Vaccine Storage, Handling and Transportation for Publicly Funded Vaccines in New Brunswick

December 2024
Department of Health
Public Health New Brunswick

Contents

1.0 POLICY

Purpose: This policy outlines the best practices for the storage, handling, and transportation of publicly funded vaccines in New Brunswick (NB). Its goal is to ensure vaccine efficacy, maintain the cold chain, and guarantee safety. This policy is enacted under the authority of the *Public Health Act.*

Scope: Intended for use by all those who store, handle, transport and administer publicly funded vaccines in New-Brunswick.

Objective: To ensure the integrity and efficacy of vaccines throughout their lifecycle, minimizing risks such as compromised immunizing agents and potential transmission of vaccine-preventable diseases, while adhering to regulatory requirements. This policy aims to address vaccine management guidelines for all immunization providers, decreasing vaccine losses, maintaining public confidence, and maximizing public health outcomes.

It's important to note that while this policy aims to generally cover various aspects of vaccine management, it may not address every scenario.

Policy: Each facility handling vaccines must develop, implement, and monitor Standard Operational Procedures (SOPs) in line with this policy. This includes adhering to vaccine cold chain standards, providing education and quality assurance, and maintaining written procedures for storage, handling, and transportation to ensure vaccine integrity.

All vaccine-related activities, such as ordering, receipt, storage, inventory management, temperature monitoring, and vaccine wastage, must be accurately documented. These records should be securely stored and readily available for review.

All staff and immunizers involved in vaccine handling must adhere to the guidelines outlined in this policy. Any concerns or deviations

should be promptly reported to the designated authority.

2.0 TRAINED PERSONNEL

2.1 DESIGNATED INDIVIDUALS

All facilities **must** designate a primary and backup individual responsible for the overall vaccine management, including ordering, storage, temperature monitoring, and transportation. The designated individual **must** be appointed to oversee the training of all personnel. These individuals are required to have:

- A comprehensive understanding of the importance of maintaining the cold chain.
- Proficiency in vaccine storage and handling practices.
- Competence in vaccine temperature monitoring.
- Equipment maintenance and troubleshooting procedures.
- Capability to identify and respond to breaks in the cold chain.
- Vaccine inventory management.
- Disposal of vaccines and diluents as directed by policy.
- Knowledge of safe vaccine transportation methods as outlined in this policy.
- Familiarity with routine and emergency protocols including cold chain breaks, temperature excursions, transportation issues, and power failures within their facility.

2.2 IMMUNIZERS

All personnel involved at any stage of vaccine storage, handling, and transportation **must** participate in immunization competency training.

For immunization competency training guidelines, refer to the New Brunswick Immunization Program Guide (NBIPG): Immunization Competency Requirements for All Immunization Providers.

3.0 COLD CHAIN MANAGEMENT

The term “cold chain” is used describe a system of equipment and procedures that are in place to ensure that vaccines are maintained in optimal temperature and light conditions per the manufacturer’s product monograph. Maintaining the cold chain is a shared responsibility of all individuals from the time a vaccine is manufactured until it is administered. The cold chain starts from the manufacturer and ends with the client receiving the vaccine.

Any interruption of the cold chain has the potential to decrease the potency of vaccines that, if used, could result in decreased levels of protection in individuals and/or communities. Loss of vaccine is costly and may result in a supply shortage that impacts immunization programs.

The majority of cold chain incidents can be prevented when written standards are in place and adhered to.

3.1 COLD CHAIN MONITORING DEVICES

Warm and cold mark indicators are types of cold chain monitors used year-round that indicate whether vaccine containers have reached temperatures that are either too warm or too cold. Trace-R Mark and FCP Cold are utilized during the distribution of vaccines from the Central Serum Depot to providers. Upon receiving vaccines, ensure markers are checked for any cold chain breaches, and adhere to the manufacturer’s specified temperature thresholds. These indicators do **NOT** replace temperature monitoring of vaccine refrigerators or for subsequent vaccine transport in the communities. For in-community transport, the use of min-max thermometers is recommended.

Deliveries of vaccines in New Brunswick, sourced either from local wholesalers/vendors or directly from manufacturers, may use other various temperature monitoring solutions to maintain the cold chain, such as the following Temptale devices: Sensitech.

4.0 SELECTING VACCINE STORAGE EQUIPMENT

Selecting the right equipment for vaccine storage, tailored to your facility and inventory needs, is crucial for maintaining the integrity and efficacy of vaccines. This section provides detailed guidance on the types of reliable equipment necessary for effective vaccine storage, including the criteria for selecting them.

4.1 REFRIGERATORS

All publicly funded vaccines must be stored in a purpose-built temperature-controlled vaccine refrigerator (2°C to 8°C), **equipped with temperature monitoring devices and an alarm to signal when temperature parameters are exceeded.** Household and bar refrigerators no longer meet the New-Brunswick standards for vaccine storage and are not to be used.

Vaccine refrigerators require careful selection, considering factors such as the facility's size, technical features of the refrigerator, and vaccine storage needs. They should accommodate the maximum volume of vaccines needed at any time during the year and allow sufficient air circulation around vaccine packages within the unit. The following is a list of suggested suppliers of purpose-built refrigerators which can be considered for your facility:

- Accucold® Vaccine Refrigerators
- Esbe Scientific

- VWR® Plus Series Compact Laboratory Refrigerators with Natural Refrigerants | Refrigerators (avantorsciences.com)

After Selecting Your Refrigerator:

- Place the refrigerator in a secure location, ideally in a room with a lockable door to prevent unauthorized access, especially after office hours. If this is not possible, position the refrigerator in a low-traffic area. Consider environmental factors that could affect the temperature, such as proximity to windows, heat sources, or air conditioning vents. Ensure the ambient temperature in the room is stable to prevent fluctuations inside the refrigerator when opening and closing the door.
- Plug the refrigerator into a protected electrical outlet that cannot be accidentally unplugged or turned off. Avoid using outlets controlled by wall switches. Clearly label outlets or switches controlling the vaccine refrigerator with signage and also at the plug to prevent accidental unplugging.
- Have a dedicated circuit for the fridge (i.e., have nothing else plugged into the circuit). Label fuses and circuit breakers to alert others not to turn off power to the vaccine storage unit.
- Connect the refrigerator to a back-up power source. Refer to the next section in this policy.
- Do not store food, drink or laboratory specimens in vaccine refrigerators. Medications should be stored in separate refrigerators, however in "small practices" if stored alongside vaccines in the same refrigerator, they must be kept in separate labelled trays or containers to prevent medication errors. Ensure clear labeling of trays or containers.

For more information on selecting a vaccine refrigerator, refer to the National Vaccine Storage and Handling Guidelines for Immunization Providers (2015), **Section 3.4** – Refrigerators and Freezers

4.2 BACKUP POWER SUPPLY

All publicly funded vaccine fridges in New Brunswick **must** have a back-up power supply and establish a working agreement with at least one alternative storage facility capable of maintaining the appropriate temperature range during an emergency. The recommended backup power equipment will vary based on the size of your facility:

- **Smaller facilities** should consider purchasing an Uninterruptible Power Supply (UPS) device in case of a power failure or have a temperature alarm system in place such as Data loggers:
    - Ensure there is 24-hour access to the facility and install an alarm system to immediately notify the person in charge of vaccines in the event of a power failure.
    - An on-site generator can eliminate the need to transport vaccines to an alternative storage facility during a power outage. Make sure to have enough fuel on hand to run the generator for at least 72 hours.
- **For larger facilities**, backup generators are typically configured to automatically supply power to the refrigerator during outages. Ensure the refrigerator is connected to a dedicated electrical outlet.

All sites storing publicly funded vaccine should have an operational plan in place in the event of a power failure (refer to Section 10).

4.3 THERMOMETERS

Always keep a vaccine-specific min/max thermometer or “Data logger” in the refrigerator, ensuring it is designed specifically for vaccine storage. Temperature checks and recordings should be done twice daily. Ideally, opt for a thermometer that can be read from outside the refrigerator.

Minimum-maximum Thermometer Devices:

The following is a list of suggested suppliers of min/max thermometers suitable for clinic use and can be considered for your facility:

- Home | Avantor (avantorsciences.com)
- VWR® Traceable® Refrigerator/Freezer Plus™ Thermometers | Digital Thermometers (avantorsciences.com)

As each min-max thermometer varies, carefully read, and follow each manufacturer's operating instructions. Place the min-max thermometer or digital thermometer probe centrally within the refrigerator, avoiding placement in the back, near the door, or directly adjacent to cooling elements.

Data Loggers:

Consider implementing these continuous-monitoring temperature alarm or notification systems, particularly for vaccine storage units with significant inventory. These systems provide timely alerts for after-hours emergencies with capabilities to notify the designated person via cellular phone. Information from data loggers should be downloaded and/or printed out each month and retained for one year. Providers can purchase the following dataloggers from a list of suggested suppliers:

- Traceable® WIFI Data Logging Refrigerator/Freezer Thermometer Compatible with TraceableLIVE® Cloud Service
- Sensitech | Temperature Monitors
- Esbe Scientific

For more information on thermometers, refer to the National Vaccine Storage and Handling Guidelines for Immunization Providers (2015), Section 3.6 – Thermometers and Temperature Monitors

4.4 BOTTLED WATER

Purpose-built vaccine refrigerators are required in New-Brunswick since Sept 2022. Bottled water is generally not necessary in these units as they are specifically designed to maintain consistent temperatures and optimal conditions for vaccine storage.

4.5 INSULATING MATERIALS REQUIRED FOR VACCINE TRANSPORT

1. **Ice packs:**
    - Frozen packs are the primary source of cooling in vaccine transport containers and required to maintain the cold chain during transportation of vaccine out of refrigeration storage. They should be stored in a separate freezer and be completely frozen before use.
2. **Refrigerated packs or water blankets:**
    - Size: Water blankets typically come in sizes 29x29x29 cm
    - Highly effective in maintaining stable cold chain temperatures, acting as a buffer between vaccines and ice packs to prevent freezing. They also insulate vaccines from extreme cold or heat, protecting against temperature fluctuations during transport.
    - Should be kept refrigerated between 2°C and 8°C before use to ensure their effectiveness. They are to be stored separately from vaccines to avoid disrupting vaccine storage conditions.
3. **Filler Materials:**
    - Used to prevent shifting and cushioning within the vaccine transport container. While these materials do not offer the same temperature control benefits as more specialized insulating materials like water blankets or ice

packs. These materials are added after the primary cold chain materials have been packed.

- Acceptable materials include brown crumpled packing paper, bubble wrap and Styrofoam peanuts.

Refer to the section 8 of this document for guidelines on preparing vaccine carriers for transport.

4.6 COOLERS FOR VACCINE TRANSPORT

It is essential to use these medically appropriate containers, particularly when transporting vaccines outside the office or facility, such as for homebound patients. While both hard-sided and soft-sided coolers can be used, **hard-sided coolers** are considered best practice for protecting vaccines from temperature fluctuations and light exposure.

To ensure proper temperature control, each location must utilize coolers that are specifically designated for vaccine transportation, also known as vaccine carriers. These carriers should have:

- **Solid walls** with a secure lid
- **Insulating thickness:** A thickness of at least 30 mm to 80 mm to maintain temperature stability between 2°C and 8°C.
- **Styrofoam Coolers:** Newer Styrofoam coolers with at least two inches thick walls are acceptable. Recreational Styrofoam coolers with thin walls, such as those to hold food and beverages are **not suitable** for use as vaccine transport containers.

Providers can acquire qualified vaccine transport coolers from these suggested suppliers:

- **Hard sided coolers:**

  Cryopak Industries
  Contact : Venessa Marsala

Email: vmarsala@cryopak.com
Product Codes: FEPS00709, FEPS00816

- **Soft sided coolers:**

  Marsys Inc
  Contact: Jason Netherton

Refer to **section 8** of this document for guidelines on preparing vaccine carriers for transport.

5.0 MAINTENANCE OF VACCINE EQUIPMENT

Facilities must develop, implement, and properly maintain vaccine equipment. They must also keep an equipment logbook and keep it according to their organizations' requirements for maintaining documents. Samples of a “Refrigerator and Thermometer Maintenance and Monthly Vaccine Inventory” can be found in ***Appendix H*** of the National Vaccine Storage and Handling Guidelines for Immunization Providers 2015.

Additionally, facilities must designate a person responsible for regular maintenance checks to extend the useful life of all appliances. This individual should also be proficient in troubleshooting equipment failures and ensuring continuous operational coverage. General guidelines are provided in this policy.

5.1 REFRIGERATOR MAINTENANCE

Given the variability in refrigerator technology, it is impossible to provide a one-size-fits-all approach for managing vaccines across all units. Therefore, it is essential for vaccine management staff to be

thoroughly familiar with the specific refrigerator they are using, check manufacturer specifications and in general monitor the following:

Daily Checks:

- Check and log the refrigerator temperature twice daily using the NBIPG Temperature Log Template. Always reset the min-max thermometer after recording the readings.
- No food, drink or patient medications should be kept in the vaccine fridge.
- Regular checks also provide the opportunity to inspect the unit for any misplaced, expired or unlabeled opened multi-dose vaccines.

Quarterly Checks (every 3 months):

- Arrange to have the fridge serviced regularly according to the facility's requirements. In New Brunswick private vendors known to provide refrigeration services can be contacted to provide maintenance for vaccine fridges The following are the quarterly check recommendations:
- Clean the refrigerator thoroughly.
- Check the door seals to ensure they are intact, and the door closes properly.
- Clean the coils, filter and motor.

For more information, refer to your refrigerator manufacturer's website and Section 3.5: Refrigerator and Freezer Maintenance of the National Vaccine Storage and Handling Guidelines for Immunization Providers (2015).

5.2 THERMOMETER DEVICE MAINTENANCE

In addition to daily temperature readings, thermometer devices require regular maintenance. Check the manufacturer specifications and in general monitor the following:

Bi-annual Checks (every 6 months with the start/end of daylight savings time):

- Ensure the temperature calibration continues to be accurate within at least ± 1.0ºC. This will also depend on the type of device you have at your facility and contact the manufacturer for instruction or suggested calibration timelines.
- Change batteries and always keep an extra set of batteries on hand as needed.
- Cables or probes are not damaged.
- There is an adequate supply of blank temperature monitoring log and ink pens for recording.
- If your moving vaccines outside your facility for community use, check your minimum-maximum thermometers (preferred temperature devices).

Refer to Section 3.7: Thermometer maintenance of the National Vaccine Storage and Handling Guidelines for Immunization Providers (2015).

5.3 POWER SUPPLY

Regular maintenance and testing of backup power equipment are crucial for maintaining vaccine efficacy during power outages.

- Conduct quarterly tests and annual servicing of the generator.
- Test backup battery power sources every three months and service them yearly.
- Follow the manufacturer's guidelines for proper testing procedures.

For guidelines on handling vaccines during power outages, refer to **section 10** of this policy.

5.4 INSULATING MATERIAL

Water blankets, gel packs and bubble wrap must be replaced every 2 years or as needed due to material break down and decreased effectiveness of ability to maintain adequate temperatures.

6.0 VACCINE INVENTORY

Vaccine inventory management is key for maintaining a reliable supply of vaccines while minimizing wastage. The Department of Health Public Health Branch procures and provides publicly funded vaccines for the New Brunswick Immunization Program. This program includes routine immunizations for infants, children, and adults, targeted programs for high-risk individuals, and communicable disease follow-up.

To ensure a steady supply of vaccines, Public Health maintains multiple contracts. Most vaccines are purchased through a joint federal/provincial/territorial partnership, while some are acquired directly by Public Health or through the Health Canada Special Access Program (SAP).

This section outlines the procedures for forecasting, ordering, receiving, reporting and properly disposing of vaccines.

6.1 FORECASTING VACCINE STOCK LEVELS

To ensure a consistent and efficient supply of vaccines in the immunization clinic or practice, maintaining optimal inventory levels using the **Kanban method** to avoid overstocking or shortages. Consider the unit of issue and the storage space requirements, i.e., multidose vials or pre-filled syringes.

1. **Establish Monthly Inventory Levels**

    a. **Determine the Monthly Usage**: Calculate the monthly usage for each vaccine product. For example:
        - Multiply the monthly stock usage by 110%.
            - Example: If 100 doses of MMRV vaccine are administered monthly, maintain 110 doses in stock.
    b. **Frequency:** Place orders twice a month to replenish stock to the predetermined monthly inventory levels.

c. **Supply Limits:** Maintain no more than a one-month supply of vaccines in the clinic or practice refrigerators at any given time.
d. **Peak Period Anticipation**: Anticipate peak periods for specific product use (e.g., school entry or Influenza season) and adjust orders accordingly.
e. **Inventory and Expiry Date Monitoring**: Implement a system, such as inventory management software (e.g., Excel) to regularly monitor vaccine inventory and expiration dates.

6.2 ORDERING PROCESS

a. **For Routine Vaccines (other than COVID-19, Influenza and Pneumococcal Vaccines):** Utilize the Public Health Information Solutions (PHIS) for those with access to PHIS or the NBIPG Publicly Funded Vaccines and Biologics Ordering Form ensuring all sections of the form are filled out.

b. **To Order COVID-19, Influenza and Pneumococcal Vaccines**: Refer to the New Brunswick Respiratory Season Vaccine Guide, section 2: *How to Order Your Vaccines*.

c. **High Risk Individual Orders:** Order vaccines for high-risk individuals and communicable disease follow-up on an as-needed basis only.

d. **Ordering in Excess:** Justification is required for ordering beyond the recommended levels, either in the comments section of the order form or in an email to the Vaccine Operation Centre.

e. **Telephone Orders:** Will only be considered in urgent circumstances and must be finalized with a completed order form from the site before any vaccine distribution.

f. **Pharmacies Orders:** should refer to VOC guidelines for placing orders through the DIS SharePoint.

6.3 REPORTING ADMINISTERED VACCINES

Accurately record inventory levels for all publicly funded vaccines and be prepared to report these when requested.

a. **Monthly Inventory Completion:** Those using the Public Health Information Solution (PHIS) or the Drug Information System (DIS), must complete monthly inventory.
b. **To Report COVID-19, Influenza and Pneumococcal Vaccine Inventory:** Refer to the section on "*How to Report Your Vaccine Wastage and Inventory*" in the New Brunswick Respiratory Season Vaccine Guide.

6.4 PROCEDURES FOR RECEIVING AND INSPECTING VACCINES

Vaccine distribution in New Brunswick involves coordination between various facilities to ensure the integrity and timely delivery of vaccines. Key distribution centers include:

a. Central Serum Depot (CSD)
b. Sub Depots (Refer to the NBIPG - List of Sub Depots)
c. Private vendors such as McKesson or Matrix

Most facilities in New Brunswick will only be receiving vaccines from the first two distributers.

Once the products have been received:

1. **Inspect and verify the shipment:**

Ensure all personnel accepting vaccine deliveries are fully aware of the procedures for receiving vaccine products:

- **Verify:** that the cold chain has been maintained during transit by checking temperature monitors and indicators.
- **Confirm:** the received product packing slip matches the

original order placed, including quantities, types, and expiration dates.
- **Inspect**: the shipping package, vaccines and diluents for evidence of physical damage.
- **Log:** satisfactory products into inventory for use. PHIS users receive in PHIS.
- **Refrigerate:** the products immediately upon receipt.

2. **Report any discrepancies:**

Notify the sub-depot, CSD, or VOC immediately about discrepancies, such as:

- Incorrect quantities or lot numbers, expired products, or compromised cold chain.
- At the time of vaccine administration, the immunizer examines the product to ensure its integrity. The appearance should match the manufacturer's description in the product monograph. Follow the manufacturer's recommendations for preparing the product for use.
- If the product is not as described by the manufacturer or is faulty:
    - **Involve**: the immunization coordinator to verify the problem.
    - **Label**: the vaccine as "DO NOT USE" and quarantine it, maintaining the cold chain (2° C to 8° C or as noted in the product monograph) until it is determined whether the product can be used.
    - **Notify**: the CSD, which will provide guidance and next steps.
    - **Complete**: the NBIPG Vaccine Supply Problem Report form and return it to the CSD as directed.

3. **Return shipping containers:**

Return all shipping containers to the CSD (unless otherwise instructed):

- Ensuring to include the ice packs, gel packs and the water blankets.

- **Do not write on, remove, or tape over the labels on the shipping containers. Add yellow "Empty" sticker.**
- Use the preprinted waybills provided by Canada Post and place them outside the coolers before shipping.

6.5 DISPOSAL OF UNUSABLE OR EXPIRED VACCINES

Outdated vaccines or vaccines exposed to a temperature excursion (refer to Section 9 of this document) and deemed unusable must be returned to the CSD or as directed, either directly or through the local sub-depot. **These vaccines do not need to be kept in the cold chain.**

Vaccines that have not expired will not be accepted back by the local sub depot or CSD for re-distribution. Direction for re-distribution may be considered in the event of vaccine supply shortages and will be provided by CSD or the VOC. This will only be considered if the immunizer can provide documentation confirming the vaccine was always maintained in cold chain conditions.

For further direction, contact CSD or the VOC.

7.0 VACCINE STORAGE

Proper storage conditions are critical to maintaining the potency and effectiveness of vaccines from the moment they arrive at your facility until administration. Always refer to the manufacturer's storage and stability guidelines in the product monograph to ensure proper storage temperatures are observed. Special attention should be given to COVID-19 vaccines, as they may have different storage requirements that must be strictly followed to maintain efficacy.

This section provides storage practice guidelines on organizing vaccine products within your refrigerators to prevent spoilage and vaccine wastage:

1. **Vaccine Protection**

- **Original Packaging:** Keep vaccines in their original boxes until ready for use to protect them from light exposure.
- **Light Protection:** Protect vaccines from sunlight and fluorescent light as needed. Always check the product monograph for specific information regarding light exposure.
- **Refrigerator Access:** Minimize opening and closing the refrigerator door, and always ensure that it is closed tightly after use.
- **Refrigerator Power:** The refrigerator is plugged in the appropriate electrical outlet in the event of a power failure.

2. **Organization and Airflow**

- **Adequate Air Circulation**: Place vaccines with a 2–3 cm gap between the boxes and the refrigerator walls or shelves to prevent temperature compromise and ensure proper airflow.
- **Breathable Storage**: Organize vaccines in bins or baskets with breathable plastic slotted sides.
- **Grouping and Labelling**:
    - Similar vaccines are grouped together.
    - Ensure all bins or baskets are properly labelled.
    - Place a product location map on the outside of the refrigerator to facilitate quick access and minimize door openings.
    - Clearly mark vaccines that have been quarantined or have limited use.
    - Store vaccines on internal shelves, not on door shelves.

3. **Visibility and Rotation:**

- Ensure all opened multi-dose vaccines are labeled with the expiry date and time and stored in appropriately labeled containers with their original boxes.
- Ensure expiry dates are visible (whenever possible).
- Rotate vaccine stock so that vaccines closer to their expiration date will be used first.

4. **Inventory Monitoring and Management:**

- Regularly monitor vaccine inventory expiry dates, including diluents, in accordance with this policy.
- Remove expired vaccines from the refrigerator and return them as directed by this policy.
- A designated individual is responsible for daily refrigerator checks, conducting regular service checks, maintaining the daily temperature log, and being aware of alternative solutions for emergencies such as power outages or equipment failure.

For more information, refer to the Canadian Immunization Guide: Storage and handling of immunizing agents . Additionally, check your facilities storage and handling safety procedures by consulting ***Appendix L*** of the National Vaccine Storage and Handling Guidelines for Immunization Providers (2015).

8.0 VACCINE TRANSPORTATION

Vaccines will be transported in accordance with this policy. Each facility will have a designated vaccine transportation plan outlining procedures for loading, unloading, and securing vaccine vials and syringes during transit.

Vaccination supplies, including syringes and needles, should also be transported in a manner that ensures their integrity and sterility.

Always refer to the manufacturer's storage and stability guidelines in the product monograph to ensure proper transportation temperatures and observe the deadlines for temperature stability. Special attention should be given to COVID-19 vaccines, as they may have different storage and transportation requirements that must be strictly followed to maintain efficacy.

8.1 TRANSPORTING VIALS

Vaccine temperatures, storage, and handling guidelines have indeed evolved over the years, particularly in response to the introduction of COVID-19 vaccines. For COVID-19 vaccines like Pfizer-BioNTech and Moderna, guidelines have been adjusted to allow for thawed vials to be transported at 2°C to 8°C. It is important to note that after dilution, these vaccines must be used within the specified time frames to ensure they remain effective.

Only undiluted (properly thawed) vials shall be transported, in their appropriate vaccine carriers, along with the necessary equipment and supplies brought on-site for reconstitution as needed. This practice ensures the integrity and stability of the vaccines during transport and minimizes the risk of contamination and errors.

Ensure appropriate coolers, ice packs, and insulating materials are used to maintain the required temperature conditions as outlined in this policy.

8.2 TRANSPORTING PRE-FILLED SYRINGES

Pre-filled syringes are not permitted for transport *unless* they are shipped directly from the manufacturer in pre-filled syringes designed specifically for this purpose. Vaccines reconstituted by the immunizer rather than the manufacturer, are not permitted to be transported outside a facility.

It is essential that the manufacturer's pre-filled syringes remain in their original packaging during transport and transported correctly according to the guidelines in this policy. In office or community settings, vaccines should only be withdrawn from vials immediately before administration.

For more information refer to the section called "Pre-loading vaccine in syringes" in the Canadian Immunization Guide Part 1: Vaccine Administration Practices.

8.3 PREPARING YOUR VACCINES FOR TRANSPORT

When packing vaccines for transportation, each office, facility, or location must have a process in place and ensure the following principles are met:

1. **Prior to Transport:**

    - **Quantity:** Only transport and prepare the amount of vaccine needed.

    - **Temperature Monitoring Device:** Each cooler/carrier must be equipped with a temperature monitoring device. Immunizers should be familiar with the operation of the specific device being used. Utilize a digital thermometer that displays minimum and maximum (min/max) temperatures such as the example below:

        - Ensure that the alarm is set between 2°C and 8°C.
        - Know how to clear the min/max settings after recording and reset the thermometer.
        - If the min-max unit has an alarm, switch it to the “ON” position.
        - Keep extra batteries on hand. If the display becomes dim, change the battery before further thermometer use.
        - Place the glycol end/temperature probe in an empty vaccine box during transport.

2. **Condition your Cooler:**

    - Allow vaccine carriers to cool for at least **30 minutes** with ice packs and water blankets placed inside before inserting the vaccines.

3. **Packing the Cooler:**

    - **Ice Pack Base**: Cover the bottom of the cooler with an ice pack. These should be completely frozen before use to maintain the required temperature.
    - **Refrigerated Layer**: Place a water blanket between 2°C and 8°C on top of the ice pack.
    - **Filler Materials**: Use bubble wrap or crumpled brown packing paper as an insulating layer above the water blanket.
    - **Thermometer Placement:** Place the thermometer in the middle of the bubble wrap, with the end of the probe in an empty vaccine box.
    - **Reverse the Packing Layers:**
        - Place another layer of filler material.
        - Add a water blanket.
        - Place an ice pack on top.

4. **Add the Vaccines**

Once the cooler has been conditioned (after 30 min) and is at the desired temperature (2°C to 8°C):

- Remove the top ice pack, refrigerated layer and filler material.
- Add the vaccines in their original packaging upright in the middle; put the thermometer beside them.
- Wrap the filler material over the vaccines. Ensure to fill any spaces between vaccine boxes with filler to prevent shifting of contents.
- Add the refrigerated layer over the filler material.

- Place the ice pack back on top.
- Close the lid and allow the cooler to sit for a few minutes to stabilize before transport.

5. **Include a Temperature Log Template - Record min/max temperatures:**
    - After initially packing the cooler.
    - At the start of transport.
    - When you arrive at the clinic site **and every 30 minutes thereafter.**
    - At the end of the clinic.
    - Prior to returning the vaccines into the refrigerator.
6. **Vaccine supplies:**
    - Bring enough administration supplies, such as diluent (if needed), various sized needles, syringes, gauze and alcohol swabs for the number of expected recipients.
    - It is recommended to bring an extra cooler with additional water blankets and ice packs monitored between 2-8 degrees, especially during warmer temperatures.
7. **During Transport:**
    - Do not place vaccines in the trunk or leave them in an unattended vehicle.
    - Protect transport containers from direct sunlight, fluorescent light and vehicle air vents.
    - Secure storage containers during transport to minimize vials from drops, shocks, and vibrations such as in the passenger seat.
    - Do not leave your vaccine cooler unattended in a vehicle.

8. **At the Clinic Site:**
    - Monitor digital readings during the clinic.
    - If the min/max temperature falls outside the 2-8°C range, check the position of the glycol/probe, replace or add ice packs to maintain the temperature, or share a vaccine cooler with another nurse if unable to stabilize temperatures. If the temperature does not stabilize immediately, treat this as a temperature excursion and follow the appropriate guidelines outlined in this policy.
9. **Post transport:**
    - Return any unused, unopened vials to their original refrigerator location ***ONLY*** if the cold chain temperatures have been properly maintained and logged.
    - Return ice packs to the freezer water blanket or gel packs to the refrigerator.
    - Return the min-max thermometer and glycol to their appropriate storage location.

9.0 TEMPERATURE EXCURSION GUIDELINES

Vaccines are sensitive products that can lose their effectiveness when exposed to suboptimal temperatures or light conditions, known as excursions. The impact of an excursion on a vaccine depends on various factors, including the type of vaccine, the duration of exposure, and the extent to which storage conditions deviate from recommendations (e.g., being outside the recommended temperature range or exposed to sunlight or fluorescent light).

In the event of a potential storage breach, follow these guidelines:

1. **Involve the Vaccine Coordinator:** Notify the vaccine coordinator or their backup immediately.

2. **Assess and Protect the Vaccines**: Evaluate the risk to the vaccines if the current storage temperatures are too high, too low, or if they are exposed to light. Take immediate action to protect the product, which may involve relocating the vaccines to an alternative storage facility or placing them in temporary carriers.

   Refer to the "Vaccine Transportation" section of this document for further guidance on appropriate handling.

3. **Quarantine Compromised Vaccines**: Identify and label compromised vaccines as "DO NOT USE" and quarantine them. Maintain ideal storage conditions (2°C to 8°C) or as specified in the product monograph during the investigation. PHIS users: Do not receive in PHIS. Complete an ***"Adverse Storage Condition***" located directly in PHIS.

4. **Determine Excursion Details:**
   - **Nature:** Identify whether the excursion involved excessive heat, freezing, or light exposure.
   - **Duration**: Determine how long the vaccines were exposed to suboptimal conditions.
   - **Degree:** Ascertain the minimum or maximum temperatures the vaccines were exposed to.

5. **Troubleshoot Equipment:** Check the thermometer monitoring device and refrigerator. Refer to the manufacturer's manual if equipment malfunction is suspected.

6. **Consult Product Monographs:** Refer to the product monograph for stability information. If the monograph lacks guidance, contact the product manufacturer to determine if it can still be used.

7. **Label Usable Vaccines:** If vaccines are deemed usable, label them with the date of the excursion and use them before vaccines that were not exposed to excursions.
8. **Document/Complete a Loss Summary Report:** Fill out the NBIPG Vaccine and Biologics Loss Summary Report form for all excursions, regardless of the outcome, and email or fax it to the Central Serum Depot (CSD) at 506-648-6477.

9. **Return Unusable Vaccines:** Return unusable vaccines to the CSD directly or through a local sub-depot along with a copy of the Vaccine and Biologics Loss Summary Report.

10.0 EMERGENCY RESPONSE IN THE EVENT OF A POWER FAILURE

No vaccine storage equipment is entirely fail-safe, and issues may arise due to power outages, equipment malfunctions, or normal wear and tear. Therefore, all sites must have Standard Operating Procedures (SOPs) in place for such emergencies and to establish a partnership with at least one alternative storage facility—even if your facility has a backup generator.

In the event of a power failure, immediately contact the designated individual responsible for managing power outages and vaccine storage. Depending on the nature of the outage, follow the appropriate procedures detailed below.

10.1 SCHEDULED OR TIME-LIMITED POWER OUTAGES

1. **Preparation Before the Power Outage:**
   - **Review Protocols:** Ensure staff review and understand their internal SOPs well before any scheduled power outage.
   - **Verify Contact Information:** Confirm current contact details for your alternative storage facility and key delegated personnel responsible for vaccine storage.
   - **Organize Necessary Supplies:** Prepare insulated containers, ice packs, temperature monitoring devices, and

relevant documentation forms for any anticipated transport.
- **Power Supply:** Ensure the unit is plugged into the correct backup power outlet.
- **Record Baseline Temperature:** Document the refrigerator temperature immediately before the scheduled outage to have a baseline.

2. **During the Power Outage:**
    - **Maintain Vaccine Storage**: Keep vaccines in the non-functioning refrigerator and use ice packs if necessary to maintain the temperature below +8°C.
    - **Limit Access:** Do not open or limit access to the fridge until power is restored or it is determined that the vaccines need to be sent to the re-determined alternative storage facility.
    - **Control Ambient Temperature:** Maintain a low ambient temperature in the office; close window blinds in summer and protect from extreme cold in winter.
    - **Monitor Temperatures:** Record vaccine fridge temperatures (maximum, minimum, and current) **every hour until restored.** Use a continuous data logger in each storage unit to track real-time temperature fluctuations and set up alerts for temperature excursions.
    - **Prepare for Transport if Necessary:** Consider moving vaccines if the temperature drops below 3°C or rises above 7°C to the alternate pre-designated site as soon as possible.
        - If for some reason this is not possible, vaccines should be carefully packed in appropriate insulated vaccine carrier per guidelines in this policy and temporarily stored on the premises.
        - If a temperature excursion occurs, immediately contact the manufacturer with specific detailed information. The manufacturer will provide guidance on whether the vaccine is suitable for use based on the information recorded.

3. **Documentation:**
    - **Temperature Log:** Maintain a temperature log for each hour, recording actions taken as needed. Samples of

"Vaccine Storage Troubleshooting Record" can be found in ***Appendix I*** of the National Vaccine Storage and Handling Guidelines for Immunization Providers 2015.

- **Document Excursion Details:** If a power failure leads to a temperature excursion, document the circumstances including:
  - The exact times of the excursion.
  - Temperature readings.
  - Steps taken to address the situation.
  - Any communication with manufacturers and instructions received with the outcome in a detailed report. For further direction on where to dispose unusable vaccines after a temperature excursion, refer to the guidelines in this policy.
  - Samples of Cold Chain Failure Report Forms can be found in ***Appendix F*** of the National Vaccine Storage and Handling Guidelines for Immunization Providers 2015.

- **Record Power Restoration:** Document the exact time the power was restored and refrigerator temperatures (maximum, minimum, and current).
- **Alternative facility Documentation:** If vaccines are transported to their alternate facility, record the vaccine temperatures immediately before transport. If transport exceeds one hour, log temperatures at hourly intervals. Document the temperature immediately upon arrival and any actions taken to ensure vaccine safety during the transfer.
  - **Ensure Compliance:** Verify that vaccine temperatures are consistently maintained within the required range while stored at the alternate facility. Any deviations should be noted and addressed immediately.

10.2 AFTER POWER RESTORATION

1. **Gradual Reassessment of Vaccines:**
   - **Stabilize Temperatures:** Allow refrigerator temperatures to stabilize before assessing the status of any vaccines. Do not use or discard vaccines until they have been deemed usable

or not.
- **Review Temperature Data Logger Records:** Analyze the data from your temperature monitoring devices to ensure that no additional temperature excursions occurred after the power was restored.
- **Verify Alternative Storage Protocols:** If vaccines were transferred, ensure the alternative storage facility follows similar protocols and communicates any issues promptly.

2. **Return to Regular Monitoring & Reporting:**
   - **Continue Temperature Monitoring:** Monitor and document refrigerator temperatures twice daily for at least 48 hours after power is restored to confirm stability.
   - **Document and report**: Any incidents as per your facilities' policies and procedures.

10.3 EXTENDED POWER OUTAGES OR SEVERE WEATHER EVENTS

In the event of a severe weather that could lead to a widespread power outage, review the following steps to prepare in advance and ensure vaccine integrity:

1. **Before the Storm:**
   - **Monitor Weather Forecasts:** Stay updated on weather alerts and forecasts, particularly if a storm is anticipated to impact your facility.
   - **Prepare for Potential Power Outage:** Follow established procedures outlined in Sections 10.1 and 10.2 for managing scheduled or unscheduled power outages, ensuring temperature monitoring and protection of vaccines.
   - **Check Storage Capacity at Alternative Facilities**: Contact your pre-designated backup storage location to verify they have available space to store your vaccines, particularly during high-demand times like the respiratory illness season, when storage capacity may be limited.

2. **During the Storm:**
    - **Ensure Safe Transportation:** If power is lost and vaccine transport is necessary, reconfirm that the alternative storage facility can accept your vaccines as widespread outages might affect their capacity or ability to maintain proper storage conditions.
    - **If Capacity is Limited:** If the capacity at the alternate facility is restricted or unavailable, implement your on-site emergency protocols for maintaining vaccine integrity until power is restored.

11.0 REFERENCES

1. Canadian Immunization Guide: Storage and handling of immunizing agents: Canadian Immunization Guide

2. CDC Manual, Immunization Section, BCCDC. Accessed on April 20th ,2024 at http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm.

3. CDC Vaccine Storage and Handling Toolkit, January 2023. Accessed on June 1st at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
4. Health Canada Guidelines for environmental control of drugs during storage and transportation (GUI-0069). Accessed on May 24th, 2024, at https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidelines-temperature-control-drug-products-storage-transportation-0069.html

5. Manitoba Health, Cold chain protocol: Packing vaccines for transport. Government of Manitoba. https://www.gov.mb.ca/health/publichealth/cdc/coldchain/protocol7.html

6. National Vaccine Storage and Handling Guidelines for Immunization Providers, 2015 (archived and available for referencing). https://www.canada.ca/en/public-health/services/publications/healthy-living/national-vaccine-storage-handling-guidelines-immunization-providers-2015.html.

7. North Carolina Department of Health and Human Services. (2021). Vaccine storage and handling toolkit. https://immunization.dph.ncdhhs.gov/providers/ncip/pdf/2021_vaccine_storage_and_handling_toolkit.pdf

8. Vaccine Storage and Handling Guide, protect your vaccine – Protect your patients, US Center for Disease Control, October 2011. Accessed June 11th, 2024, at https://www.cdc.gov/vaccines/hcp/admin/storage/index.html.

9. Packing vaccines for transport – Ontario Public health https://www.youtube.com/watch?v=gf0xHqQXuVo

10. Public Health Act, New Brunswick. https://www2.gnb.ca/content/dam/gnb/Departments/ag-pg/PDF/RegulationsReglements/2021/2021-67.pdf

11. Vaccine Storage and Handling Guide, Ontario Ministry of Health and Long-Term Care http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/reference/vaccine%20_storage_handling_guidelines_en.pdf.

12. Vaccine Storage and Handling Guide, protect your vaccine – Protect your patients, US Center for Disease Control, October 2011. https://www.cdc.gov/vaccines/hcp/admin/storage/index.html