NS Department of Health and Wellness

Vaccine Storage and Handling Guidelines for Immunization Providers

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Vaccine Storage and Handling Guidelines for Immunization Providers

Introduction

Immunization is a one of the most valuable public health interventions available to prevent and control infectious diseases and is vital in protecting the health of our population.

Vaccine storage and handling are key components in maintaining the efficacy of immunization programs.

These guidelines have been developed to provide recommendations for vaccine storage and handling for all health-care providers.

General Vaccine Storage Guidelines

- Always arrange vaccines the same way inside the refrigerator to avoid errors.
- Protect vaccines from light at all times by keeping them in the manufacturer- supplied box.
- Remove vaccines from the refrigerator just before they are to be used 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 vial, print the date opened on the label after opening.
- For reconstituted products, refer to the manufacturer's 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 vaccines that have not been stored between 2°C and 8°C until an assessment has been made by public health.
- Do not use any vaccines that are beyond their expiration date. The expiration date of vaccines must be checked each time they are used. The person responsible must also check the expiration dates each month when completing an inventory of the agents stored in the refrigerator. If a vaccine is past its expiration date, it must be removed from the refrigerator immediately, marked "**DO NOT USE**," or discarded.
- Adhere to strict aseptic technique when handling vaccines.

Vaccine Fridges

Vaccines should be stored in a dedicated vaccine refrigerator. Maintain the refrigerator temperature between 2°C and 8°C. Refrigerators should be selected carefully and used properly.

Any refrigerator used for vaccine storage must be:

- ✓ able to maintain recommended vaccine storage temperatures (between 2°C and 8°C),
- ✓ large enough to hold one month's inventory,
- ✓ equipped with a thermometer or data logger (the recommended type of thermometer is Canadian Scientific or another Minimum-Maximum (Min-Max) thermometer that is calibrated to +/- 1ºC accuracy), and
- ✓ dedicated to the storage of vaccines only.

Although there may be some commercial grade small fridges designed specifically to maintain drugs and vaccines, any other style of small, single door fridge (e.g. bar fridge) is unpredictable in terms of maintaining temperatures within the required range of 2° to 8° C and should NOT be used to store vaccines.

Refer to the National Vaccine Storage and Handling Guidelines for Immunization Providers, Public Health Agency of Canada, for recommendation on appropriate fridges for vaccine storage.

As manufacturers of vaccine are gradually moving toward the use of pre-filled syringes, it is important to plan for the increased space requirements the changes in vaccine packaging will require.

Here are some key tips for organizing the vaccine fridge:

- ✓ Stock vaccine on a first-in is the first used to make sure products that expire first are used first and check monthly
- ✓ Stock only one month's supply
- ✓ Store full bottles of water on empty shelves and in the door to reduce the effect of opening the door on the temperature of the unit.
- ✓ Don't store vaccines on door shelves, as the temperature on the door fluctuates greatly on opening of the fridge and is usually much warmer than in the centre of the unit.
- ✓ Store only vaccines in the refrigerator
- ✓ Check and log temperature twice a day
- ✓ Keep vaccine between +2C to +8C
- ✓ Open the door only when necessary
- ✓ Never leave vaccine outside the refrigerator

Procedures for Vaccine Orders and Pickup:

ORDER ONLY ONE MONTH'S WORTH

Order vaccine monthly from your local public health office. Keep vaccine stock at a minimum by ordering only the *quantity of vaccine you will use for the period of one month.*You will be requested to provide the number of doses currently in stock when placing your order.

Immunization providers or delegates who are picking up a vaccine order from a district Public Health office are required to bring a hard sided cooler, insulating material such as bubble wrap and frozen ice packs.

Suggested supplies:

- Hard sided cooler e.g. igloo. Do NOT use Styrofoam coolers because the temperature does not remain constant.
- Frozen ice packs
- Insulating material e.g. bubble wrap, to be placed between ice packs and vaccine.
- Min-Max Thermometer

MONTHLY AUDIT

Audit your inventory of biological products once monthly. Check for outdated products. Remove all expired biologicals and store in a clearly marked box/bag. Return to the Biologicals Depot with an accompanying list of the vaccines, number of doses with lot number and medical centre contact information with all returns.

FOR ROUTINE VACCINE REQUESTS

Complete a Requisition for Publicly Funded Vaccine, by contacting your local Public Health office. Allow 2 – 3 business days for delivery.

FOR NON-ROUTINE VACCINE REQUESTS (I.E. individuals with high risk conditions)

Please refer to the NS Immunization Manual Chapter 10 for the vaccine eligibility for high risk conditions. You can consult with your local Public Health office to request vaccine. if you are unsure if your patient is eligible.

Vaccine Cold Chain Break Management and Reporting

When vaccines are exposed to temperatures of less than 2°C or more than 8°C, the result is a break in the cold chain. Vaccines affected by a break in the cold chain must be packaged separately, identified with a sticker reading “DO NOT USE,” and stored in a refrigerator at between 2°C and 8°C separately from vaccines in current use. Consult with your local public health office to determine whether or not they can be used.

If you become aware of inappropriate vaccine storage conditions, report the following to your local Public Health office using the attached Vaccine Cold Chain Exposure Report Form;

- date and time of incident
- the issue, e.g. fridge failure, power failure
- 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
- minimum and maximum temperature readings from the Min/Max thermometer inside the vaccine storage unit
- presence of water bottles in the refrigerator
- action that has been taken to protect the vaccines e.g. placed in a working fridge
- the product’s appearance (e.g., ice formation may be evident)
- document the inventory of the affected vaccines. Include vaccine name, lot number, expiry date, and quantity.

Emergency Preparedness and Vaccine Storage and Handling

When immunization providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might affect vaccine storage conditions, urgent procedures should be implemented in advance of the event.

In preparation for any emergency, the following steps should be taken:

1. Identify all alternative storage facilities with back-up power (generator), where the vaccine can properly be stored and monitored. Have arrangements for transportation of vaccines.
2. Pack the refrigerator with adequate cold packs and water bottles while the power is still on.
3. Ensure availability of appropriate packing containers, cold packs, etc.
4. Prepare a list of emergency phone numbers that may be needed during the emergency such as:
    a. Power company
    b. Temperature alarm monitoring company
    c. Back up storage facility
    d. Transport company
    e. Weather service
5. Document name, expiry date and number of each vaccine in the refrigerator.
6. Record refrigerator temperature, time and date.

Post Event: For vaccines exposed to temperatures outside 2°C to 8°C range:

1. **Do not discard vaccines.**
2. Store exposed vaccines in the fridge, in a separate container/bag marked “Cold Chain” with a record of complete list of products, expiry dates, quantities of each vaccine, the maximum-minimum temperatures exposed to, and the duration of exposure. If specific time/temperature details are not available, assume the refrigerator malfunctioned immediately after the power outage and assume that the refrigerator took 2 hours to warm to temperature outside the range 2°C to 8°C.
3. Once a determination is made by your local public health that these vaccines can be used, mark the products as being exposed to cold chain break.
4. Use the vaccines exposed to cold chain break before using any additional vaccine supplied to you.
5. Document name, number, expiry date of vaccines returned and send to the main Public Health office in the District Health Authority.

Contact information for Public Health Services offices in the district health authorities can be accessed at: http://novascotia.ca/dhw/about/phs-offices.asp .

Reporting Requirements

Reporting of Immunizations to Public Health

Each person receiving an immunization should receive an individual record for personal retention and reference.

Each practice or agency should develop protocols for documentation of immunization in accordance to professional documentation standards.

Generally, the following information is required for documentation:

- Name
- DOB
- Gender
- Health Card Number
- Vaccine Given
- Lot Number
- Date Given (Day, Month, Year)
- Site
- Route
- Dose
- Professional signature and designation

As key participants in the publicly funded immunization program, all Immunization providers must provide detailed information for each immunization provided to their local Public Health Office. This will assist public health to provide up to date records on request, and will be used in calculating provincial immunization coverage rates.

Reciprocal forms are the most common post- immunization form that can be completed and sent to Public Health. However, a copy of the client's immunization record can be provided instead. We want to help you avoid unnecessary duplication of efforts. Sample childhood and adult immunization records are provided in this toolkit.

If the practice or agency utilizes the Nightingale EMR, no further notification is necessary as those immunization records are provided directly to the Department of Health and Wellness through secure means.

- Name
- DOB
- Gender
- Health Card Number
- Vaccine Given
- Lot Number
- Date Given (Day, Month, Year)
- Site
- Route
- Dose

Reporting of Adverse Events Following Immunization (AEFI)

During their development, vaccines undergo rigorous testing for safety and efficacy. During these "pre-licensure trials" efforts are made to capture every single adverse event that follows immunization. By the time a vaccine is authorized for marketing, the safety profile for common adverse events is well known. Most reactions to vaccines are mild and self-limited. These can be local (e.g. tenderness or redness at injection site) or systemic (e.g. fever, joint or muscle pain) but are minor in severity. It is always important to counsel vaccinees or their guardians regarding the possible occurrence of such reactions

Under the Nova Scotia Health Protection Act and the Regulations under the Act, an Adverse Event Following Immunization is notifiable and must be reported to the Medical Officer of Health, through local Public Health using the Adverse Events Following Immunization (AEFI) Form. Report only those AEFI that are unexpected or more serious than outlined in the product monograph.

Appendix A: Vaccine Cold Chain Exposure Report Form

INCIDENT REPORT:	**VACCINE COLD CHAIN FAILURE Part 1**	**Page**	**of**

Site Location:		Date of Incident:	
Phone Number:		Date Reported to PHS:	
Fax Number:		Date Reported to DHW:	
Name of Contact Person:		Address:	

STEP 1: CHECK ONE BOX (UNDER EITHER A, B, C, OR D) THAT BEST DESCRIBES THE PROBLEM:

A.	Power Interruption:	A.1	☐ Power Outage	A.2	☐	Power Interruption to Equipment
B.	Equipment Problem:	B.1	☐ Equipment Breakdown	B.2	☐	Other Temperature Problem
C.	Handling Error:	C.1	☐ Vaccine Left Out	C.2	☐	Refrigerator Door Left Open
D.	Shipment Problem:	D.1	☐ Temp Reading ▲ or ▼	D.2	☐	Product Damaged in Transit

PLEASE DESCRIBE THE EVENT

E. Exposed Temperature C°

Highest: _____ Duration: _____

Lowest: Duration:

Immediate Advice to Person Reporting (check as completed):

☐ Isolate vaccine in question in a bag/container and keep within 2°-8°C

☐ Clearly mark the bag/container "Do Not Use: Quarantined"

☐ Mark exposed vaccines with a permanent marker indicating the cumulative length of time exposed to a cold chain break

STEP 2: ANSWER EACH QUESTION BELOW (E to I):

E.	Was a min/max thermometer in the fridge?	Yes ☐	No ☐	
F.	Were water bottles in the fridge and ice packs in the freezer at the time of this event?	Yes ☐	No ☐	
G.	Was there a temperature log maintained for this fridge?	Yes ☐	No ☐	
H.	What was the air temperature of the room where vaccines were stored?			
I.	What actions have been taken to correct the problem?			

Total value of vaccines lost to cold chain break. **(REQUIRED)**

$

Completed by:	**Date:**

Part 2 of 2: Incident Report: Vaccine Cold Chain Failure:

Site Location:_____ **Date of Incident:**_____

Name of Contact Person: _____ **Date Reported to Public Health:**_____

Phone Number: _____ **Fax Number:**_____

accine Name	Lot Number	Expiry Date	# of Doses	# of Previous Exposures and Duration	Manufacturer	USE: Mark as Exposed	DO NOT USE
Act Hib					**SP**		
					SP		
Adacel Polio					**SP**		
					SP		
Boostrix					**GSK**		
					GSK		
Boostrix Polio					**GSK**		
					GSK		
Fluviral					**GSK**		
					GSK		
Gardasil					**Merck**		
					Merck		
Havrix					**GSK**		
					GSK		
Imovax Rabies					**SP**		
					SP		
Imogam Rabies Immunoglobulin					**SP**		
					SP		
Menveo					**Novartis**		
					Novartis		
MMR 11					**Merck**		
					Merck		
NeisVac-C					**GSK**		
					GSK		
Pediacel					**SP**		
					SP		
Pneumovax 23					**Merck**		
					MF		
Prevnar 13					**Pfizer**		
					Pfizer		
Priorix Tetra					**GSK**		
					GSK		
Recombivax HB					**MF**		
					MF		
Td Adsorbed					**SP**		
					SP		
Twinrix					**GSK**		
					GSK		
Tubersol					**SP**		
					SP		
Varilrix					**GSK**		
					GSK		
		Total Value of Vaccine Lost					

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: _____ Year 20_____	Room Temp	REFRIGERATOR TEMPERATURE								Initial
Day of the Month		AM				PM				
		Time	Current C°	Min C°	Max C°	Time	Current C°	Min C°	Max C°	
1										
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31										
Signatures										

Appendix B: Adverse Events Following Immunization

It's the Law: Reporting Adverse Events Following Immunization (AEFI)

What to Report

You are required **BY LAW** to report to Public Health Services the following adverse events that may occur following immunization.

Serious Adverse Events

Report within 1 working day
Any serious reaction that:

- Is life-threatening — e.g., anaphylaxis, Guillain-Barré Syndrome
- Causes or prolongs hospitalization ≥ 24 hours
- Results in permanent disability or congenital malformation
- Is fatal

Other Adverse Events

Report within 5 working days

- Neurological events including febrile and afebrile convulsions
- Associated events where medical attention is required
- Events where consideration must be given to postpone or contraindicate future immunizations
- Unexpected events with no alternative explanation

What NOT to Report

Do not report minor expected reactions such as localized tenderness, as outlined in the product monograph, unless they are more severe or more frequent than expected.

How to Report

1. Consult your district Public Health Services office to determine if an AEFI form should be completed.
2. If required, download and complete the AEFI form: www.phac-aspc.gc.ca/im/aefi-form-eng.php
3. Send the completed form to your local or district Public Health Services office.

South Shore Health
Public Health Services
Tel: 543-0850
Fax: 543-8024

South West Health
Public Health Services
Tel: 742-7141
Fax: 742-6062

Annapolis Valley Health
Public Health Services
Tel: 542-6310
Fax: 542-6333

Colchester East Hants Health Authority
Public Health Services
Tel: 893-5820
Fax: 893-2614

Cumberland Health Authority
Public Health Services
Tel: 667-3319
Fax: 893-2614

Pictou County Health Authority
Public Health Services
Tel: 752-5151
Fax: 893-2614

Guysborough Antigonish Strait Health Authority
Public Health Services
Tel: 867-4500 ext. 4800
Fax: 863-5111

Cape Breton District Health Authority
Public Health Services
Tel: 563-2400
Fax: 563-2005

Capital Health
Public Health Services
Tel: 481-5800
Fax: 481-5889

Public Health Services
NOVA SCOTIA
www.gov.ns.ca/dhw

13087/MAR12 REV11-12

Appendix C: Immunization Provider Resource List

- ✓ Vaccine tear sheets for childhood immunizations http://novascotia.ca/dhw/cdpc/info-for-professionals.asp
- ✓ NS Routine Immunization Schedule
  - Adult: http://novascotia.ca/dhw/cdpc/documents/13155_AdultImmunizationSchedule_En.pdf
  - Childhood:
    - http://novascotia.ca/dhw/cdpc/documents/13151_ChildhoodImmunizationSchedule_En.pdf
    - http://novascotia.ca/dhw/cdpc/documents/13078_NsChildhoodImmPoster_En.pdf
  - School: http://novascotia.ca/dhw/cdpc/documents/13153_SchoolImmunizationSchedule_En.pdf
- ✓ Canadian Immunization Guide www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php
- ✓ NS Immunization Manual http://novascotia.ca/dhw/cdpc/documents/Immunization-Manual.pdf
- ✓ Department of Health and Wellness Information for Professionals site http://novascotia.ca/dhw/cdpc/info-for-professionals.asp
- ✓ Immunize Canada http://www.immunize.ca/en/health-care-providers.aspx
- ✓ Pain Management http://www.immunize.ca/en/health-care-providers/painmgt.aspx
- ✓ Immunization competencies for Health Professionals http://www.phac-aspc.gc.ca/im/pdf/ichp-cips-eng.pdf
- ✓ AEFI reporting Form http://www.phac-aspc.gc.ca/im/pdf/raefi-dmcisi-eng.pdf

Appendix D: Public Health Services Offices

http://novascotia.ca/dhw/publichealth/phs-offices.asp