Newfoundland and Labrador Immunization Manual	
Section 7	Management of Biological Products

7.1 Biological Products Available from the Department of Health and Community Services

Background

All products for use in the immunization, testing and screening programs of the Department of Health & Community Services are provided free of charge to public health nurses for publicly funded immunization programs. It is essential that the utmost care be taken in the transport, storage and administration of these products, in order to minimize wastage and protect the potency of the vaccine. For many products, once they have been exposed to a cold chain break, they are no longer effective or may cause a gradual loss of potency.

Orders for biological products are placed by the public health nurses to the CDCNs as per RHA protocol. Regional head offices then coordinate these orders and send to the office of the Chief Medical Officer of Health in second last week of each month on or before the 25th of each month by completing the *Requisition for Biological Preparations* (Appendix J). Normally vaccines will be shipped to the regional depots the first week each month. Orders will not be shipped after Wednesday except where there is an urgent need for vaccine. Vaccine is then redistributed to individual district offices and physician's offices by the regional depot.

This section of the Immunization Manual outlines the recommended procedures for ordering, transport and storage of all biological products. Detailed information on vaccine storage and handling is available on the Public Health Agency website and is contained in the document titled: National Vaccine Storage and Handling Guidelines:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0069_temp_control_dproducts_storage_transportation_ltr-doc_e.html

7.2 Policy and Procedure for Vaccine Ordering and Return of Unused Vaccine

Policy

Routine orders are placed by the region monthly, on or before the 25th day each month. Emergency orders may be placed, on the approval of the Medical Officer of Health when necessary.

Procedure

- Complete the Requisition for Biological Preparations or the electronic version of same. (See Appendix J.)
- Review the biological product stock on hand monthly, including that product which is available throughout the RHA.
- Calculate the amount of each product needed, using as close an estimate as possible of district requirements. This information may be gathered from various sources such as birth rate, school lists etc.
- Regions should maintain no more than an estimated two months supply at any time.
- Note expiry dates and rotate stock so that shorter dated products will be used first. **Note**: there are some exceptions when vaccine may be extended past the expiry date, watch for labels.
- Submit the monthly order to the Regional Health and Community Services Office according to regional policy.
- Return any vaccine in stock in the district that is unlikely to be used at least one month before the expiry date with the completed Biological Preparation Return Report. Notify the Communicable Disease Control Nurse and then the Regional Depot will then lead the redistribution of this product
- Return all expired vaccine with completed Biological Preparation Return Report to Provincial Depot, Vaccine Program, Miller Centre, 100 Forest Road, St. John's, NL, A1A 1E5

7.3 Transport and Storage of Biological Products (Maintaining Cold Chain)

Vaccine must be maintained at proper storage temperatures from the time it leaves the manufacturer until it is injected into the recipient, this process is known as the cold chain. This may pose challenges as vaccine moves from the central depot to the regions and outlying communities. To facilitate maintaining the cold chain several recommendations are in place for the varied areas where vaccine may be stored.

General Storage Recommendations

- Store vaccine with soon to be expired vaccine at the front, these are to be used first.
- When using multi-dose vials, staff must write "date first opened" on the vial. Opened multi-dose vials **should be used within 30 days or as directed on the product monograph**. For example 5TU PPD must be used within 30 days of opening if strict aseptic technique is maintained each time the vial is used. The expiry date from time of opening may vary and the instructions on the product monograph of each vaccine should be followed.
- All biological products are subject to deterioration unless stored under carefully controlled temperatures. The range for most products is from **2° to 8° C** above freezing point and well below room temperature. Additional information can be found with the product monograph.
- Biological products, including those that have expired, must be kept in refrigerators with reliable temperature controls. When used in satellite clinics, they should be maintained at **2° to 8° C**.

The following are recommendations to maintain the cold chain:

Transport

- From provincial depot to regional office
- From regional office to public health offices, physician's offices and off site clinics such as schools.

    - Vaccine is packed in insulated/thermal carriers with ice packs and a temperature monitor, if applicable.
    - Vaccine is clearly labeled with **"VACCINE - STORE AT 2° to 8° C".**
    - Vaccines should not be transported in the trunk or rear of the van or car in private vehicles.
    - Only couriers knowledgeable in maintaining proper temperatures 2° - 8° C should be used.
    - Ensure that vaccine is delivered directly to a designated person who will be responsible for maintaining the cold chain.
    - Ensure that the person to receive vaccine is aware of the delivery time.
    - To avoid freezing, **the ice packs should be allowed to remain at room temperature for 3-5** minutes before being placed next to the vaccine. The vaccine should remain in the protective cardboard or a paper bag and bubble wrap to avoid direct contact with the ice pack.

Upon receipt of a shipment the vaccine is immediately

- Transferred to a refrigerator
- The temperature monitors are checked and attached form completed
- If evidence of freezing is present the vaccine must not be used.
- When vaccine is being transported in small amounts off site or is in a clinic without a refrigerator and is in a thermal bag; the recommended time for this type of storage is 4-6 hours.
- The thermal bag must be able to maintain vaccine temperature between 2°C – 8°C during transport and through clinics; the thermal bag should meet the following criteria:
  - It is large enough to store vaccines and ice packs
  - The external surface is durable and robust
  - The insulation thickness is 30mm to 80mm.
  - The lid is tight fitting
  - It has strong handles for carrying
- To avoid freezing, vaccine remains in the protective cardboard or a paper bag and bubble wrap to avoid direct contact with the ice pack.
- Only vaccine is stored in the thermal bag, all other supplies such as syringes, alcohol, etc. should be stored in a separate carrier.
- Keep thermal bag closed when not in use.
- Place thermal bag in the passenger area of the car to avoid extremes of cold or heat in the trunk of a car.

Remember the ice packs should be allowed to remain at room temperature for 3-5 minutes (until they have sweated) before placed with vaccine in the thermal bag or cooler

Use of Temperature Monitors

General Information

Temperature monitors come in two types, one for monitoring less than **2°C** and one for monitoring over **8°C.** The monitor used for longer trips is the electronic monitor and training for use of that product is completed on an individual basis. The other products used for monitoring include:

COLD MARK ® is used to identify exposure to temperatures below 2°C and is used to monitor the possibility of the shipment freezing. **WARM MARK** ® is used to identify exposure to temperatures above 8°C. Both monitors are used for all shipments that take over 2 hours.

Procedure

When these products are used please ensure the following:

- Place monitor in centre of shipment, fasten to a vaccine package.
- Never place monitor directly on the ice pack.
- Check monitor as soon as vaccine is opened.
- Document temperature monitor results on shipping form - date received and condition of monitor.

- Sign shipping form and return to CDCN.

Use of Electronic Temperature Recorders

In regions outside the Avalon Peninsula recording devices (**Temp Tales**) are included in the vaccine shipment. On receipt of vaccine shipment these devices are checked for a cold chain break before the devices are returned to Vaccine Program, Miller Centre, 100 Forest Road, St. Johns, NL for reading via a computer system. If the recorder indicates the vaccine has been outside the correct range the region will be notified not to use that vaccine.

Temp Tales are sometimes used by local Regional Health Authorities for transporting vaccines from the regional depot to the satellite sites. Once received these must be returned to the RHA as per Health Authority policy.

Storage of Vaccines in Refrigerators

- Regular household refrigerators or bar sized refrigerators are not recommended, but may be the only option in satellite or temporary clinics. Full size refrigerators must be used.
- Refrigerators used to store vaccines and other medical supplies should not be used to store other products, such as food or other medical supplies or specimens. Vaccines should be stored in the central part of the refrigerator, with space on all sides to allow good air circulation.
- Do not store vaccines on refrigerator doors, or near the cooling units, as these areas represent the extremes of temperature within the refrigerator.
- Refrigerator doors should be opened only as often as is necessary, and for only as long as is necessary to replace or remove the product.
- Place bottles of water (1 or 2 L soft drink type) on the door, at the top and bottom of the vaccine in the refrigerator. This will help to maintain the temperature at a constant level. See diagram on page 7.3-5.
- Refrigerator plugs (and wall outlets) should be located in an area where they will not be knocked out by accident. Alternatives include wiring the refrigerator cord directly into the outlet, or attaching a protective cage over the outlet and a sign **Do Not Unplug** attached.
- Wall outlets into which a refrigerator is plugged should not be required for other appliances, such as vacuum cleaners or coffee pots. There should be a dedicated refrigerator outlet.
- Refrigerators that may be accessible to others (non public health staff) should be locked when not in use or located in an office that can be locked.
- All refrigerators should be defrosted, when there is an accumulation of more than 1 cm. of ice inside the freezer compartment.
- Interior temperatures should be monitored daily using a refrigerator thermometer. The optimum temperature for most vaccines is between 2◦ and 8◦C.
- All sites where vaccines are stored should have an **emergency plan** in place in the event of a power outage or other such an event with clear defined responsibilities and action.
- Monitor any suspected problems with refrigerators and contact regional offices immediately in the event of mechanical breakdowns.

- Household refrigerators should not be used for storing large amounts of vaccine. Refrigerators used as vaccine depots should be properly monitored for temperature and should have an alarm system installed.
- One person should be responsible for documenting the refrigerator temperature once a day. (See Appendix L).

Diagram of Refrigeration Storage

Freezer

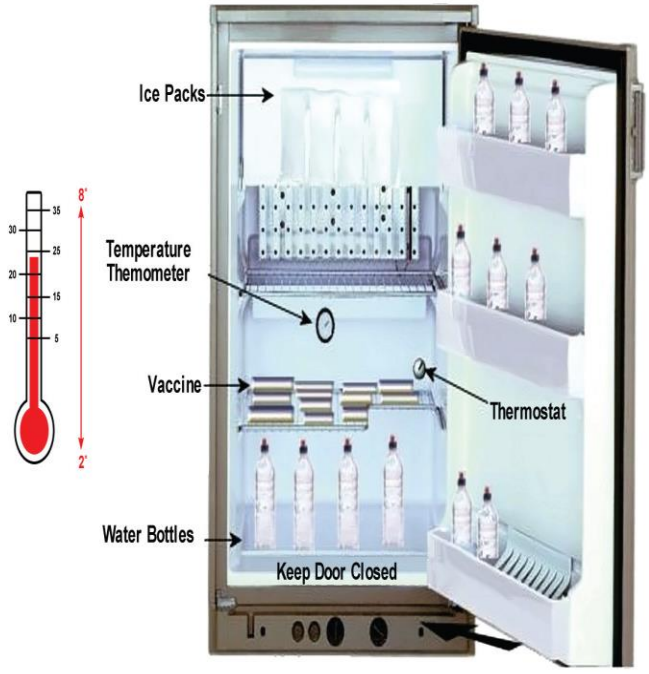
Ice packs

Thermometer

Vaccine

Water Bottles
to stabilize temperature

Keep door closed



See Section 9 Appendix L for Temperature Monitoring Document.

http://www.health.gov.nl.ca/health/publichealth/cdc/Temperature%20Monitoring%20Log.pdf

7.4 Biological Preparations Return/Wastage

Remember: Not all incidents of improper storage will result in spoiled vaccine

Biological products that may have been stored under less than optimum conditions must be immediately placed under ideal storage conditions and mark DO NOT USE. There are several events which may lead to vaccine reaching a temperature that is not optimal. The following are recommendations to follow in such events.

In the event of power failure:

Place vaccine in another monitored fridge. If this is not available then:

- Store vaccine in insulated packaging as you would for transport.
- Notify your supervisor or regional office.

If you find the refrigerator is without power or is not working properly

- Ascertain how long the fridge has been malfunctioning and check vaccine to see if it is cool to touch.
- Record maximum and minimum temperature of refrigerator when discovered.
- Place suspect vaccine in a box or bag and label DO NOT USE and date.
- Place this box or bag with suspect vaccine in another monitored refrigerator or insulated storage.
- Contact Communicable Disease Nurse, MOH or Provincial office (729-3430) for further direction.

If you find vaccine left out on counter or outside refrigerated area

- Place product in a box or bag and label DO NOT USE and date.
- Place suspect vaccine in refrigerator or insulated storage.
- Assess the room temperature as this is necessary to determine vaccine stability.
- Ascertain when the vaccine was last used (when was the last clinic at that site, who was the nurse).
- Contact Communicable Disease Nurse, MOH or Provincial office (729-3430) for further direction.

Return of Unused Vaccine to Provincial Depot

- All vaccines that are unused in the office are returned in original packaging to the main regional office for return to the Provincial Depot, accompanied by a Biological Preparations Return Report (see Appendix K). A copy of the vaccine wastage report should also be forwarded to the Provincial Office. The Regional Office will forward the vaccine and Biological Preparations Return Report to the Provincial office. Vaccines which have been opened or drawn up in a syringe are discarded in the sharps container and a Biological Preparations Return Report completed.

Biological Preparations Return Report

Biological Preparations Return Report is completed for all amounts of vaccine which have been determined to be unusable. See Appendix K. This report is forwarded to the Communicable Disease Control Nurse for your area (region).

Management of vaccine wastage

- District nurses return any unused, expired or spoiled vaccine to the Regional CDCN office with a Biological Preparations Return Report (Appendix K). This would include vaccine to any locations where vaccine has been distributed (i.e. physician's offices).
- The regional CDCN office will return the product and a copy of the Biological Preparations Return Report to the Provincial Depot, Vaccine Program, Miller Centre, 100 Forest Road, St. John's, NL, A1A 1E5. A (Biological Preparations Return Report Appendix K) is to be completed and forwarded to the regional office, with a copy to the provincial office. This would include vaccine to any locations where vaccine has been distributed.