

Immunization Toolkit for Immunization Providers

Communicable Disease Prevention and Control Division Public Health Branch Department of Health and Wellness

Contents

Introduction	.3
General Vaccine Storage and Handling Guidelines	.4
Vaccine Refrigerators	.5
Organizing the Vaccine Fridge	.6
Routine Vaccine Orders And Pickup	.8
Vaccine Cold Chain Break Management And Reporting	.9
Emergency Preparedness And Vaccine Storage And Handling	L O
Reporting of Immunizations	1
Reporting of Adverse Events Following Immunization (AEFI)	12
Appendix A: Vaccine Cold Chain Exposure Report Form	13
Appendix B: Reciprocal Notification Form1	16
Appendix C: Adverse Events Following Immunization	۲
Appendix D: Immunization Provider Resource List	18

Introduction

This document has been developed to provide guidance and recommendations related to components of the publicly funded immunization program for Nova Scotia.

- to enhance the efficiency safety and effectiveness of the publicly funded immunization program
- to ensure maintenance of vaccine and biological product potency and reduce wasting of publicly funded products
- to provide guidelines for the standardized management and reporting of adverse events following immunization
- to provide recommendations for vaccine storage and handling for all healthcare providers

General Vaccine Storage and Handling Guidelines

- □ Do not stockpile vaccine
- □ Count vaccine stock in fridge monthly
- \Box Order he amount of vaccine you expect to use in one month^{1,2}
- □ Arrange vaccines the same way inside the refrigerator to avoid errors
- □ Protect vaccines from light at all times
- □ Maintain the cold chain between 2° to 8°C at all times
- □ Reconstitute vaccines immediately prior to use
- $\hfill\square$ Use the diluent provided with the vaccine and do not substitute other diluents
- \Box Print the date vaccine is opened on the label of multi-use vials
- □ Refer to the manufacturer's package insert for stability information after opening
- □ Contact public health before using vaccine stored outside the 2° to 8°C range
- $\hfill\square$ Do not use any vaccines that are beyond their expiration date
- □ Remove all expired product from the fridge each month
- □ Adhere to strict aseptic technique when handling vaccines
- $\hfill\square$ Have an emergency plan in case of a power outage
- \Box Check and log temperature twice a day

¹ Complete a Requisition for Publicly Funded Vaccine, by contacting your local Public Health office. Allow 2 – 3 business days for delivery.

² Please refer to the <u>NS Immunization Manual</u> Chapter 10 for vaccine eligibility for high risk conditions. You can consult with local <u>Public Health</u> to request vaccine for high risk conditions on a case by case basis or if you are unsure if your patient is eligible

Vaccine Refrigerators

Any refrigerator used for vaccine storage must be:

- \Box Large enough to hold one month's inventory³
- \Box Equipped with a min-max thermometer or data logger ⁴
- \Box Able to maintain vaccine storage temperatures between 2°C and 8°C⁵
- □ Dedicated to the storage of vaccines only

³ 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.

⁴ The recommended type of thermometer is Canadian Scientific or another Minimum-Maximum (Min-Max) thermometer that is calibrated to +/- 1°C accuracy

⁵ 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. For more detail refer to the <u>National Vaccine</u> <u>Storage and Handling Guidelines</u>

Organizing the Vaccine Fridge

- $\hfill\square$ Remove expired vaccine from the fridge
- □ Return all expired unopened vaccine to local public health
- □ Order the amount of additional vaccine you will need for one month
- \Box Ensure products that expire first are placed in front the fridge
- □ Store vaccine between 2°C and 8°C
- $\hfill\square$ Store full bottles of water on empty shelves and in the door
- □ Don't store vaccines on door shelves
- $\hfill\square$ Store only vaccines in the refrigerator
- $\hfill\square$ Open the door only when necessary

Keep Vaccine Safe

Ordering Vaccine

- Complete a refrigerator inventory once a month, prior to placing your order.
- · Maintain no more than a one month supply of vaccine.
- Order vaccine for your patient population only.

Storing Vaccine

- Store all vaccine between 2°C and 8°C.
- Keep a digital high-low thermometer in refrigerator and record temperature twice daily.
- Contact your local Public Health office 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 a functioning refrigerator until you have made contact with Public Health.



- 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 the 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 nonmedical purposes such as staff lunches to limit opening your refrigerator door.
- Leave space between products in the refrigerator to allow air to circulate.

Handling Vaccine

- Never leave vaccine outside of the refrigerator.
- Remove vaccine from the refrigerator only for 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.
- Refer to package insert to determine how long a multi-dose vial can be used after the first dose is withdrawn.

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.
- For long distance travel, wrap bubble-wrapped vaccine in newspaper for extra insulation and place a thermometer in the cooler.

Disposal of Vaccine

- Vaccine expires at the end of the month (ie. June /12 means June 30, 2012).
- Return all expired/spoiled vaccine and unused vials to your local Public Health office.

Recording Vaccine

- Complete reciprocal notification form or EMR immunization report and submit to your local Public Health office monthly.
- Document in patient chart vaccine given, dose, site, route, date, Lot #, and person who administered the vaccine.

Public Health contact information:

South Shore Health Bridgewater Tel: 543-0850 Pictou County Health Authority New Glasgow Tel: 752-5151 Guysborough Antigonish Strait Health Authority

Cape Breton District Health

Sydney Tel: 563-2400

Authority

Capital Health Dartmouth Tel: 481-5800

Antigonish Tel: 867-4500 ext 4800

South West Health Yarmouth Tel: 742-7141

Annapolis Valley Health Wolfville Tel: 542-6310

Colchester East Hants Health Authority

Truro Tel: 893-5820

Cumberland Health Authority Amherst. Tel: 667-3319





Routine Vaccine Orders and Pickup

Supplies required for routine monthly vaccine pick up from your local public health office:

- □ hard sided cooler
- $\hfill\square$ insulating material such as bubble wrap
- □ frozen ice packs
- □ Min-Max thermometer

Vaccine Cold Chain Break Management and Reporting

If you become aware of inappropriate vaccine storage conditions, *do not discard the vaccine*. Report details of the cold chain break to your local Public Health office.

- \Box do not discard vaccines
- $\hfill\square$ mark the products as being exposed to cold chain break
- \Box store exposed vaccines in the fridge, in a container/bag marked "Cold Chain"
- □ complete the Vaccine <u>Cold Chain Exposure Report</u> Form in <u>Appendix A</u>
- \Box document action that has been taken to protect the vaccines
- \Box note the product's appearance (e.g., evidence of ice formation)
- □ document the names of the vaccine, lot number, expiry date, and quantity
- $\hfill\square$ use the exposed vaccines deemed safe to use before using new vaccine
- \Box document name, number, expiry date of vaccines not safe to use
- □ return unopened vials of exposed vaccine in to local public health

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:

- □ Identify all alternative storage facilities with back-up power
- □ Have arrangements for transportation of vaccines
- $\hfill\square$ Pack the refrigerator with adequate cold packs and water bottles while

the power is still on

- □ Ensure availability of appropriate packing containers, cold packs, etc.
- □ Prepare a list of emergency phone numbers:
 - □ Power company
 - □ Temperature alarm monitoring company
 - \Box Back up storage facility
 - □ Transport company
 - □ Weather service
 - □ Document vaccine details name, expiry, # doses
 - $\hfill\square$ Record refrigerator temperature, time and date

Post Event: For vaccines exposed to temperatures outside 2°C to 8°C range refer to section titled <u>Vaccine Cold Chain Break Management and Reporting</u>.

Reporting Requirements

Reporting of Immunizations to Public Health

Each person receiving an immunization should receive an individual record for personal retention and reference containing the following information: immunization:

- $\hfill\square$ Name of the person immunized
- □ Gender
- □ Health Card Number
- □ Vaccine name
- Lot Number

 $\hfill\square$ Date Given (Day, Month, Year)

- □ Site
- □ Route
- □ Dose
- □ Professional signature

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.

Reporting of immunization records to local <u>Public Health</u> can be done through:

- $\hfill\square$ Automatic monthly report from the Nightingale EMR
- □ <u>Reciprocal notification form</u> (Appendix B)
- $\hfill\square$ Copy of the client's immunization record

When reporting the immunization to local public health, the following information should be provided:

- $\hfill\square$ Name of the person immunized
- □ Gender
- Health Card Number
- □ Provider or clinic name
- □ Vaccine Name

- □ Lot Number
- \Box Date Given (Day, Month, Year)
- □ Site
- □ Dose
- □ Route

Reporting of Adverse Events Following Immunization (AEFI)

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. Minor expected reactions as outlined in the vaccine product monograph do not need to be reported. (<u>Appendix C</u>)

Report AEFI to public health when the event meets any of the following:

- $\hfill\square$ has a temporal association with a vaccine
- $\hfill\square$ has no other clear cause at the time of reporting
- $\hfill\square$ is serious in nature
- $\hfill\square$ is life threatening
- $\hfill\square$ results in death
- \Box requires hospitalization \geq 24 hours
- $\hfill\square$ prolongs an existing hospitalization
- $\hfill\square$ results in residual disability
- $\hfill\square$ is associated with a congenital malformation
- \Box is unusual or unexpected
- \Box occurs in a cluster

Appendix A: Vaccine Cold Chain Exposure Report Form

IN	CIDENT REPORT:	VACCINE COLD CHAIN FAILURE Part 1	Page of		
Sit	e Location:	Date of Incident:			
	one Number:	Date Reported to PHS:			
	k Number:	Date Reported to DHW:			
Na	me of Contact Person:	Address:			
ST	EP 1: CHECK ONE BOX (UNDER EITHER A, B, C, OR D) THAT BEST DESCRIBES THE PROBLEM:	PLEASE DESCRIBE THE EVENT		
Α.	Power Interruption:	A.1 Power Outage A.2 Power Interruption to Equipment			
В.	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			
		Immediate Advice to Person Re	eporting (check as completed):		
E.	Exposed Temperature	C° Highest: Duration: Isolate vaccine in question i	in a bag/container and keep within 2°-8°C		
			iner "Do Not Use: Quarantined"		
		Mark exposed vaccines with	n a permanent marker indicating the		
		Lowest: Duration: cumulative length of time e	exposed to a cold chain break		
ST	EP 2: ANSWER EACH Q	UESTION BELOW (E to I):	Total value of vaccines lost to cold chain		
		nometer in the fridge? Yes No	break. (REQUIRED)		
E.	Was a min/max therm	\$			
F.	Were water bottles in	*			
G.	Was there a temperat				
Н.	What was the air tem				
١.	What actions have be	en taken to correct the problem?			

Completed by:

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

Site Location:	
Name of Contact Person:	
Phone Number:	

Date of Incident:

Date Reported to Public Health:_____

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		
luce and Dalaise					SP		
Imogam Rabies					SP SP		
Immunoglobulin					Novartis		
Menveo					Novartis		
Menjugate					SP		
					SP		
Menomune					SP SP		
MMR 11					Merck		
					Merck		
NeisVac-C					GSK GSK		
					SP		
Pediacel					SP		
					Merck		
Pneumovax 23					MF		
					Pfizer		
Prevnar 13					Pfizer		
					GSK		
Priorix Tetra					GSK		
					MF		
Recombivax HB					MF		
					SP		
Td Adsorbed					SP		
					GSK		
Twinrix					GSK		
					SP		
Tubersol					SP SP		
Varilrix					GSK GSK		
		Total Value		e Lost	JJK		
1			or vacun	C LUSI			

Temperature Log										
1. Record the current temperature and the minimum/maximum fridge temperature twice daily: when you first open the office and before closing.										
Mon: Yr:		REFRIGERATOR TEMPERATURE						Initial		
Day of the Month	Room Temp	AM PM								
		Time	Current C°	Min C°	Max C°	Time	Current C°	Min C°	Max C°	
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
21										
22										
23										
24										
25										
26										
27										
28										
29										
30										
31										
Signatures										

Appendix B: Reciprocal Notification Form



Public Health Services DHA

novascotia.ca/dhw

This form is to be completed by the person administering a vaccine. A copy is to be sent to the local Public Health Office. A opy is to be sent to or retained by the health care provider.

PATIENT INFORMATION											
Sumame	one Number										
Address Address				Postal Code							
	If Attending School, Name of School Y Y Y M D D M F Other Health Card Number Date of Birth Sex Health Care Provider's Name (Please Print) Health Care Provider's Phone Number										
ANTR	GEN ADMINISTERED	D. CHECK (🖌) BOXE	S WHERE APPROP	RIATE							
DTaP-IPV-Hib 1st 2nd 3rd 4th Meningococcal group C Tdap-IPV	Hepatitis B 1st 2nd 3rd Hepatitis A 1st 2nd MMR 1st 2nd 2nd	Varicella 1st 2nd Pneumococcal Polysaccharide Td MMRV 1st 2nd	Influenza 11st 2nd Hib Tdap Other 1st 2nd 3nd 4th	Pneumococcal Conjugate 1st 2nd 3rd Hepatitis A & B 1st 2nd 3rd Other 1st 2nd 3rd Other 1st 2nd 3rd							
Sitter	Sta	Silte:	Site:	Sitte:							
Dosage:	Dosage:	Dosage:	Dotage:	Dosage:							
Route:	Routs:	Route:	Routa:	Route							
Lot #:	Lot #:	Lot #:	Lot #:	Lot #:							

Date Given (YY/MWDD)

Signature of Person Giving Vaccine

Office / Location where Immunization was Given

13189/JUN13 REV13-14

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



13087/MAR12 REV11-12

Appendix D: Immunization Provider Resource List

NS Immunization Manual

Public Health Applications

- Application for Notifiable Disease Surveillance (ANDS)
- Canadian Network for Public Health Intelligence

Immunization Competencies for Health Professionals

Immunization Schedule for Adults

Immunization Schedule for Children

School Immunization Schedule

Routine Childhood Immunization Schedule in NS for Health Professionals

Tetanus Prophylaxis in Wound Management Poster

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

National Vaccine Storage and Handling Guidelines

Canadian Immunization Guide

Epidemiology and Prevention of Vaccine-Preventable Diseases: The Pink Book

Vaccine Information Sheets

Immunize Canada

Pain Management

AEFI Reporting Form