

Vaccine Storage and Handling Protocol, 2018

Population and Public Health Division,
Ministry of Health and Long-Term Care

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Preamble

The Ontario Public Health Standards: Requirements for Programs, Services, and Accountability (Standards) are published by the Minister of Health and Long-Term Care under the authority of section 7 of the *Health Protection and Promotion Act* (HPPA) to specify the mandatory health programs and services provided by boards of health.^{1,2} The Standards identify the minimum expectations for public health programs and services. Boards of health are accountable for implementing the Standards including the protocols and guidelines that are referenced in the Standards. Protocols are program and topic-specific documents incorporated into the Standards which provide direction on how boards of health shall operationalize specific requirement(s) identified within the Standards.

Purpose

Vaccine wastage due to spoilage or expiry is a concern for all immunization programs. This protocol has been developed to achieve greater standardization in the management of provincial vaccine inventories to ensure the proper storage and handling of vaccines, strengthen quality assurance activities, and provide education in an effort to minimize and reduce provincially funded vaccine wastage and promote vaccine safety and efficacy.

Reference to the Standards

This section identifies the standards and requirements to which this protocol relates.

Immunization

Requirement 7. The board of health shall provide comprehensive information and education to promote effective inventory management for provincially funded vaccines in accordance with the *Vaccine Storage and Handling Protocol, 2018* (or as current). This shall include:

- a) Training at the time of cold chain inspection;
- b) Distributing information to new health care providers who handle vaccines; and

Providing ongoing support to health care providers who handle vaccines, including guidance on effective inventory management.

Requirement 8. The board of health shall promote appropriate vaccine inventory management in accordance with the *Vaccine Storage and Handling Protocol, 2018* (or as current) in all premises where provincially funded vaccines are stored. This shall include:

- a) Prevention, management, and reporting of cold chain incidences; and
- b) Prevention, management, and reporting of vaccine wastage.

Requirement 9. The board of health shall ensure that the storage and distribution of provincially funded vaccines, including to health care providers practicing within the

health unit, is in accordance with the *Vaccine Storage and Handling Protocol, 2018* (or as current).

Operational Roles and Responsibilities

Inventory Management

Staff Designated to Monitor Vaccine Storage and Handling Practices

- 1) The board of health shall:
 - a) Maintain the supply of publicly funded vaccine through proper vaccine storage and handling practices and proper inventory management;
 - b) Use Panorama or any other method specified by the Ministry of Health and Long-Term Care (the “ministry”) for vaccine inventory management on an ongoing basis;
 - c) Designate at least one staff member who has the responsibility for vaccine inventory management processes including vaccine ordering, storage, distribution, and return in each location where publicly funded vaccine is stored.

Responsibilities include:

 - i) Ordering vaccines;
 - ii) Overseeing proper receipt and storage of vaccine deliveries;
 - iii) Documenting vaccine inventory information;
 - iv) Organizing vaccines within storage units;
 - v) Setting up and monitoring digital temperature monitoring devices;
 - vi) Reading and recording maximum, minimum and current refrigerator temperatures twice daily;
 - vii) Rotating stock routinely so vaccines with the earliest expiration dates are used first;
 - viii) Removing expired vaccine from storage units;
 - ix) Responding to out-of-range temperatures (temperature excursions);
 - x) Maintaining all documentation, such as inventory and temperature logs;
 - xi) Training other staff;
 - xii) Monitoring operation of storage equipment and systems; and
 - xiii) Ensuring appropriate handling of vaccines during a disaster or power outage;
 - d) Designate one person as the lead for the board of health who will be responsible for developing and implementing standard operating policies and procedures for the following inventory activities based on the current inventory method specified by the ministry and Panorama Inventory Data Standards and Best Practices,³ these include:
 - i) Ordering;
 - ii) Maintenance of inventory;
 - iii) Returns; and

- iv) Managing vaccine recalls;
- e) Designate and train an alternate to cover these responsibilities if the lead is not available. The alternate shall be trained in routine and emergency policies and procedures related to vaccine storage and handling;
- f) Orient responsible staff to the program to ensure they are aware of requirements for vaccine storage and handling, product sensitivities, storage equipment, temperature monitoring devices, and inventory management procedures; and
- g) Use the *Vaccine Storage and Handling Guidelines, 2012* (or as current) to educate and instruct health care providers who store publicly funded vaccine.⁴

Inventory Counts

- 1) The board of health shall:
 - a) Conduct a physical inventory count of all publicly funded vaccines at least four times a year, quarterly, comparing vaccine inventory to totals listed in Panorama or any other method specified by the ministry. Discrepancies shall be recorded in Panorama or any other method specified by the ministry;
 - b) Organize the vaccine by expiry date to ensure the shortest expiry date is at the front and the longest expiry date is at the back and group lot numbers together;
 - c) Physically count the amount of each vaccine type and record the counts for all inventories in Panorama;
 - d) Compare the physical counts to Panorama inventory amounts according to Panorama Inventory Data Standards and Best Practices;³
 - e) Adjust the Panorama Inventory, according to Panorama Inventory Data Standards and Best Practices,³ as required; and
 - f) Remove all expired vaccine from the vaccine supply and adjust the Panorama Inventory to reflect the removal of expired vaccine according to the Panorama Inventory Data Standards and Best Practices.³

Review of Vaccine Quantities Required for Immunization Programs

- 1) The board of health shall:
 - a) Engage in planning and forecasting at a minimum, once every 12 months to maintain an adequate inventory of vaccine to meet the routine needs of health care providers administering publicly funded vaccines and immunization clinics administered by the board of health in each upcoming year for all vaccine by:
 - i) Calculating the net usage, at a minimum, from the previous year, for each vaccine. Net usage = vaccines received from OGPMS (Ontario Government Pharmaceutical and Medical Supply Service) – reusable vaccine returned to OGPMS – wastage (from all sources);
 - ii) Adding and/or removing vaccine quantities from the net usage based on:
 - I) Demographics;
 - II) Population growth;
 - III) Immunization coverage; and
 - IV) Epidemiology;

- b) Evaluating vaccine wastage and trends. Any vaccine that cannot be used is considered to be wasted. The maximum vaccine wastage rates measured in doses, over a 12-month period (as specified by the ministry), shall not exceed 5% for any vaccine product. If wastage exceeds this level, additional inventory control measures shall be taken to reduce it. Wastage levels for each vaccine shall be reported to the Population and Public Health Division (PPHD) of the ministry upon request; and
- c) By maintaining no more than a two-month vaccine supply at the board of health. The board of health may maintain a larger supply of vaccine during health emergencies (e.g., case and contact management), immunization clinics, or an adverse condition that may cause delays in the delivery of vaccine by any mode of transportation.

Vaccine Order Process

Vaccine Ordering by the Board of Health

- 1) The board of health shall:
 - a) Order appropriate amounts of vaccine to minimize wastage and meet the demand of the population being served. Storing a larger volume than required can increase the risk of wastage as vaccine doses may expire before they can be used or they may become compromised while being stored;
 - b) Place vaccine orders according to the scheduled OGPMS delivery dates. The board of health may order outside of the scheduled OGPMS delivery dates during health emergencies (e.g., case and contact management), or during an adverse condition that may cause delays in the delivery of vaccine by any mode of transportation;
 - c) Avoid placing last-minute or rush orders. Prior to placing a vaccine order, the board of health shall:
 - i) Review their current inventory by:
 - I) Physically counting the vaccines on hand and updating Panorama through cycle counts or quantity on hand adjustments (according to Panorama Inventory Data Standards and Best Practices³); or
 - II) Generating the quantity on hand report (according to Panorama Inventory Data Standards and Best Practices³);
 - ii) Call the OGPMS to determine vaccine expiry dates, if the board of health requires more than a two-month supply of vaccine. The board of health shall only order quantities of vaccine that can be used (administered or distributed) prior to vaccine expiry; and
 - iii) Follow Panorama Inventory Data Standards and Best Practices for creating and submitting vaccine orders to the OGPMS.⁴

Receiving Vaccine at the Board of Health

- 1) Designated and trained board of health staff or their back-up shall:
 - a) Be available to receive and store vaccines when they are expected to arrive;

- b) Never leave vaccine in a shipping container, unpacked or unattended; and
- c) Know that vaccine deliveries require immediate attention.

Board of Health Staff Receiving the Monitored Shipment by Refrigerated Truck

- 1) The board of health staff shall:
 - a) While the driver is present:
 - i) Immediately open all the transport containers and assess the digital temperature monitoring device(s);
 - ii) Confirm that the number of containers received in the shipment matches the number of containers on the manifest;
 - iii) Examine the shipment for evidence of damage; and
 - iv) Print the name of the receiver, the date and time of receipt and sign the manifest to acknowledge the receipt of the order.
 - b) Once the driver leaves:
 - i) Unpack the shipment and place vaccines in the refrigerator;
 - ii) Review the order against the packing slip(s) to confirm that the order is correct;
 - iii) Receive and record vaccine into inventory for use if the digital temperature monitoring device(s) indicates that the cold chain was maintained between +2°C to +8°C;
 - iv) Place the shipment under quarantine in the refrigerator and immediately report the incident to the Immunization Policy and Programs Unit at the Population and Public Health Division (PPHD) if the digital temperature monitoring device(s) indicates an out-of-range reading. The order shall be kept refrigerated at the board of health until PPHD provides further direction; and
 - v) Determine if there are any concerns with the vaccine order. The board of health shall contact OGPMS within 72 hours of the receipt of the shipment if there are any concerns, otherwise the order will be considered complete and correct.

Board of Health Staff Receiving the Monitored Shipment by Air

- 1) The board of health staff shall:
 - a) Be responsible for all further arrangements for the receipt of vaccines once notified by OGPMS, specifically:
 - i) Check the time of the arrival of the shipment with the airline;
 - ii) Make arrangements for the pickup of the vaccine immediately upon its arrival at the airport and transport it to the board of health's vaccine refrigerator to maintain the cold chain;
 - iii) Check that the number of containers(s) received matches the number of container(s) on the waybill. When the board of health signs for the receipt of a shipment, a notation shall be made on the receiving slip as follows: subject to inspection of digital temperature monitoring device(s) and the date and time of receipt;
 - iv) Notify OGPMS, if the order does NOT arrive at the airport;

- v) Provide education regarding all cold chain requirements, if a third party (i.e., courier service) is involved in the pick-up and transport of the vaccine from the airport to the board of health;
- vi) Upon receiving the vaccine shipment, immediately open all the container(s) and assess the digital temperature monitoring device(s);
- vii) Receive the vaccines into inventory for use, if the digital temperature monitoring device(s) indicates that the cold chain was maintained;
- viii) Place the shipment under quarantine in the refrigerator and immediately report the incident to the Immunization Policy and Programs Unit at the Population and Public Health Division (PPHD) if the digital temperature monitoring device(s) indicates an out-of-range reading. The order shall be kept refrigerated by the board of health until PPHD provides further direction; and
- ix) Contact OGPMS within 72 hours of the receipt of the shipment and make a notation on the OGPMS manifest, if there are any problems with the order.

Vaccine Ordering by Health Care Providers

- 1) The board of health shall assess health care providers' orders so that vaccine quantities meet the demand and an attempt to minimize wastage is made.

Health Care Providers Ordering Vaccine from the Board of Health

- 1) For health care providers that order vaccines from the board of health, the board of health shall establish an ordering process that, at minimum, includes:
 - a) A health care provider vaccine order form for publicly funded routine vaccines, high risk vaccines, and school based programs which includes:
 - i) Holding Point (HP) Name (Name of facility/health care provider name/practice name);
 - ii) HP Code and/or HP contact information (address);
 - iii) Date of order;
 - iv) List of current publicly funded vaccines and eligibility criteria as necessary;
 - v) Current Inventory of each vaccine that is on hand at the health care provider's premises;
 - vi) Vaccine quantity required;
 - vii) Compliance with cold chain requirements with signature and/or temperature log book submission; and
 - viii) For high risk vaccines, documentation of eligibility (name of client, date of birth reason);
 - ix) A statement, which the health care provider must sign and agree to, that indicates that vaccine refrigerator temperatures have been maintained between +2°C to +8°C (unless the board of health has been notified otherwise) and that maximum, minimum, and current temperatures have been recorded twice daily. Alternatively, temperature log books are to be submitted and reviewed prior to or with each vaccine order;
 - x) Board of health contact information and directions on when and how to submit the order (e.g., mail, fax, online).

- xi) Information on what to expect once the order has been placed.
 - xii) Requirements for pick-up of vaccine (i.e., properly conditioned insulated container, digital temperature monitoring device, appropriate packaging material).
 - xiii) The distribution of vaccines with the shortest expiry dates first so that short-dated stock is used first; and
 - xiv) A review of vaccine inventory, checking for expired vaccines before packing orders.
- 2) The board of health shall review:
- a) Quantities and adjust orders as required to minimize the potential for vaccine wastage, not allowing more than a one-month supply of vaccine to be stored in premises;
 - b) The health care provider's historical ordering and usage data;
 - c) The health care provider's current inventory on hand when orders are submitted; and
 - d) The health care provider's historical information on vaccine storage and handling quality assurance and vaccine ordering practices and accountability.

For Health Care Providers Who Order Vaccines Directly from the OGPMS:

- 1) The board of health shall:
- a) Instruct health care providers to order vaccines directly from the OGPMS using the current vaccine order form provided by the ministry;
 - b) Instruct health care providers that no more than a one-month supply of vaccine is to be stored on their premises; and
 - c) In collaboration with the OGPMS, review quantities and adjust orders as required to minimize potential vaccine wastage.
- 2) The board of health shall assist OGPMS with assessing the appropriateness of vaccine orders as required by:
- a) Reviewing quantities and adjust orders as required to minimize the potential for vaccine wastage, not allowing more than a one-month supply of vaccine to be stored in premises;
 - b) Reviewing the health care provider's historical ordering and usage data;
 - c) Reviewing the health care provider's current inventory on hand when orders are submitted;
 - d) Reviewing the health care provider's historical information on vaccine storage and handling quality assurance and vaccine ordering practices and accountability; and
 - e) Advising OGPMS if there are issues related to vaccine storage and handling quality assurance and request that orders for the health care provider be held as appropriate.

Distributing Publicly Funded Vaccines to Health Care Providers

- 1) The board of health shall be the point of contact for health care providers ordering publicly funded vaccines and for all health care provider quality assurance and accountability activities. The board of health shall:
 - a) Determine a regular order schedule for health care providers. Ordering schedules are once a week, every two weeks or monthly. Air transport schedules may vary with the season;
 - b) Work with health care providers to determine the best inventory levels to maintain based on storage capacity, recommended order frequency, and other factors deemed appropriate by the board of health;
 - c) Allow exceptions (emergency orders) to the established schedule and pattern when necessary to prevent the disruption of immunization services. Emergency orders shall be verified by the board of health prior to processing an order. Repeated emergency orders due to inadequate order planning, storage and handling issues, or other vaccine quality assurance problems may result in the board of health arranging a site visit for a vaccine storage and handling best practice assessment;
 - d) Instruct health care providers to maintain temperature log books at a minimum until the next annual (routine) inspection by the board of health;
 - e) Educate health care providers regarding provincial policies as stated in the *Vaccine Storage and Handling Guidelines, 2012* (or as current);⁴ and
 - f) Conduct a routine annual inspection prior to distributing publicly funded vaccines to a health care provider.

Vaccine Return Process

Vaccine Return Process at the Board of Health

- 1) The board of health shall develop and implement policies and procedures for vaccine returns based on the current inventory methods specified by the ministry and Panorama Inventory Data Standards and Best Practices.⁴ Policies and procedures shall include:
 - a) At a minimum, a semi-annual non-reusable (wasted) vaccine return process. Non-reusable (wasted) vaccines that cannot be used by the board of health or health care providers shall be returned to the OGPMS, unless otherwise specified by the ministry, at least semi-annually. If vaccines are not to be returned to the OGPMS as specified by the ministry, they should be disposed of in approved biomedical waste containers according to local, provincial and/or federal regulations. All non-reusable doses (that are returned or disposed of) shall be recorded using Panorama's Return and Adjustment functionality. The reasons for returning non-reusable vaccines are listed below (please refer to the Glossary for relevant definitions);

- b) Vaccine doses wasted due to any of the following reasons are to be returned to OGPMS:

 - i) Spoiled vaccine due to a cold chain incident;
 - ii) Defective Product;
 - iii) Discontinued Product;
 - iv) Damaged Product; and
 - v) Expired Product;

- c) Vaccine doses wasted due to any of the following reasons are not to be returned to OGPMS and should be disposed of according to local, provincial and/or federal regulations, however they should be recorded in Panorama as wastage:
 - i) Suspected vaccine contamination;
 - ii) Dose(s) remaining in a multi-dose vial that has expired;
 - iii) Insufficient dose from a multi-dose vial;
 - iv) Vaccine administration issue(s);
 - v) Unused pre-drawn syringe(s); and
 - vi) Count discrepancy;
- d) The return of reusable vaccine that cannot be used by the board of health or health care providers to the OGPMS. The maximum reusable vaccine rate measured in doses shall not exceed 10% for any vaccine product over a 12-month period (as specified by the ministry). If reusable vaccine exceeds this level, additional inventory control measures shall be taken to reduce it;
 - i) Only vaccine that has been maintained at the board of health (i.e., never distributed to a health care provider) in the required storage conditions as indicated on the product monograph, with at least four months of shelf-life (unless otherwise specified by the ministry) can be redistributed by OGPMS;
 - ii) In the case of emergency redistribution, the ministry shall notify the board of health when vaccine that has not been maintained at the board of health can be redistributed. Redistributed vaccine must be accompanied by the current temperature log book or any other method specified by the ministry indicating that the vaccine has been maintained at the required storage conditions as specified in the vaccine product monograph;
- e) The packing of reusable and non-reusable vaccines for return to OGPMS. Reusable and non-reusable vaccines must be packaged separately. Only the reusable vaccines must be stored and transported under the required cold chain temperature conditions. The packages must be clearly identified by attaching the appropriate approved vaccine return label to the outside of the package;
- f) Procedure for health care providers who receive publicly funded vaccine to return non-reusable vaccine;
- g) Security measures for the housing of wasted vaccine; and
- h) A contract in place with a disposal company for products that cannot be returned to OGPMS.

Vaccine Return Process for Health Care Providers

- 1) The board of health shall, for health care providers that who order vaccines directly from the board of health:
 - a) Instruct health care providers to return all non-reusable vaccines to the board of health;
 - b) Ensure the non-reusable vaccine is accompanied by a return form;
 - c) Physically count the returned vaccine and verify the amounts provided on the return form;
 - d) Enter non-reusable vaccines into Panorama under the correct provider HP code; and
 - e) Monitor provider return reports for compliance with one month supply. Boards of health shall contact premises that have excessive returns and review their ordering processes.
- 2) For health care providers that order vaccines directly from OGPMS, instruct the health care provider to:
 - a) Return all non-reusable vaccines directly to the OGPMS unless otherwise specified by the ministry;
 - b) Complete the current vaccine return form or any other method specified by the ministry;
 - c) Attach the form with the returned vaccines; and
 - d) Contact the OGPMS for a Return Authorization Number (RAN).

Vaccine Handling and Use

Storage by the Board of Health

- 1) The board of health shall keep vaccine in the refrigerator, except when removing dose(s) for:
 - a) Shipping to health care providers;
 - b) Transporting to immunization clinics; or
 - c) Transferring vaccines to an alternative refrigerator, insulated container, or facility due to power outages, refrigerator failure, or maintenance.

Storage of Vaccine and Diluents in a Refrigerator

- 1) The board of health shall store vaccine in a purpose-built refrigerator.
 - a) Keep the refrigerator door openings to a minimum to help keep internal temperatures stable;
 - b) Store vaccines in their original packaging with lids closed until ready for administration to protect the vaccine from light and provide additional thermal protection and stability. Never store loose vials or prefilled syringes outside of their packaging as this increases the risk of administration errors, exposes vaccine to light, and makes it more difficult to track expiration dates and manage inventory;

- c) Store diluent with the corresponding refrigerated vaccine, if possible. Refer to the product monograph or package insert to determine the required storage conditions for the vaccine diluent (e.g., refrigeration or room temperature);
- d) Use the diluent provided by the manufacturer for the corresponding vaccine;
- e) Attach labels to shelves to clearly identify where each type of vaccine and diluent is stored. If diluent is stored separately from the corresponding vaccine, label the container where it is stored;
- f) Group vaccine products together by their types and lot number. Place each vaccine type in a separate container that is labeled with the vaccine name(s);
- g) Place vaccines and diluents in the center of the unit, two to three inches away from walls, ceiling, floor, and door. Avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents;
- h) Not pack the purpose-built refrigerator too tightly as this can restrict air circulation and impact vaccine temperatures;
- i) Allow space between vaccines and diluents to promote air circulation and maintain a consistent temperature;
- j) Rotate vaccine inventory after the receipt of a vaccine delivery so that short expiry dated vaccines are placed in the front. Vaccines with the longest expiry dates should be kept at the back;
- k) Label vaccines previously exposed to a cold chain incident and use them first, as there is a potential for wastage if products are exposed to a second (and subsequent) cold chain incident(s);
- l) Clearly mark fee-for-service vaccine inventory and separate it from the publicly funded vaccines;
- m) Remove expired vaccines immediately from the refrigerator to reduce the risk of them being used. Expired vaccines should be returned to the OGPMS as non-usable; and
- n) Store sterile biological products (i.e., blood products, tuberculin skin testing solution) that require refrigeration in a different container/bin than vaccines. Always store sterile biological products below vaccines and on a different shelf to prevent contamination and reduce the likelihood of medication errors.

Vaccine Expiration Dates

- 1) The board of health shall:
 - a) Use the product up to and including the last day of that month, when the expiration date has only a month and year. If a day is included with the month and year, the product can only be used through the end of that day; and
 - b) Use the product before the expiration date, if the:
 - i) Reconstituted vaccines have a limited time frame for use once the vaccine is mixed with a diluent;
 - ii) Multi-dose vials have a specified time frame for use once they have been entered/punctured; and

- iii) Manufacturer-shortened expiration dates when a vaccine is exposed to a cold chain incident.

Vaccine Storage and Handling Equipment Requirements

Physical Requirements at the Board of Health

- 1) The board of health shall:
 - a) Use purpose-built refrigerators (also referred to as pharmacy, laboratory, or industrial-quality refrigerators) for storing vaccine inventories. The purpose-built refrigerator shall:
 - i) Have a feedback system, which has narrow tolerances with internal temperatures, providing appropriate temperature regulation;
 - ii) Have ongoing air circulation for even temperature distribution;
 - iii) Have an evaporator operating at +2°C, preventing the vaccine from freezing;
 - iv) Have air circulation that is fan-forced;
 - v) Have a temperature recovery system;
 - vi) Be built to handle ambient temperature changes;
 - vii) Accommodate vaccine inventory, taking into consideration times of the year when a large inventory of vaccines shall be stored in the refrigerator (e.g., influenza season) without crowding;
 - viii) Be maintained at temperatures between +2°C and +8°C. The thermostat should be set at midrange to achieve a temperature of about +5°C, which will decrease the likelihood of temperature excursions;⁵
 - ix) Have a digital temperature monitoring system with an alarm that is set at +3°C and +7°C. This should provide adequate response time to respond to the alarm and implement corrective measures prior to temperatures following above or below the recommended temperature range;
 - x) Be secured, with the refrigerator and/or the room, where the vaccine is housed, locked by designated staff after office hours; and
 - xi) Not be used for storing ice/gel packs (including water blankets). A separate refrigerator and/or freezer should be used for this purpose.
 - b) Place the purpose built refrigerators in a room:
 - i) That is well-ventilated, temperature-controlled that is away from direct sunlight and with space between the unit, ceiling, and any wall. Seasonal variations in room temperature may affect the refrigerator temperatures;
 - ii) Where the temperature is monitored and maintained between +20°C and +25°C;
 - iii) Where the cover of the motor compartment is not blocked;
 - iv) Where the refrigerator unit is leveled with the doors opening and closing smoothly and fitting squarely against the refrigerator unit; and
 - v) That allows for air circulation around the back and sides of the unit, as recommend by the manufacturer.

- c) Take the following precautions to protect the storage unit's power supply:
 - i) Connect vaccine refrigerators to a dedicated electric circuit so that enough power is available to operate it safely without overloading the system;
 - ii) Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged;
 - iii) Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers;
 - iv) Label fuses and circuit breakers to alert people not to turn off power to storage units and include immediate steps to take if power is interrupted;
 - v) Avoid using power outlets that can be tripped or switched off, including:
 - I) Built-in circuit switches;
 - II) Outlets that can be activated by a wall switch; and
 - III) Multi-outlet power strips.
- d) Have an alarmed temperature monitoring system for each vaccine refrigerator. The alarm must be either a voice or electronic message that will be telephoned or e-mailed to on-call staff or a security service OR a recognizable audio tone that is monitored during office hours by staff and after office hours by a security service. The security service or on-call staff must be trained in appropriate procedures for responding to an alarm. The alarmed temperature monitoring system should have a battery back-up system in case of an electricity disruption.

Routine Maintenance at the Board of Health

- 1) The board of health shall:
 - a) Check storage unit door seals regularly for signs of wear and tear. Seals should not be torn or brittle, and there should be no gaps between the seals and the body of the unit when the door is closed. If seals need to be replaced, contact a repair technician immediately. Unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units;
 - b) Check door hinges and adjust so that the doors open and close smoothly and fit squarely against the body of the unit;
 - c) Clean unit coils and motor as dust and dirt buildup can affect transfer of heat from the coils and prevent the unit from working efficiently;
 - d) Clean the inside of the unit to prevent bacterial and fungal growth. Clean the unit quickly to minimize the risk of the temperature going out of range;
 - e) Have vaccine refrigerator maintenance agreements in place. Maintenance agreements shall include:
 - i) Regular maintenance of vaccine refrigerators completed at least once annually;
 - ii) Testing of the vaccine refrigerator alarm system;
 - iii) Calibration of the vaccine refrigerator's digital temperature monitoring device(s) by a certified technician once annually; and
 - iv) Documentation of the results of maintenance activities and tests;

- f) Maintain the equipment manual and maintenance logbooks for each piece of vaccine storage and handling equipment and create a summary of maintenance information that includes the following:
 - i) Name and contact information for the refrigerator service provider;
 - ii) Itemized list of vaccine refrigerators within the board of health, including location, the date each piece of equipment was installed, size, and serial numbers; and
 - iii) Maintenance history and status of vaccine refrigerators.
- g) Replace all vaccine refrigerator batteries (e.g., for alarm system(s) and digital temperature monitoring device(s)) at least annually, or as required; and
- h) Report breakdowns immediately and transfer vaccine to an alternate storage refrigerator while the refrigerator is being repaired.

Stabilizing Temperatures in New and Repaired Refrigerators at the Board of Health

- 1) The board of health shall:
 - a) For repaired refrigerators or refrigerators that experienced a power outage, the vaccine refrigerator temperatures shall be stabilized between +3°C to +7°C (strive for +5°C) prior to placing vaccine back into the refrigerator; and
 - b) For new refrigerators, vaccine refrigerator temperatures shall be stabilized between +3°C to +7°C (strive for +5°C). Monitor temperatures for 2 to 7 consecutive days. Maximum, minimum, and current temperatures need to be recorded twice daily and shall be within the required storage temperature range prior to storing vaccine in the refrigerator.⁵

Digital Temperature Monitoring Devices for Vaccine Refrigerators and for Vaccine Transport at the Board of Health

- 1) The board of health shall have a digital temperature monitoring device for:
 - a) Each vaccine refrigerator (a data logger is required);
 - b) Each transport container; and
 - c) At least one backup digital temperature monitoring device in case a primary device malfunctions or is out for calibration testing, making sure the backup device has a different calibration testing schedule than the primary device.
- 2) A board of health's digital temperature monitoring devices shall have a(n):
 - a) Alarm for out-of-range temperatures;
 - b) Low-battery indicator;
 - c) Digital display of the current, minimum, and maximum temperatures;
 - d) Accuracy within +/-1.0°C;
 - e) Temperature increment of 0.1°C; and
 - f) Certification that it is calibrated and at a minimum, replaced once annually (or once the duration of certification of accuracy has been reached) or recalibrated by

a certified technician. Since all digital temperature monitoring devices experience “drift” over time that affects their accuracy, calibration testing is needed every one to two years or according to the manufacturer’s suggested timeline.⁵

Data Loggers

- 1) Data loggers are continuous monitoring and recording devices that provide detailed information on all temperatures recorded at preset intervals. Data loggers provide the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range. When using data loggers, the board of health shall:
 - a) Continuously record all vaccine refrigerator temperatures;
 - b) Review the print-outs from the data logger when the vaccine refrigerator temperatures are below +2°C or above +8°C;
 - c) Change batteries annually, or as required;
 - d) Check the digital temperature monitoring device twice daily, when the board of health opens and before the board of health closes, to confirm that vaccine refrigerator temperatures remained between +2°C and +8°C. Record minimum, maximum, and current temperatures in the current temperature log book or any other method specified by the ministry after each check;
 - e) Continue twice daily observation and the recording of the refrigerator temperatures or the installation of an alarm system which alerts staff within and outside of work hours when there is a temperature excursion;
 - f) Program the continuous temperature recording system for at least a 30 minute interval for recordings;
 - g) Place the data loggers in the middle of the refrigerator with vaccines surrounding it;
 - h) Place the data logger away from doors or walls of the refrigerator;
 - i) Download data loggers on a weekly basis and when an alarm is triggered and retained as per board of health policy. Keep logs for a minimum of one year;
 - j) Download the data from the data logger immediately when an out of range temperature occurs to determine the duration of the cold chain incident and to determine if vaccine is suitable for continued use or no longer viable;
 - k) For data loggers that are utilized to record the minimum, maximum, and current temperatures twice daily, data shall be downloaded after the temperature recordings in order to reset the minimum, maximum and current temperature readings from the previous readings; and
 - l) For data loggers that are utilized in conjunction with a maximum-minimum thermometer, data can be downloaded on a weekly basis (if no out-of-range temperatures occur) provided that the minimum, maximum and current temperature readings are documented from the maximum-minimum thermometer.

Digital Maximum-Minimum Thermometers

- 1) Digital maximum-minimum thermometers show the current temperature and the minimum and maximum temperatures that have been reached since the last time the

maximum-minimum thermometer was reset. When using digital maximum-minimum thermometers, the board of health shall:

- a) Manually reset the thermometer each time the temperatures are recorded;
- b) Use device specific operating instructions as each digital maximum-minimum thermometer has slightly different operating instructions; and
- c) Change batteries annually, or as required.

Checking the Accuracy of a Health Care Provider's Digital Temperature Monitoring Device

- 1) Checking the digital temperature monitoring device for accuracy is recommended to ensure that temperature measurements are accurate and cables and sensors are not damaged. The board of health shall check digital temperature monitoring devices for accuracy after:
 - a) Issues are detected with the device (e.g., after a cold chain incident); and
 - b) One year of device use.
- 2) The board of health shall instruct health care providers to replace or recalibrate the device annually (or once the duration of certification of accuracy has been reached), or send the device back to the manufacturer for recalibration. If these steps have not been completed then the board of health shall check for the accuracy of the health care provider's device by testing the accuracy of the premises' device against the board of health's calibrated device by:
 - a) Determining the accuracy of the devices. If the accuracy of the device is unknown assume an accuracy of +/- 1.0°C;
 - b) Establishing the acceptable variance by adding the accuracy of devices together;
 - i) E.g., Health care provider's device has an accuracy of +/- 1.0°C and board of health's calibrated device has an accuracy of +/- 0.5°C, the acceptable variance is +/- 1.5°C.
 - c) Placing the board of health's calibrated device into the health care provider's refrigerator and letting it stabilize to the temperature of the refrigerator (this should take approximately 5 to 10 minutes depending on the refrigerator and thermometer);
 - d) Comparing the board of health's device results with the health care provider's device results; and
 - e) Instructing the health care provider to replace their device if the difference between the two current temperature readings is greater than the acceptable variance.

Placement of Digital Temperature Monitoring Device at the board of Health

- 1) The board of health shall:
 - a) Refer to the owner's manual for instructions on digital temperature monitoring device placement.

- b) Place the digital temperature monitoring device's digital display outside the unit or in a position inside the unit so temperatures can be read without opening the door.

Monitoring Refrigerator Temperatures at the Board of Health

- 1) Monitoring vaccine storage equipment and temperatures is a daily responsibility to ensure the safety of the vaccine supply. The board of health shall implement routine monitoring activities to identify out-of-range temperatures quickly and take immediate action to correct them, preventing loss of vaccines. The board of health shall:
 - a) Document the time and the current, maximum and minimum temperatures of the refrigerator in the Temperature Log Book twice daily (beginning and end of each business day) and reset the digital temperature monitoring device after recording/downloading the readings;
 - b) View the temperatures every time the refrigerator is accessed;
 - c) Maintain temperature logs and data logger temperature downloads for a minimum of one year (unless board of health policy requires a longer retention period);
 - d) Inspect the storage unit during the twice-daily checks, and, if required, reorganize any misplaced vaccines, and remove any expired vaccines; and
 - e) Check unit doors throughout the day and always at the end of the day to ensure they are tightly closed to prevent temperature changes and light exposure.

Vaccine Transport

General

- 1) The board of health shall:
 - a) Transport all vaccines in insulated containers supplied by the OGPMS with the appropriate packing configuration (i.e., summer or winter). Alternative insulated containers for vaccine transport can be used upon approval by the ministry, provided that:
 - i) The insulated containers are internally validated and capable of maintaining the vaccine at the required temperatures for the required duration for transportation and/or storage;
 - ii) There is documentation that shows that the insulated containers have been internally validated; this documentation may be provided from the manufacturer or produced following testing by the board of health; and
 - iii) The documentation is submitted to the ministry prior to use of the insulated container.
 - b) Have a digital temperature monitoring device for all insulated containers used for transporting vaccines;
 - c) Order insulated containers from OGPMS for board of health or health care providers use;
 - d) Verify that health care providers are using insulated containers with the appropriate packing materials, packing configuration and a digital temperature monitoring device when transporting vaccine from the board of health so that

- vaccines are maintained within the +2°C to +8°C temperature range for the maximum length of time that might be required for transport and/or storage;
- e) Not use insulated containers for the transport of vaccines for prolonged periods as their cold life (the container's ability to maintain the required temperature range) is limited:
 - i) Most insulated containers can maintain the required temperatures for a maximum of four hours. However, the external temperature, the number of times the insulated container is opened and closed, the amount of vaccine that is being stored and the type of packaging material used may reduce the amount of time vaccines can be stored in the insulated container.
 - ii) If vaccines will be stored in the insulated container for more than four hours during transport, the ice pack(s) and/or gel pack(s) should be removed and replaced with a new set of conditioned frozen and/or refrigerated ice pack(s) and/or gel/pack(s);
 - f) Clearly mark all insulated containers storing vaccines in a visible location with the following label: "VACCINES – REFRIGERATE IMMEDIATELY." Before placing vaccines into the refrigerator, they must be removed from the insulated container(s); and
 - g) Not transport vaccines in insulated containers in the trunk of a car due to the risk of exposure to extreme temperatures.

Conditioning Frozen Ice/Gel Packs and Insulated Containers

- 1) The board of health shall condition frozen ice/gel packs and the insulated container prior to use by:
 - a) Leaving the ice/gel pack at room temperature for approximately 45 minutes to 1.5 hours depending on the size of the ice pack.⁶ The ice pack is conditioned as soon as water begins to 'slosh' slightly inside the ice pack; and
 - b) Chilling the inside of the insulated container prior to use by placing frozen ice pack(s) and/or gel pack(s) inside or by placing the container inside the refrigerator for a few hours.⁶

Packing the Insulated Container for Vaccine Transport

- 1) To prevent episodes of freezing, which can happen very easily in all insulated containers, usually in the first two hours after packing, the board of health shall⁶:
 - a) Place the conditioned ice pack(s) and/or gel pack(s) on the top and on the bottom of the insulated container;
 - b) Wrap the ice blanket around the vaccine to prevent the vaccines from coming into contact with the ice pack(s) and/or gel pack(s);
 - c) Determine the correct combination of ice pack(s) and/or gel pack(s) so that the insulated container is able to maintain the required temperature range for:
 - i) The maximum length of time the vaccine might have to be in the insulated container;
 - ii) The amount of vaccines to be transported; and
 - iii) The given external temperatures (e.g., winter climate vs. summer climate).

- d) Pack the freeze-sensitive vaccines in the centre of the container and the freeze tolerant vaccines closest to the ice pack(s) and/or gel pack(s);
- e) Place a digital temperature monitoring device in the centre of the vaccine stock; and
- f) Place bubble wrap, Styrofoam chips, crumpled or shredded newspaper or other suitable insulating material inside of the insulated container, bottom, top and sides.

Digital Temperature Monitoring for Insulated Containers During Vaccine Transport

- 1) Boards of health shall use a digital temperature monitoring device when transporting vaccines in an insulated container to monitor temperatures during vaccine transport.

Board of Health Immunization Clinics

- 1) The board of health shall:
 - a) Monitor and record temperature readings in the insulated container:
 - i) Before leaving the board of health with the insulated container;
 - ii) Upon arrival at the clinic location prior to starting the immunization clinic;
 - iii) Each time the cooler is opened and at least every hour during the immunization clinic;
 - iv) Before and after breaks i.e., lunch breaks; and
 - v) Upon completion of the clinic but before transport back to the board of health;
 - b) Visually inspect the digital temperature monitoring device each time the insulated container is opened;
 - c) Minimize the number of times that the insulated container is opened during the immunization clinic;
 - d) Upon arrival to the board of health after the immunization clinic:
 - i) Place vaccine into inventory for use if the digital temperature monitoring device(s) indicates that the cold chain was maintained between +2°C to +8°C during the clinic and transport; and
 - ii) Place the vaccine under quarantine in the refrigerator if the digital temperature monitoring device(s) indicates an out-of-range reading and immediately assess the cold chain incident.

Air and Courier Transport Services

- 1) The board of health shall advise courier transport services contracted to transport vaccine that vaccines are perishable and are required to be refrigerated immediately upon receipt and transported under required cold chain conditions. Education and training shall be completed with courier services so that the delivery personnel are knowledgeable about vaccine storage and handling practices. As courier transport services are responsible for the storing and handling of vaccine, a routine inspection shall be completed annually with courier transport services.

- 2) When using air and courier transport service, the board of health shall inquire about estimated travel times and choose insulated containers accordingly.
- 3) The board of health shall place a digital temperature monitoring device in each insulated container. Once a health care provider receives the insulated container from the courier, the board of health shall instruct the health care provider to:
 - a) Immediately open all the transport containers and assess the digital temperature monitoring device(s);
 - b) Examine the shipment for any evidence of damage;
 - c) Inform the courier and make a notation on the manifest if there are any cold chain discrepancies or obvious damage; and
 - d) Once the courier leaves, the board of health shall instruct the health care provider to:
 - i) Unpack the shipment and place the vaccines in the refrigerator; and
 - ii) Contact the board of health immediately if there are any problems with the vaccine order including temperature excursions.

Information and Education Strategies

General:

- 1) The board of health shall:
 - a) Provide information to health care providers that store publicly funded vaccine including:
 - i) Importance of the cold chain, including that vaccines are perishable, must be refrigerated immediately upon receipt, must be transported under required cold chain conditions, and must be transported in properly labelled insulated containers;
 - ii) Vaccine storage and handling practices;
 - iii) How to recognize a cold chain incident; and
 - iv) Appropriate action to be taken in the event of a vaccine exposure. Vaccine that has been exposed to a cold chain incident must be reported within 24 hours or the next business day to the board of health;
 - b) Provide ongoing education, as required, with respect to appropriate vaccine ordering, storage, and cold chain management throughout the year for all health care providers who store and administer publicly funded vaccines;
 - c) Instruct health care providers that:
 - i) One person in each premise needs to be designated to monitor vaccine storage and handling practices, and ensure that vaccines are kept at the required temperatures;
 - ii) A back-up is also designated who can complete vaccine storage and handling responsibilities; and
 - iii) All staff members should be trained in reading the vaccine refrigerator thermometers, and documenting and monitoring the vaccine storage

- temperatures to provide 'back up' in the event of staff vacations or other absence;
- 2) The board of health shall ensure that settings to which it distributes publicly funded vaccines meet the following requirements:
 - a) Digital temperature monitoring devices are in place on all refrigerators used to store publicly funded vaccines;
 - b) Digital temperature monitoring device is checked twice daily and the temperature is documented upon arrival and before office closing to confirm that the refrigerator temperatures remained between +2°C and +8°C;
 - c) *Vaccine Storage and Handling Guidelines, 2012* (or as current) and materials are available at the health care provider's premises and are easily accessible;⁴ and
 - d) Have a documented routine (annual) inspection for each health care provider prior to receiving publicly funded vaccine(s).

Inspections

- 1) The board of health shall conduct the following inspections in health care provider premises that store publicly funded vaccine to assess vaccine storage and handling practices:
 - a) Routine inspection on an annual basis; and
 - b) Cold chain incident inspections, as required.

Routine Inspections

- 1) The board of health shall:
 - a) Conduct a(n):
 - i) Routine annual inspection for the purpose of assessing the health care provider's level of compliance with vaccine storage and handling requirements, including cold chain requirements, and to provide an opportunity for board of health staff to provide information, resources and consultation regarding the proper storage and handling of vaccines, cold chain management and the proper temperature monitoring systems that should be in place to optimize vaccine potency; and
 - ii) On-site routine inspection and orientation for newly enrolled immunization service providers prior to distributing publicly funded vaccine to them; and routine inspections on an annual basis thereafter regardless of whether or not a cold chain incident inspection has been conducted;
 - b) Contact in advance, newly enrolled premises or those previously compliant with provincial vaccine storage and handling requirements to:
 - i) Pre-arrange a routine inspection visit at a specific date and time; or
 - ii) Provide an overall time period in which the board of health will be conducting the routine inspection, and request that the premises be prepared for a visit at any time during this period;
 - c) Conduct an unannounced routine inspection, if the premise has been previously non-compliant with provincial vaccine storage and handling requirements;

- d) Review and inspect the following vaccine storage and handling items as per all the sections indicated in the Vaccine Cold Chain Inspection Maintenance Report form including:
 - i) Vaccine storage;
 - ii) Vaccine storage and handling equipment (e.g., temperature monitoring and recording device, refrigerator);
 - iii) Vaccine refrigerator temperatures;
 - iv) Vaccine temperature log book;
 - v) Vaccine handling;
 - vi) Vaccine inventory;
 - vii) Contingency plan; and
 - viii) Availability of vaccine storage and handling resource material;
- e) Complete the current Vaccine Cold Chain Maintenance Inspection Report form, or as specified by the ministry, during the inspection and indicate the premises' compliance with each of the vaccine storage and handling requirements and recommendations. A copy of the report shall be provided to the health care provider and retained at the board of health according to local record retention schedules; and
- f) Report the results of these inspections to the ministry upon request, using the current Vaccine Cold Chain Maintenance Inspection Report form or any other method specified by the ministry.

Cold Chain Incident Inspection

- 1) The board of health shall:
 - a) Conduct cold chain incident inspections following a cold chain incident;
 - b) Conduct cold chain incident inspections to:
 - i) Determine whether vaccine can be used by the health care provider or must be returned to the board of health;
 - ii) Investigate the cause of the cold chain incident;
 - iii) Provide follow-up education in order to prevent the occurrence of future incidents; and
 - iv) Ensure that adequate cold chain conditions can be maintained prior to continuing the vaccine supply to the health care provider;
 - c) Investigate all reports of cold chain incidents in health care provider premises to which it has distributed publicly funded vaccines within 24 hours (or the next business day) of receiving a report of such an incident;
 - d) Determine whether an on-site cold chain incident inspection is required at the premises or whether the investigation can adequately be handled over the telephone. (Note: it is recommended that on-site inspections be conducted following cold chain incidents that are related to non-compliance with the *Vaccine Storage and Handling Guidelines, 2012*;⁴)
 - e) Provide consultation and technical assistance to health care providers who have experienced cold chain incidents;

- f) Ensure that the steps as outlined in the Cold Chain Incidents, Within Board of Health section of this protocol (as stipulated below) are followed;
- g) Communicate and document the board of health's assessment of the cold chain incident, and/or issues related to non-compliance, the monetary value of the vaccine loss, and the required remediation strategy(ies) to health care providers who are non-compliant with the minimum vaccine storage and handling requirements as specified in the *Vaccine Storage and Handling Guidelines, 2012* (or as current) or have experienced a cold chain incident.⁴ A specified remediation time frame shall be established with the health care;
- h) Withhold vaccines until compliance issues have been resolved or until completion of other follow-up deemed necessary to ensure appropriate vaccine storage and handling has been verified. For health care providers who order vaccines directly from the OGPMS, the board of health shall instruct the OGPMS to discontinue further vaccine deliveries to the health care provider premises until the requirements have been met; and
- i) Issue an advisory from the medical officer of health (or designate) to the health care provider's premises advising that access to publicly funded vaccines has been suspended due to non-compliance with the required remediation strategy(ies) or repeated cold chain incidences have occurred. Once remediation activities have been undertaken as recommended by the board of health, vaccine supply can be restored. For health care providers who order vaccines directly from the OGPMS, the board of health shall instruct the OGPMS to resume filling orders for health care providers.

Cold Chain Incidents

Within the Board of Health

- 1) The board of health shall contact the ministry following a cold chain incident during vaccine delivery from the OGPMS within 24 hours (or the next business day). The ministry is responsible for assessing conditions and making recommendations.

Within the Board of Health or at a Health Care Provider's Premises

- 1) The board of health shall take the following steps after a cold chain incident within the board of health or at a health care provider's premises:
 - a) Store exposed vaccines in a separate container marked "DO NOT USE" in a refrigerator or insulated container with the appropriate packing material (e.g., ice packs) and with a digital temperature monitoring device(s) until the board of health determines which vaccines are usable and which vaccines are not to be used (wasted);
 - b) Calculate the maximum length of time the temperature was outside +2°C to +8°C. If specific time/temperature details are not available, assume the refrigerator malfunctioned immediately after the last digital temperature monitoring device check;

- c) Assess vaccines involved in the cold chain incident and provide advice for use/return based on the recommendations of the vaccine manufacturer or the current Canadian/Provincial/Territorial Vaccine Stability Chart, if available. If the vaccines have been exposed in a previous incident, board of health staff shall contact the vaccine manufacturer as indicated in the current Canadian/Provincial/Territorial Vaccine Stability Chart;
- d) Mark vaccines involved in a cold chain incident that have been determined to be usable in order to identify them in case of a second exposure. These vaccines must be distributed and/or administered before unexposed vaccines, regardless of expiry date;
- e) Return vaccines involved in a cold chain incident that have been determined to be unusable to the OGPMS. These vaccines do not require refrigeration;
- f) After any cold chain incident that has occurred either at the board of health or at a health care provider's premises, the board of health shall, after the investigation of the incident, enter the information in Panorama or any other method specified by the ministry; and
- g) Maintain a record of the cold chain incident(s).

Contingency Planning

At the Board of Health

- 1) The board of health shall:
 - a) Establish a contingency plan for vaccine storage and handling in the event of a vaccine refrigerator malfunction, electricity disruptions, or other emergency that may compromise vaccine storage conditions. The vaccine storage and handling contingency plan shall cover the following:
 - i) Maintaining the vaccine inventory within the board of health if the vaccine refrigerator is connected to a generator;
 - ii) Establishing in advance at least one alternative storage facility where vaccines can be appropriately stored and monitored if the board of health does not have a generator. The facility should have adequate vaccine storage capacity. The contingency plan shall include detailed instructions for transporting vaccines to the alternate storage site. In situations where an alternative vaccine storage facility cannot be identified within a reasonable distance, maintain the appropriate packing materials to temporarily and safely store vaccine at the board of health; and
 - iii) Training for board of health staff so that they understand the contingency plan and their responsibilities for maintaining the cold chain;
 - b) Post the contingency plan on or near all board of health vaccine refrigerators;
 - c) Designate a primary and back-up contact person to set up and maintain a monitoring and/or notification system for proper storage and handling of vaccines during the implementation of the contingency plan;
 - d) Keep emergency supplies on hand to accommodate their maximum vaccine supply, including:

- i) Insulated containers;
- ii) Insulating material (e.g. crumpled paper, bubble wrap, and Styrofoam pellets);
- iii) Packaging material, ice pack(s) (including ice blankets) and/or gel pack(s);
- iv) Calibrated digital temperature monitoring devices;
- v) A flashlight; and
- vi) Batteries.

During Refrigerator Malfunction/Electricity Disruption at the Board of Health

- 1) When a refrigerator malfunction occurs, the board of health shall:
 - a) Document the time and the maximum, minimum and current temperature of the refrigerator in the Temperature Log Book and reset the maximum-minimum thermometer (if applicable);
 - b) Not allow the vaccine to remain in a non-functioning unit for an extended period of time;
 - i) Most refrigerated vaccines will remain stable at elevated temperatures for a limited period of time. Purpose-built refrigerators, especially those with glass doors, may not be able to maintain temperatures for longer than 30 minutes. Factors including the amount of vaccine being stored in the refrigerator, the external temperatures (e.g., summer vs. winter) and the type, model and age of the vaccine refrigerator will affect the duration of time vaccines within the unit will be kept within the +2°C to +8°C range;
 - c) During a scheduled or a time-limited electricity disruption where the power is expected to be restored before the vaccine refrigerator temperature rises above the recommended range, the board of health shall: following steps:
 - i) Keep the refrigerator door closed until the power is restored to maintain an acceptable temperature range for as long as possible; and
 - ii) Record maximum, minimum and current temperatures:
 - I) Continue to monitor the temperatures inside the vaccine storage unit at 30 minute intervals if the digital temperature monitoring device allows digital temperature monitoring without opening the storage unit doors;
 - d) If it is unsure that the problem can be corrected in time to maintain an appropriate temperature, the board of health shall initiate its contingency plan by:
 - i) Transferring vaccines to alternative storage facility (that is connected to a generator) by:
 - I) Contacting the alternative vaccine storage facility to notify them of the need to store vaccine at their location;
 - II) Conducting an inventory of vaccines while packing all vaccines, using insulated containers with appropriate packing materials and digital temperature monitoring devices;
 - III) Recording the time an insulated container temperature before transporting the vaccines to and upon arrival at the alternative storage facility; and
 - IV) Continuing to read and record the maximum, minimum and current refrigerator temperatures twice daily; and

- e) Alternatively, if an alternative storage facility cannot be identified within a reasonable distance, place the vaccine in insulated containers with appropriate packaging material and digital temperature monitoring devices and record the temperature at the board of health by:
 - i) Labeling the insulated containers; and
 - ii) Continuing to monitor the temperatures inside the insulated container at 30 minute intervals if the digital temperature monitoring device allows digital temperature monitoring without opening the insulated container.

When the Refrigerator Malfunction Has Been Corrected or the Electricity Supply to the Refrigerator Has Been Restored at the Board of Health

- 1) The board of health shall:
 - a) Document the following:
 - i) Maximum, minimum and current temperatures inside the vaccine storage units;
 - ii) Length of time the power has been off; and
 - iii) Time when the electricity supply is restored;
 - b) Maintain the vaccines in the refrigerator or remove the vaccines from the insulated container and place them into the refrigerator and resume regular vaccine storage and handling practices, as long as the refrigerator and insulated container were able to maintain the required +2°C to +8°C temperature range;
 - c) Maintain the vaccines in the insulated container and continue to monitor temperatures inside the container if the insulated container was able to maintain the required +2°C to +8°C temperature range, but the vaccine refrigerator was unable to maintain the required storage range. Place the vaccine back into the refrigerator once it is able to maintain +3°C to +7°C (strive for +5°C);
 - d) Undertake the following if the vaccine storage units (refrigerator(s) or insulated container(s)) were unable to maintain the required temperatures:
 - i) Calculate the maximum length of time the temperature was outside 0°C to +8°C;
 - ii) Complete a Panorama ASC (Adverse Storage Condition). Refer to the Panorama Inventory Data Standards and Best Practices;³
 - iii) Assess vaccines involved in the cold chain incident by contacting the product manufacturer to determine which vaccines are still usable and which are wastage;
 - iv) Mark vaccines involved in a cold chain incident that have been determined to be usable, in accordance with manufacturers' recommendations, in order to identify them in case of a future exposure(s);
 - v) Return unusable/wasted vaccines to OGPMS. Refer to the Panorama Inventory Data Standards and Best Practices;³ and
 - vi) Return vaccines to the refrigerator once temperatures have returned to between +3°C to +7°C.

For Health Care Providers

- 1) The board of health shall:
 - a) Work with health care providers in their jurisdiction to develop operational contingency plans for any premises that store publicly funded vaccines; and
 - b) Make health care providers aware of the practices to follow in the event of a refrigerator malfunction or electricity disruption.

When the Refrigerator Malfunction Has Been Corrected or the Electricity Supply to the Refrigerator Has Been Restored for Health Care Providers

- 1) The board of health shall direct health care providers to contact the board of health for assistance in the identification and assessment of cold chain incidents after a refrigerator malfunction or electricity disruption.
- 2) The board of health shall complete an assessment of the affected vaccines. Any unusable/wasted vaccines should be returned to the board of health by the health care provider. Mark all reusable vaccine as exposed, according to the directions provided by the board of health.
- 3) The board of health shall facilitate completion of a Panorama ASC, according to the Panorama Inventory Data Standards and Best Practices.³
- 4) The board of health shall instruct and verify that health care providers enacting any recommendations made by board of health staff to prevent or mitigate the risk of future exposures from occurring.

Glossary

Calibration: Calibration is the process of configuring an instrument to provide a result within an acceptable range (e.g., +/-0.5°C). Although the exact procedure may vary from device to device, the calibration process generally involves using the instrument to test samples of one or more known values called calibrators. The process teaches the instrument to produce results that are more accurate than those that would occur otherwise. Device calibration is one of the primary processes used to maintain device accuracy.

Cold chain: Includes all of the materials, equipment, and procedures used to maintain vaccines in the required temperature range of +2°C to +8°C from the time of manufacture until the vaccines are administered to individuals. In addition, protection from light is a necessary condition for some vaccines.

Cold chain incident or vaccine exposure: Occurs when vaccine is exposed to a temperature outside the required temperature range of +2°C to +8°C for any period of time and the potency of the vaccine is potentially compromised. The vaccine temperature excursion tolerance and permissible time excursion is determined by each vaccine manufacturer.

Cold chain inspection: Boards of health conduct cold chain inspections to investigate the cause of the cold chain incident, determine whether vaccine can be used by the health care provider or returned to the board of health, provide follow-up education in order to prevent the occurrence of future incidents and ensure that adequate cold chain conditions can be maintained prior to continuing the vaccine supply to the health care provider

Conditioning (related to ice/gel packs): leaving the ice pack(s) (including flexible ice blankets) and gel pack(s) at room temperature to allow the ice or gel at the core to rise to about 0°C. This minimizes the risk of exposing vaccines to freezing temperatures.

Cycle count: Cycle Count is an inventory management process where a small subset of inventory is counted on any given day. Cycle counts are less disruptive to daily operations as only selected holding point locations and/or products are counted, audited, and recounted. Normal transactions can continue for the rest of the inventory not being counted. The cycle counts provide an ongoing measure of inventory accuracy and can be tailored to focus on items in the holding point locations selected. Freezing inventory for a cycle count is optional.

Damaged product: Vaccine and/or package that has been physically harmed; this prevents its use.

Defective product: Vaccine and/or package that has a flaw(s) or imperfection(s).

Demographics: Statistical data about the characteristics of a population, such as the age, gender and income of the people within the population.

Digital temperature monitoring device: An electronic device that measures temperatures and provides a digital display of the temperature reading. This can include devices such as a:

Data logger: A digital temperature monitoring device that records temperatures continuously at programmed intervals. Temperature recordings are stored in the device's memory and can then be downloaded for review and storage.

Maximum-minimum thermometer: A digital temperature monitoring device that records the maximum and minimum temperature that has been reached over a period of time (since the last reset).

Diluent: Liquid substances used to reconstitute lyophilized vaccines prior to administration. Manufacturers of freeze-dried vaccine also supply the matching diluents.

Epidemiology: Epidemiology is the study of how often diseases occur in different groups of people and why. Epidemiological information is used to plan and evaluate strategies to prevent illness and as a guide to the management of patients in whom disease has already developed.

Expired vaccine: If the month and year are specified, the vaccine expires at the end of the month. Vaccine returned to the OGPMS with less than four months of shelf life

(unless otherwise specified by the ministry) is considered expired, although the expiry date may not have passed.

Exposed vaccine: Vaccine that is stored or handled at temperatures below +2°C or above +8°C for any period of time, or that is not stored according to the manufacturer's recommendations.

Health care provider (in relation to this Protocol): A regulated health care professional who manages publicly funded vaccines and provides immunization services.

Holding Point (HP) Code: The unique code provided to the facility associating it with the practice.

Holding Point Name: The business name of the facility storing publicly funded vaccine.

Immunization coverage: The percent of people who receive one or more vaccine(s) of interest in relation to the overall population

Insulated container or vaccine transport container: An insulated container is a solid walled container with a tight lid. The container shall be able to store and transport vaccines at the required temperature for the necessary duration of time.

Maximum and minimum temperature: A vaccine storage unit's warmest and coldest temperature readings during a set period of time.

Non-reusable (wasted) vaccine: Any vaccine that cannot be used is considered to be wasted. Wasted vaccine includes doses wasted for the following reasons: expired, spoiled (due to a cold chain incident), defective, discontinued, damaged, dose(s) remaining in a multi-dose vial that have expired, insufficient dose(s) from a multi-dose vial, suspected contamination, vaccine administration issue(s), unused pre-drawn syringe(s) and count discrepancy

Physical count: The process of physically counting the vaccines and diluents in the refrigerator. The physical counts are then compared to the quantities reported in Panorama.

Population growth: An increase in the number of people that reside in a country, province, county, or city. To determine whether there has been population growth, the following formula is used: (birth rate + immigration) - (death rate + emigration).

Potency: The ability of a vaccine to produce a predictable and expected level of immune response in the vaccine recipient.

Purpose-built refrigerator: A purpose-built vaccine refrigerator (also referred to as a pharmacy, lab-style or laboratory grade refrigerator) is the recommended standard for storing vaccines to keep them within the required +2°C to +8°C range to ensure potency, safety and effectiveness.

Quantity on hand report: The purpose of this report is to indicate Operational Quantity on Hand for an item or a list of items.

Quarantine: Maintaining vaccines that have been exposed to a potential cold chain incident separate from other vaccines.

Routine (annual) inspection: Routine inspections assess the health care providers' level of compliance with vaccine storage and handling requirements, including cold chain requirements. Routine inspections enable board of health staff to provide information and resources regarding the proper storage and handling of vaccines and the proper temperature monitoring device that should be in place to optimize vaccine potency.

Spoiled vaccine: Vaccine that cannot be used due to exposure(s) to temperatures below +2°C or above +8°C for a specific period of time. This will depend on the specific vaccine.

Temperature excursion or out-of-range temperatures: Occurs when vaccine is exposed to a temperature outside the required temperature range of +2°C to +8°C for any period of time

Temperature log books: Temperature log books are provided to the board of health by the ministry, they are used to document maximum, minimum and current temperatures twice daily.

Temperature recovery system: A mechanism that allows the refrigerator to return to its set temperature after being exposed to out of range temperatures (e.g., after opening the door to remove vaccine).

Vaccine administration issue(s) (in relation to wastage): During vaccine administration, a dose that is only partially (or not) administered to a vaccine recipient is considered wastage.

Vaccine forecasting: Estimating the quantity of vaccines needs necessary for immunization programs delivered by the board of health and health care providers

Wasted vaccine: Any vaccine that cannot be used is considered to be wasted. Wasted vaccine includes doses wasted for the following reasons: expired, spoiled (due to a cold chain incident), defective, discontinued, damaged, dose(s) remaining in a multi-dose vial that have expired, insufficient dose(s) from a multi-dose vial, suspected contamination, vaccine administration issue(s) ,unused pre-drawn syringe(s) and count discrepancy.)

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