 <p>Winnipeg Regional Health Authority Office régional de la santé de Winnipeg Caring for Health À l'écoute de notre santé</p> <p>WRHA IMMUNIZATION PROGRAM CLINICAL PRACTICE GUIDELINES</p>	TITLE	
	STORAGE AND HANDLING GUIDELINE	
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1.0 **PURPOSE**

To outline processes that ensure vaccines are transported, stored and maintained at recommended temperatures to maintain potency and effectiveness.

2.0 **DEFINITIONS**


- 2.1 Cold chain: refers to all equipment and procedures used to ensure that vaccines are protected from inappropriate temperatures and light, from the time of transport from the manufacturer to the time of administration.
- 2.2 Maximum-minimum thermometer: A thermometer which, when placed in a refrigerator (inside a box of vaccine), indicates the maximum and minimum temperatures reached since the thermometer was last read.
- 2.3 Adverse Storage Conditions: is defined as an exposure outside of the manufacturers recommended storage conditions

3.0 **SCOPE & GOAL**

- 3.1 Each site shall have one person and a back-up person designated as a vaccine coordinator to ensure vaccines are handled correctly, procedures are documented and all personnel receive appropriate cold chain maintenance training.
- 3.2 Each site shall have a process to maintain and manage vaccine inventory.
- 3.3 Optimal vaccine storage is required according to the manufacturer's recommendations.
- 3.4 Monitoring of the vaccine cold chain is required to ensure the biologics are being stored and transported at recommended temperatures.
- 3.5 Each site will have a cold chain guideline to be followed in a situation where there has been a break in the cold chain.

4.0 **PROCEDURE**

- 4.1 Staff training
 - 4.1.1 Designated staff will be fully trained in routine and urgent vaccine storage and handling protocols.
 - 4.1.2 All staff members will be familiar with the site policies and procedures for vaccine storage and handling. This also includes staff members, such as receptionists and mail handlers, who receive vaccine shipments.

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4.1.3 Ensure the janitorial and security staff are aware of the policies and procedures should any problems occur with vaccine storage equipment, especially after hours.

4.2 Vaccine Ordering & Inventory

4.2.1 Vaccine orders should be no more than one month's supply. This will minimize storage time and risk of an adverse storage condition. At a minimum, the vaccine supply inventory should be completed on a monthly basis.

For Population and Public Health: Mass clinics sites are to order the amount of vaccine they need for the immunization clinics and arrange delivery according to program direction.

4.2.2. Quarantine any expired product and store in a container within the fridge marked "Expired – Do Not Use". Expired or unusable products previously received by Manitoba Health can be returned as soon as possible to the Provincial Vaccine Warehouse for potential cost recovery or proper disposal:

For Population and Public Health: Ensure inventory adjustments have been completed in PHIMS/Panorama as per: Adverse Storage Conditions QRC [ASC-QRC \(phimsmb.ca\)](http://phimsmb.ca)

- for when placing products under quarantine.
- for when products have been returned or disposed of. [Returns-QRC \(phimsmb.ca\)](http://phimsmb.ca)

Along with your returned vaccines, please complete and include the Manitoba Health Return Form found in The Immunizing Agents and Biologics Return Policy & Procedure: [Vaccine and Biologics Return Policy and Procedure](#)

For questions regarding the return of products contact the Provincial Vaccine Warehouse for return instructions at: (204) 948-1333 Toll-Free: 1-855-683-3306


4.2.3 A monthly inventory of the vaccine supply should be done at a minimum.

For Population and Public Health: Inventory is completed in PHIMS/Panorama. Mass clinics: a quantity on hand adjustment (QOH) should be completed after every clinic or as soon as possible.

4.2.4 Ensure products with the earliest expiry dates are used first and kept in front of the same product with longer expiry dates.

4.2.5 Receiving Vaccines

- Upon receipt of a vaccine shipment, place the vaccine in a vaccine refrigerator immediately.
- Verify the expiry date of the vial(s) upon its arrival.
- Examine the product for any damage.
- Determine if the cold chain has been respected by verifying the time and date of shipment and arrival of the product(s)

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- Call the Provincial Vaccine Warehouse if immunologic products have or may have been exposed to “environmental insult(s) or improper handling during transport.”
- When the vaccine order arrives, check vaccine quantities against those ordered and the packing slip.

For Population and Public Health: receipt of vaccines is completed in PHIMS- refer to [Receive-Requisition-QRC \(phimsmb.ca\)](http://phimsmb.ca)

4.3 Vaccine Storage Equipment Maintenance

4.3.1 Keep the refrigerator at the standard temperature between 2° and 8° C.

4.3.2 Biologic (commercial) refrigerators are **recommended** for storage of vaccines.

4.3.3 For-non-biologic refrigerators:

4.3.3.1 Bar fridge units are NOT recommended for the storage of immunizing agents and biologics.

4.3.3.2 Domestic refrigerators are NOT recommended, but are acceptable for storage of immunizing agents and biologics if the following criteria are met:

- Install a fail-safe (e.g. Velcro) closing mechanism to ensure that the refrigerator door does not swing open accidentally.
- Do not store food, beverages or biologic specimens in the same refrigerator as vaccines.
- Place closed bottles of (non-drinking) water or saline solution (e.g. 2 litre size) in places where vaccine should not be stored (e.g. drawers and door of refrigerator). This will minimize changes in temperature if there is frequent refrigerator opening or power failure. These bottles may be used in the freezer compartment.

4.3.4 A minimum-maximum thermometer will be used in **all** biologic refrigerators. Place the thermometer probe inside a vaccine box in the centre of the vaccine refrigerator.


4.3.5 Store vaccine with more recent expiry dates at the front.

4.3.6 Group by product using plastic baskets. Keep opened vial(s) in the same basket.

4.3.7 Date, time and initial vials when opened and/or reconstituted.

4.3.8 Freezers used to store vaccines shall:

- Maintain at a temperature below 0° Celsius.
- Contain ice packs in order to maintain a more constant temperature in the event of a power failure.
- Be defrosted when 1 cm of ice builds in the freezer section.

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4.4 Vaccine Storage Temperature Monitoring:

4.4.1 A minimum-maximum thermometer will be used in **all** biologic refrigerators. Refer to [Appendix A](#) - Minimum Maximum Thermometer Instructions for Use.

4.4.2 Designate a staff member to check and record the refrigerator temperature twice daily

4.4.3 Staff will record the temperature of the refrigerator on the prescribed temperature log. Refer to [Appendix B](#) -Temperature Log for Immunizing Agents and Biologics

4.4.4 Continuous monitoring temperature alarm systems (i.e. alarm companies) with round- the- clock notification of designated personnel should be installed in facilities storing large inventories to help prevent substantial losses of immunizing agents and biologics. Recording of the refrigerator temperature on the log twice daily is still required.

4.5 Adverse Storage Condition Management

4.5.1 Each site should develop procedures to be implemented in the event of a vaccine refrigerator failure. These should be posted on or near the vaccine refrigerators.

4.5.1.1 For Population and Public Health refer to:

- WRHA Population and Public Health Cold Chain Failure Response Plan (Refer to [Appendix C](#))

- WRHA After-Hours Vaccine Refrigerator Failure Rescue Procedure (Refer to [Appendix D](#)).

[Appendix D-1](#) Vaccine rescue locations

[Appendix D-2](#) Packing for vaccine transport

[Appendix D-3](#) After Hours Adverse Storage Conditions Documentation

[Appendix D-4](#) Min-Max Thermometer instructions

4.5.1.2 For *other* providers refer to:

- Manitoba Health Adverse Storage Condition Form and Procedure [Manitoba Health Adverse Storage Condition \(ASC\) Form and Procedure](#) for adverse storage condition follow-up. Complete steps and report as instructed.

4.6 Packing, Storage and Handling for Mass and or Offsite Immunization Clinics


4.6.1 Vaccine Temperature Maintenance and Transportation

- For clinics open for long periods, staff should arrange transportation of vaccine from the monitored fridges at the office to the immunization venue at intervals throughout the day.
- At the end of the scheduled clinic, vaccine will be returned to the monitored vaccine fridge.

[Appendix B-2](#) – Vaccine Temperature Monitoring Log for Off-Siite Clinics

For detailed guidelines on packing, storage and handling of vaccines for off-site immunization clinics see Manitoba health guidelines below:

[Packing, Storage and Handling for Off-Site Immunization Clinics](#)

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5.0 **VALIDATION**

- 5.1 Canadian Immunization Guide Evergreen version
- 5.2 National Vaccine Storage and Handling Guidelines for Immunization Providers (2015), Public Health Agency of Canada,
<https://www.canada.ca/en/public-health/services/publications/healthy-living/national-vaccine-storage-handling-guidelines-immunization-providers-2015.html>
- 5.3 Manitoba Health- Cold Chain Protocol Vaccine and Biologics
<http://www.gov.mb.ca/health/publichealth/cdc/coldchain/protocol.html>

RECOMMENDED READING



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