Immunization Toolkit for Immunization Providers

Communicable Disease Prevention and Control Division
Public Health Branch
Department of Health and Wellness
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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 health-care providers
General Vaccine Storage and Handling Guidelines

☐ Do not stockpile vaccine

☐ Count vaccine stock in fridge monthly

☐ Order the 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\(^\circ\) to 8\(^\circ\)C at all times

☐ Reconstitute vaccines immediately prior to use

☐ Use the diluent provided with the vaccine and do not substitute other diluents

☐ 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\(^\circ\) to 8\(^\circ\)C range

☐ 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

☐ Have an emergency plan in case of a power outage

☐ Check and log temperature twice a day

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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 NS Immunization Manual Chapter 10 for vaccine eligibility for high risk conditions. You can consult with local Public Health to request vaccine for high risk conditions on a case by case basis or if you are unsure if your patient is eligible.
Any refrigerator used for vaccine storage must be:

- Large enough to hold one month’s inventory

- Equipped with a min-max thermometer or data logger

- Able to maintain vaccine storage temperatures between 2°C and 8°C

- Dedicated to the storage of vaccines only

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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°C to 8°C and should NOT be used to store vaccines. For more detail refer to the National Vaccine Storage and Handling Guidelines.
Organizing the Vaccine Fridge

☐ 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

☐ Ensure products that expire first are placed in front the fridge

☐ Store vaccine between 2°C and 8°C

☐ Store full bottles of water on empty shelves and in the door

☐ Don’t store vaccines on door shelves

☐ Store only vaccines in the refrigerator

☐ 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 non-medical 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 (i.e. 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
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
Pictou County Health Authority
New Glasgow Tel: 725-5111
Guysborough Antigonish Strait Health Authority
Antigonish Tel: 867-4500 ext. 4800
Cape Breton District Health Authority
Sydney Tel: 563-2400
Capital Health
Dartmouth Tel: 481-5800

Public Health Services
Nova Scotia

https://www.gov.ns.ca/health/
Routine Vaccine Orders and Pickup

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

- hard sided cooler
- 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.

- [ ] do not discard vaccines
- [ ] mark the products as being exposed to cold chain break
- [ ] store exposed vaccines in the fridge, in a container/bag marked “Cold Chain”
- [ ] complete the Vaccine Cold Chain Exposure Report Form in Appendix A
- [ ] document action that has been taken to protect the vaccines
- [ ] note the product’s appearance (e.g., evidence of ice formation)
- [ ] document the names of the vaccine, lot number, expiry date, and quantity
- [ ] use the exposed vaccines deemed safe to use before using new vaccine
- [ ] 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
- 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
  - Back up storage facility
  - Transport company
  - Weather service
  - Document vaccine details: name, expiry, # doses
  - Record refrigerator temperature, time and date

**Post Event:** For vaccines exposed to temperatures outside 2°C to 8°C range refer to section titled [Vaccine Cold Chain Break Management and Reporting](#).
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:

- Name of the person immunized
- DOB
- Gender
- Health Card Number
- Vaccine name
- Lot Number
- 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 Public Health can be done through:

- Automatic monthly report from the Nightingale EMR
- Reciprocal notification form (Appendix B)
- Copy of the client’s immunization record

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

- Name of the person immunized
- DOB
- Gender
- Health Card Number
- Provider or clinic name
- Vaccine Name
- Lot Number
- 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. (Appendix C)

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

- has a temporal association with a vaccine
- has no other clear cause at the time of reporting
- is serious in nature
- is life threatening
- results in death
- requires hospitalization $\geq 24$ hours
- prolongs an existing hospitalization
- results in residual disability
- is associated with a congenital malformation
- is unusual or unexpected
- occurs in a cluster
Appendix A: Vaccine Cold Chain Exposure Report Form

<table>
<thead>
<tr>
<th>INCIDENT REPORT: VACCINE COLD CHAIN FAILURE Part 1</th>
<th>Page ____ of ____</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Location:</td>
<td>Date of Incident:</td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Date Reported to PHS:</td>
</tr>
<tr>
<td>Fax Number:</td>
<td>Date Reported to DHW:</td>
</tr>
<tr>
<td>Name of Contact Person:</td>
<td>Address:</td>
</tr>
</tbody>
</table>

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

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: ___________________________
<table>
<thead>
<tr>
<th>Vaccine Name</th>
<th>Lot Number</th>
<th>Expiry Date</th>
<th># of Doses</th>
<th># of Previous Exposures and Duration</th>
<th>Manufacturer</th>
<th>Use: Mark as Exposed</th>
<th>DO NOT USE</th>
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<td>GSK</td>
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</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Mon:</th>
<th>Yr:</th>
<th>REFRIGERATOR TEMPERATURE</th>
<th>Initial</th>
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<tbody>
<tr>
<td>Day of the Month</td>
<td>Room Temp</td>
<td>AM</td>
<td>PM</td>
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<tr>
<td></td>
<td></td>
<td>Time</td>
<td>Current C°</td>
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</table>

Signatures
Appendix B: Reciprocal Notification Form

Reciprocal Notification Form

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 copy is to be sent to or retained by the health care provider.

**PATIENT INFORMATION**

**Surname**

**Given Names**

**Phone Number**

**Address**

**Postal Code**

**Date of Birth**

**Sex**

**Health Card Number**

**Health Care Provider’s Name (Please Print)**

**Health Care Provider’s Phone Number**

**ANTIGEN ADMINISTERED. CHECK (√) BOXES WHERE APPROPRIATE**

<table>
<thead>
<tr>
<th>DTaP-IPV-Hib</th>
<th>Hepatitis B</th>
<th>Varicella</th>
<th>Influenza</th>
<th>Pneumococcal Conjugate</th>
</tr>
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<tbody>
<tr>
<td>1st</td>
<td>1st</td>
<td>1st</td>
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<td>2nd</td>
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<td>3rd</td>
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**MMR**

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<thead>
<tr>
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**Hepatitis A & B**

<table>
<thead>
<tr>
<th>Meningococcal group C</th>
<th>Td</th>
<th>MMRV</th>
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**Other**

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<th>Meningococcal group C</th>
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<td>4th</td>
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</tbody>
</table>

**Site:**

**Dosage:**

**Route:**

**Lot #:**

Date Given (YY/MM/DD)

Signature of Person Giving Vaccine

Office / Location where Immunization was Given

13189/JUN13 REV13-14
Appendix C: 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.
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