.

3.0 Practice Guidelines

3.6 Management and Reporting of Vaccine Errors

Vaccine related errors commonly include an error in vaccine type, dose, site, route, person, time or schedule.

Reporting Forms

All vaccine related errors in immunization practice should be reported using the *Nunavut Community Health Nursing Administration Manual*, Policy 05-004 and the Unusual Occurrence Report form. If the vaccine error also resulted in an adverse reaction, the Adverse Events Following Immunization (AEFI) form should also be completed (see section 3.5).

Procedure for Reporting Vaccine Errors

Step 1: The person first noticing the incident fills out the forms listed above and gives it/them to their Manager or Supervisor.

Step 2: The Manager or Supervisor sends a copy of the report to their Manager/Director and to Regional Communicable Disease Coordinator (RCDC).

Step 3: The Manager/Director uses the Incident Report for Risk Management purposes. The RCDC gives advice on management.

Step 4: The vaccine recipient should be notified of the incident and a copy of the incident is placed on the chart. Follow up as necessary.

3.0 Practice Guidelines

3.7 Management of Anaphylaxis

Contents

- 3.7.1 Anaphylaxis
- 3.7.2 Presentation
- 3.7.3 Assessment of Anaphylaxis
- 3.7.4 Anaphylaxis versus Fainting, Anxiety, Allergic Reaction, or Injection Site Reaction
- 3.7.5 Supervision of Vaccinee Post-Immunization
- 3.7.6 Anaphylaxis Management in the Community
- 3.7.7 Other Considerations
- 3.7.8 Recording of the Anaphylactic Event
- 3.7.9 Anaphylaxis Kit
- 3.7.10 Anaphylaxis Initial Management in Non-Clinical Setting
- 3.7.11 Anaphylaxis Assessment Guide and Record

3.0 Practice Guidelines

3.7 Management of Anaphylaxis

3.7.1 Anaphylaxis

Anaphylaxis is a potentially life-threatening IgE-mediated reaction that results from the sudden systemic release of allergenic mediators (e.g., histamine, leukotrienes, prostaglandins, tryptase) from mast cells and basophils. Within 10 minutes, increased vascular permeability allows transfer of as much as 50% of the intravascular fluid into the extravascular space. As a result, hemodynamic collapse might occur rapidly with little or no cutaneous or respiratory manifestations.

While anaphylaxis is extremely rare, every immunization carries an associated risk of producing an anaphylactic reaction. The estimated annual reported rate of anaphylaxis ranges from 0.4 to 1.8 reports per 1,000,000 doses of vaccines distributed in Canada. The more rapidly anaphylaxis occurs after exposure to an offending stimulus, the more likely the reaction is to be severe and potentially life-threatening.

Anaphylaxis often produces signs and symptoms within minutes of exposure to an offending stimulus. Most instances begin within 15 minutes after an injection of vaccine, but some reactions might develop later.

As 20% of anaphylaxis episodes follow a biphasic course with recurrence of the reaction after a 2 to 9 hour asymptomatic period, hospitalization or a long period of observation in the health clinic is recommended for monitoring. The presentation of the second phasic reaction may be as pronounced as that of the initial anaphylactic episode.

3.7.2 Presentation

Changes develop over several minutes and usually involve at least two body systems (affecting the skin, respiration, circulation). Unconsciousness is rarely the sole manifestation of anaphylaxis and occurs only as a late event in severe cases.

Anaphylaxis occurs as part of a continuum. Even when there are mild symptoms initially there is the potential for progression to a severe and even irreversible outcome. Fatalities during anaphylaxis usually result from delayed administration of epinephrine and from severe respiratory complications, cardiovascular complications, or both. **There is no contraindication to epinephrine administration in anaphylaxis.**

Urticaria and angioedema are the most common manifestations of anaphylaxis. Urticaria (hives) are raised, often itchy, wheals on the surface of the skin. Angioedema is a swelling similar to urticaria, but the swelling is beneath the skin rather than on the surface. The swellings are called welts. The welts usually occur around the eyes and lips. They may also be found on the hands, feet, and neck and in the throat.

Features of early or mild anaphylaxis may include swelling and hives at injection site, sneezing, nasal congestion, tearing, coughing, and facial flushing. These symptoms are generally associated with minimal dysfunction.

Features of moderate to severe anaphylaxis include obstructive swelling of the upper airway, hypotension, and marked bronchospasm (constriction of the air passages of the lung by spasmodic contraction of the bronchial muscles).

Frequency of occurrence of signs and symptoms of anaphylaxis	
Signs and symptoms	Approximate frequency
Cutaneous	90%
• Generalized urticarial (hives) and/or angioedema (welts)	85 – 90%
• Flushing	45 – 55%
• Pruritus (itchiness) with or without rash	2 – 5%
Respiratory	40 – 60%
• Upper airway angioedema	50 – 60%
• Dyspnea (difficulty breathing), wheeze	45 – 50%
• Rhinitis (nasal congestion)	15 – 20%
Dizziness, syncope (fainting), hypotension	30 – 35%
Abdominal	
• Nausea, vomiting, diarrhea, cramping pain	25 – 30%
Miscellaneous	
• Headache	5 – 8%
• Substernal (chest) pain	4 – 6%
• Seizure	1 – 2%
From: The diagnosis and management of anaphylaxis: an updated parameter. (2005). Journal of Allergy and Clinical Immunology, 115, S483-523.	

3.7.3 Assessment of Anaphylaxis

- Level of consciousness (impairment might reflect hypoxia)
- Upper and lower airways [observe for hoarse cry/voice, stridor (a high-pitched noisy sound occurring during inhalation or exhalation), cough, wheezing, or shortness of breath]
- Respiratory rate
- Pulse rate (assess for rapid, weak pulse). Examine for pallor or cyanosis around perioral area
- Skin (observe for facial flushing, itching, hives or welts)
- Gastrointestinal system (nausea, vomiting, or diarrhea)
- Injection site(s). Observe for redness, swelling, or hives.

Record full details of the assessment including signs/ symptoms, to allow for classification of the event according to the Brighton Case Definition for anaphylaxis. Use the “Anaphylaxis Assessment Guide and Record” found in section 3.7.11.

3.7.4 Anaphylaxis versus Fainting, Anxiety, Allergic Reaction, or Injection Site Reaction

Anaphylaxis must be distinguished from fainting (vasovagal syncope), anxiety, and breath-holding spells which are more common and benign reactions. The lack of hives, a slow, steady pulse rate, and cool pale skin distinguishes a vasovagal episode from anaphylaxis.

Fainting

During fainting, the individual suddenly becomes pale, loses consciousness and collapses to the ground. Fainting is sometimes accompanied by brief clonic seizure activity (i.e., rhythmic jerking of the limbs), but this generally requires no specific treatment or investigation.

Recovery of consciousness occurs within a minute or two, but clients may remain pale, diaphoretic and mildly hypotensive for several more minutes. **If unconsciousness persists for more than 2-3 minutes, call for help or ambulance (if available) and proceed as per emergency treatment for anaphylaxis.** Unconsciousness may reflect hypoxia.

Prior to immunization, ask client about history of fainting with previous immunizations.

To reduce the likelihood of fainting (and the possibility of injuries), consider the following measures to lower stress in those awaiting immunization:

- Seat every client prior to immunization
- Maintain a comfortably cool room temperature and if possible, plenty of fresh air
- Avoid long line ups in mass immunization clinics
- Prepare vaccine(s) out of view of recipients
- Provide privacy during vaccination
- If client is anxious and pale: have them lie down with legs elevated, reassure, and apply cold wet cloth to face.

If person was lying down, have them sit for a few minutes before standing.

Anxiety/Pain reaction

People experiencing an anxiety reaction may appear fearful, pale and diaphoretic and complain of lightheadedness, dizziness and numbness, as well as tingling of the face and extremities. Hyperventilation is usually evident.

If an individual appears anxious, it may be helpful to have them rebreathe into a paper bag until symptoms subside.

Breath-holding spells occur in some young children when they are upset, crying hard, and reacting to injection pain. The child is suddenly silent but obviously agitated. Facial flushing and perioral cyanosis deepens as breath-holding continues. Some spells end with resumption of crying, but others end with a brief period of unconsciousness during which breathing resumes.

Occasionally, the breath holding spell may be accompanied by brief clonic seizure activity. Similar spells may have been observed in other circumstances. No treatment is required beyond reassurance of the child and parents.

Anaphylaxis versus fainting and anxiety

	Anaphylaxis	Fainting	Anxiety
Definition	An acute systemic and potentially fatal allergic reaction to a foreign substance. IgE-mediated antibody induces histamine release from tissue mast cells.	A temporary unconsciousness caused by diminished blood supply to the brain due to painful stimuli or emotional reaction.	A protective physiological state recognized as fear, apprehension, or worry.
Onset	Usually slower, most instances begin within 30 minutes after immunization.	Sudden, occurs before, during, or shortly after immunization; recovery occurs within 1-2 minutes	Sudden, occurs before, during, or shortly after immunization; recovery occurs within 1-2 minutes
Skin	<ul style="list-style-type: none"> - Flushed, red blotchy areas (not necessarily itchy) - Itchy, generalized hive-like rash - Tingling sensation often first felt about the face and mouth - Progressive, painless swelling about the face, mouth and tongue 	<ul style="list-style-type: none"> - Pale - Excessive perspiration - Cold, clammy 	<ul style="list-style-type: none"> - Pale - Excessive perspiration - Cold, clammy
Breathing	<ul style="list-style-type: none"> -sneezing, coughing, wheezing, laboured breathing - upper airway swelling (indicated by hoarseness and/or difficulty swallowing) possibly causing airway obstruction 	<ul style="list-style-type: none"> - normal or shallow, irregular, laboured 	<ul style="list-style-type: none"> - rapid and shallow (hyperventilation)
Pulse	-rapid, weak	-slow, steady	-rapid
Blood Pressure	-decreased systolic and diastolic	- decreased systolic and diastolic	- normal or elevated systolic
Symptoms & Behaviours	<ul style="list-style-type: none"> - uneasiness, restlessness, agitation - hypotension, which generally develops later and can progress to cause shock and collapse -not all signs/symptoms will be exhibited in each person; usually one body system predominates. 	<ul style="list-style-type: none"> - fearfulness - light-headedness - dizziness - numbness, weakness - sometimes accompanied by brief clonic seizure activity 	<ul style="list-style-type: none"> - fearfulness - light-headedness - dizziness - numbness, weakness - tingling around lips and spasm in the hands and feet associated with hyperventilation - hyperventilation
Gastro-intestinal	<ul style="list-style-type: none"> - nausea and vomiting - abdominal pain, diarrhea 	<ul style="list-style-type: none"> - nausea 	<ul style="list-style-type: none"> - nausea
Other Symptoms	<ul style="list-style-type: none"> - loss of consciousness - progression of injection site reaction beyond hives and swelling 		

Allergic reaction

Allergic reactions constitute a spectrum, the extreme end of which is anaphylaxis, but milder forms may involve both the dermatologic/mucosal (e.g. urticaria, pruritis, rhinitis) and/or the respiratory systems (e.g., upper airway swelling, respiratory distress). Anaphylaxis is set apart from simple allergic reactions by the simultaneous involvement of the cardiovascular system and loss of intravascular volume, as well as respiratory obstruction.

Injection site reactions

A mild local reaction resolving by itself within a few minutes does not require special observation.

If swelling and hives occur at the injection site(s):

- Keep client under **direct observation** for at least 30 minutes to ensure the reaction remains localized
- Observe for any deterioration in condition
- If hives or swelling disappears, or there is no evidence of any progression to other parts of the body or any other symptoms within the 30-minute observation period, no further observation is necessary. Release the client from observation.
- **If any other symptoms arise**, even if considered mild (e.g., sneezing, nasal congestion, tearing, coughing, facial flushing) or if there is evidence of any progression of the hives or swelling to other parts of the body, **administer epinephrine**
- There is little risk to the unnecessary use of epinephrine, whereas delay in its administration (when required) may result in difficulty to treat anaphylaxis and in death
- Apply ice for comfort.

3.7.5 Supervision of Vaccinee Post-Immunization

Advise recipients of any biological product (i.e., vaccine, immune globulin, TB skin test) to remain under supervision for at least 15 minutes after immunization; regardless of whether or not they have had the particular product previously. **Thirty (30) minutes is a safer duration when the person has had a prior allergic reaction to the biological product or a component of the biological product. If an individual has such an allergic history, immunization should occur in an acute care setting.**

Routine supervision should ensure that vaccinees remain within a short distance of the vaccinator with the instruction that they ask someone to obtain the nurse for them immediately for assessment if they feel unwell.

Where vaccinees choose not to remain under supervision after immunization, they (or their parent/guardian) should be informed of the signs and symptoms of anaphylaxis and instructed to obtain immediate medical attention should symptoms occur.

3.7.6 Anaphylaxis Management in the Community

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 center or hospital setting following the protocol outlined in Section D-09 and D-10 of the Government of Nunavut Drug Formulary.

Action of Epinephrine

- Counteracts the histamine-induced vasodilation
- Increases heart rate and cardiac contractility to increase oxygenated blood flow to vital organs
- Acts on smooth muscles of bronchial tree thereby reducing bronchospasm
- Suppresses body's immune response (slows down histamine cascade).

Intramuscular (IM) epinephrine injections into the thigh (vastus lateralis) have been reported to provide more rapid absorption and higher plasma epinephrine levels in both children and adults than IM or subcutaneous (SC) injections administered into the arm.

Therefore, 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 child is <12 months of age and has received an IM vaccine in each thigh, give epinephrine SC into the upper outer triceps area of the infant's arm(s).

If the thigh cannot be used in a child ≥ 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 CMOH 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 CMOH recommendation regarding subsequent immunization.

References

1. 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.

3.7.9 Anaphylaxis Kit

General Guidelines

Check epinephrine vials and other emergency supplies prior to each immunization clinic and replace if outdated.

Protect epinephrine and diphenhydramine hydrochloride from light and open vial(s) only when ready to use.

Do not pre-load a syringe with epinephrine in anticipation of a reaction. Epinephrine rapidly deteriorates and loses potency when exposed to oxygen.

Suggested anaphylaxis kit contents:

- Anaphylaxis: Initial Management in non-hospital Setting (Appendix B)
- Anaphylaxis Assessment Guide and Record (Appendix C)
- 3 - 1 cc syringes and needles (25 – 27 gauge, 1" needle)
- 1 - 1cc syringe and needle (25 – 27 gauge, 1 ½" needle)
- 2 - 3 cc syringes and needles (25 – 27 gauge, 1" and 1 ½" needles)
- 2 – 1cc syringes and needles (25 – 27 gauge, 5/8") for SC route
- extra needles
- 4 ampoules of epinephrine 1:1000 (within expiration time frame)
- 2 vials of diphenhydramine hydrochloride 50mg/ml (within expiration time frame)
- alcohol swabs
- pens/paper

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 \geq 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
\geq 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
\geq 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