

Be sure vaccines protect. Handle with care!

+ 8°C

+2°C

Cold Chain Protocol Vaccines and Biologics

August 2013



Cold Chain Protocol – Vaccines and Biologics



Communicable Disease Control

Table of Contents

1.	Intro	oduction and the Importance of Cold Chain	3
	1.1	What is Cold Chain?	3
2.	Cold	l Chain Responsibilities	3
	2.1	Identification of Responsibility	3
	2.2	Assigning Duties and Tasks to Personnel	4
	2.3	Contact Lists	4
3.	Man	agement and Accountability	4
	3.1	Accountability of Vaccines and Biologics	4
	3.2	Inventory Management	4
	3.3	Expired or Unusable Products	4
4.	Stor	age Practices for Vaccines and Biologics	5
	4.1	Ordering Vaccines and Biologics from Manitoba Health	5
	4.2	Placement of Vaccines and Biologics in the Refrigerator	5
5.	Cold	l Chain Management Equipment	5
	5.1	Refrigerators for Vaccines and Biologics	6
	5.2	Types of Refrigerators	6
	5.3	Modifications to Improve Domestic Fridge Temperature Stability	6
	5.4	Refrigerator Maintenance	6
	5.5	Temperature Recording Devices	7
	5.6	Thermometer Placement	7
6.	Tem	perature Monitoring	8
	6.1	Temperature Monitoring by Assigned Personnel	8
7.	Pack	ing, Storage and Handling for Off-Site Immunization Clinics	9
	7.1	Basic Principles	9
	7.2	Equipment for Transport to Off-Site Clinics	9
	7.3	Packing for Transport	10
	7.4	Maintaining Cold Chain at an Off-Site Clinic	11

8.	Mar	naging Cold Chain Problems	11
	8.1	What to do When the Temperature is Below +2°C or Above +8°C	12
	8.2	Inventory Management of Cold Chain Failures	13
	8.3	Refrigerator Malfunctions	13
Ap	pend	ices	14
	Арр	endix 1: Instructions for the Refrigerator and Temperature Monitoring Maintenance	15
	Арр	endix 2: Defrosting a Refrigerator/Freezer	17
	App	endix 3: Malfunctioning Refrigerator Trouble Shooting Checklist	18
	App	endix 4: Algorithm to Assess Problems in Temperature Readings	19
	App	endix 5: Cold Chain Failure Response Diagram	20
	Арр	endix 6: Contact Information	21
Re	sourc	e Forms	22
	Resc	ource 1: Magnetic Vaccine Storage Diagram	23
	Resc	ource 2: Refrigerator/Temperature Monitoring Maintenance Log	24
	Resc	ource 3: Temperature Log for Vaccines and Biologics	25
	Resc	ource 4: Storage Trouble Shooting Record	27
	Resc	ource 5: Cold Chain Failure Response Form and Procedures	28
	Resc	ource 6: DO NOT UNPLUG and WARNING Notices	32
	Resc	ource 7: Immunization Input Form for Facilities and Clinics	33
W	orksh	eets	34
	Wor	ksheet 1: Checklist for Storage of Vaccines and Biologics	35
	Wor	ksheet 2: Provider or Personnel Agreement Form	36
	Wor	ksheet 3: Vaccines and Biologics Storage Tasks – Roles and Responsibilities	37
	Wor	ksheet 4: Routine and Emergency Contact List	38

1. Introduction and the Importance of Cold Chain

This protocol has been developed in order to assist Manitoba immunization providers with the storage and handling of vaccines and biologics. It is based on the *National Vaccine Storage and Handling Guideline for Immunization Providers 2007* (PHAC), and is designed to increase immunization provider awareness, understanding and compliance of appropriate storage and handling requirements. Procedures have been established in order to protect the potency and effectiveness of vaccines and biologics.

The Appendices, Resources and Worksheets enclosed at the end of the Protocol are to provide assistance to immunization providers to operationalize the cold chain monitoring of vaccines and biologics.

1.1. What is Cold Chain?

"Cold Chain" refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines and biologics, starting at the manufacturer and ending with the administration to the patient or client.

There are three basic elements needed to ensure that vaccines and biologics are handled properly:

- 1. Well trained staff
- 2. The right equipment
- 3. Standard operating procedures or guidelines

Storage issues can occur as a result of malfunctioning equipment or human error.

Vaccines and biologics are sensitive. Their potency and effectiveness may be negatively impacted if they are exposed to:

- freezing temperatures
- heat
- direct sunlight or fluorescent light

Products that have been improperly stored and/ or handled can permanently lose their potency.

2. Cold Chain Responsibilities

Relevant Reference Materials:

- Worksheet 1: Checklist for Storage of Vaccines and Biologics
- Worksheet 2: Provider or Personnel Agreement Form
- Worksheet 3: Vaccines and Biologics Storage Tasks – Roles and Responsibilities
- Worksheet 4: Routine and Emergency Contact List

People: The Key Ingredient

Proper storage and handling of vaccines and biologics depends on the knowledge and practices of the staff in the health care setting.

2.1. Identification of Responsibility

Each health care setting should designate one (1) staff member as the "Vaccine Coordinator" and another one (1) staff member as "back up".

The Vaccine Coordinator or backup will be responsible for:

- Monitoring cold chain practices.
- Ensuring all vaccines and biologics are handled correctly and procedures are documented (*Worksheet 1: Checklist for Storage of Vaccines and Biologics*, page 35).
- Ensuring that all appropriate staff receive training and annual refresher sessions on cold chain practices.

The training for *all staff members* who may be involved with handling vaccines and biologics should include (*Worksheet 2: Provider or Personnel Agreement Form*, page 36):

- What to do when deliveries of vaccines and biologics arrive
- Correct storage temperatures and handling conditions
- How to read and document temperatures
- Where the temperature records are located
- What to do when there is a cold chain failure, including who to notify and the appropriate documentation

2.2. Assigning Duties and Tasks to Personnel

All tasks related to the cold chain of vaccines and biologics should be assigned to specific staff members. The Vaccine Coordinator and the supervisor/manager should identify a division of responsibilities that works for their specific health care setting (*Worksheet 3: Vaccines and Biologics Storage Tasks – Roles and Responsibilities*, page 37).

2.3. Contact Lists

Every health care setting should have a contact list for routine and emergency storage and handling issues. The list should be reviewed annually and updated when there is a change in staff, resources or suppliers (*Worksheet 4: Routine and Emergency Contact List*, page 38).

3. Management and Accountability

Relevant Reference Materials:

• Resource 7: Immunization Input Form for Facilities and Clinics

3.1. Accountability of Vaccines and Biologics

One of the most important steps in the management of vaccines and biologics is accountability for all the publicly-funded products ordered and received from Manitoba Health.

- Every dose administered should be entered into the Manitoba Immunization Monitoring System (MIMS) to be applied to the patient's immunization record by:
 - Physician billing (doses automatically entered into MIMS monthly), or

- Sending completed MIMS Immunization Input Form for Facilities and Clinics (Resource 7, page 33) or other data entry forms as deemed appropriate to a MIMS Update site for manual data entry (Contact your local public health office to find out where the nearest update site is).
- Mark the date of first withdrawal on Multi-Dose Vials (MDV).

Note: All unused (still in cold chain) and wasted doses must also be accounted for.

3.2. Inventory Management

Designated personnel should be responsible for:

- Monthly physical inventories
- Regular stock rotations to ensure that products with the soonest expiration dates are used first and kept in front of same product with longer expiry dates.
- Using product before it expires.
- Ensuring that no more than one month's supply of stock is on hand to reduce wastage.
- Separating Manitoba Health publiclyfunded product from privately purchased product.
- Referring to the product monographs for how long MDV are viable after first puncture.

3.3. Expired or Unusable Products

Expired product can be removed from the refrigerator and stored in a container marked "Expired – Do Not Use".

Expired or unusable products previously received by Manitoba Health can be returned to the Provincial Vaccine Warehouse for potential cost recovery or destruction. To find out more:

> Contact the Provincial Vaccine Warehouse for return instructions at: (204) 948-1333 Toll-Free: 855-683-3306

4. Storage Practices for Vaccines and Biologics

Relevant Reference Materials:

Resource 1: Magnet Vaccine Storage
 Diagram

4.1. Ordering Vaccines and Biologics from Manitoba Health

Before Ordering Product:

- 1. Develop a trigger system to indicate when inventory is low and re-ordering is required; taking into consideration delivery time.
- 2. Develop and maintain complete stock records.
- 3. Verify on hand stock amounts prior to placing an order (to avoid build up of stock).

Ordering Product:

- 1. Order product based on what the health care setting can utilize in **one** month.
- 2. Ensure that trained staff will be present to receive delivery. Whenever possible, arrange for delivery when the Vaccine Coordinator or back-up will be present.
- Use the most current Vaccines and Biologics Order Form located online at: http://www.gov.mb.ca/health/publichealth/cdc/protocol/vaccinebiologics.pdf
- 4. Indicate in the comments area on the order form if there are any specific time frames or days that are best for the delivery.
- 5. Alert other personnel of order placed to prevent order duplication.

Receiving Orders:

1. The receiver *must* have appropriate training for receiving and storing vaccines and biologics. Untrained staff are to be advised that they must notify the Vaccine Coordinator or back-up *immediately* when a delivery has arrived.

- 2. Ensure that product is promptly placed in the refrigerator
- 3. Follow *all* instructions and review *all* inserts that are included in the deliveries from the Provincial Vaccine Warehouse.

4.2. Placement of Vaccines and Biologics in the Refrigerator

Vaccines and biologics should be stored in a refrigerator that can maintain constant temperatures between +2°C and +8°C and the refrigerator should be in a secure location away from unauthorized personnel and public access.

Place product in the refrigerator by (*Resource 1: Magnetic Vaccine Storage Diagram*, page 23):

- Storing only vaccines and biologics.
- Storing product only on middle shelves with product expiring first in front.
- Grouping products using mesh style or open weave plastic baskets, to allow for adequate air flow, that are clearly labelled with product name and a re-order level.

No Food or Beverages should be Stored in Refrigeration Units Containing Vaccines and Biologics.

5. Cold Chain Management Equipment

Relevant Reference Materials:

- Appendix 1: Instructions for Refrigerator and Temperature Monitoring Maintenance
- Appendix 2: Defrosting a Refrigerator/ Freezer
- Resource 2: Refrigerator/Temperature
 Monitoring Maintenance Log

Safe Storage of Vaccines and Biologics Requires:

- a refrigerator
- a freezer (for ice packs)
- a calibrated thermometer for each refrigerator
- a thermometer or thermostat for ambient temperature monitoring
- "DO NOT UNPLUG" notices and "WARNING" stickers for circuit boxes
- A back up generator, if possible

5.1. Refrigerators for Vaccines and Biologics

Refrigerators must be selected carefully and used properly. They must be:

- able to maintain the required storage temperatures through all seasons;
- large enough to hold the year's highest monthly inventory, including influenza season;
- equipped with a calibrated min/max thermometer or data logger;
- dedicated to storing only vaccines and biologics; and
- in a secure location away from unauthorized personnel and public access.

5.2. Types of Refrigerators

Bar Fridge Units

Any style of small, single door (bar style) fridge is **not recommended** for the storage of vaccines and biologics. This type of fridge is unpredictable and may not maintain temperatures necessary for product stability.

Domestic Refrigerators

Domestic combination refrigerator and freezer units, though not recommended for storage of vaccines and biologics, are acceptable. Domestic refrigerators are designed for food storage and not for storage of vaccines and biologics. **Precautions and fridge modifications are needed** (See *Modifications to Improve Domestic Fridge Temperature Stability*, below).

Purpose Built (Commercial) Vaccine Refrigerators

A purpose built (commercial) vaccine refrigerator (also referred to as pharmacy, lab-style or laboratory grade refrigerator) is the standard for storing large inventories of vaccines and biologics. The advantage is that they are specifically designed to ensure better temperature regulation.

5.3. Modifications to Improve Domestic Fridge Temperature Stability

To ensure stability of the temperature in a domestic-type fridge follow the *Magnetic Vaccine Storage Diagram* (Resource 1, page 23) and:

- Ensure no more than 50 percent (50%) of the internal volume is filled with vaccines and biologics.
- Routinely check the door to ensure that doors are tightly closed.
- Store full bottles of water or gel packs on empty shelves, on the bottom (or in bottom drawers) and in the door to help maintain stable temperature during frequent door opening or in the event of a power failure.
- Keep freezer packs in the freezer compartment.
- Minimize the number of times the door is opened to reduce temperature fluctuations.

5.4. Refrigerator Maintenance

Any refrigerator used to store vaccines and biologics needs to have maintenance cleaning and checks following a maintenance schedule. In the event of a refrigerator malfunction immediate steps should be taken to bring it back to working order. A refrigerator maintenance equipment log should be kept for all refrigerators used for the storage of vaccines and biologics. Details on refrigerator maintenance, servicing and repair can be documented within the log (*Resource 2: Refrigerator/Temperature Monitoring Maintenance Log*, page 24).

Note: For recommendations on appropriate refrigerator maintenance, please see *Appendix 1: Instructions for Refrigerator and Temperature Monitoring and Maintenance* (page 15) and *Appendix 2: Defrosting a Refrigerator/Freezer* (page 17).

5.5. Temperature Recording Devices

The only temperature recording devices recommended for monitoring refrigerator temperatures for vaccines and biologics are:

- Continuous Temperature Monitors (Data Loggers):
 - Stand alone temperature monitors that can record multiple temperatures.
 - Accompanied by computer software that allows for downloading data.
 - Provide an accurate picture of minimum and maximum temperatures and the time spent at each temperature.
- Digital Min/Max Thermometers:
 - Several types are available on the market.
 - Each has slightly different operating instructions.
 - It is important that the installation instruction from the unit manufacturer be followed and monitored.

Fluid-filled biosafe liquid thermometers, bimetal stem thermometers, and household mercury thermometers are NOT recommended for the temperature monitoring of refrigerators containing Vaccines and Biologics.

Room temperature can be taken using a standard household thermometer.

In settings where continuous temperature monitoring devices are not being used, Manitoba Health recommends the use of calibrated *digital min/max thermometers*.

- They show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset.
- It is important to manually reset the min/max thermometer each time the temperatures are recorded.
- A limitation to min/max thermometers is that the readings do not indicate when the exposure occurred and the exact length of time of exposure.

5.6. Thermometer Placement

In the refrigerator compartment, the thermometer should be placed on the middle shelf adjacent to the vaccines and biologics. A thermometer should be placed in the center of the refrigerator compartment away from the coils, walls, door, floor, and fan, and the temperature probe should be placed in the vaccine box.

In the freezer, the thermometer should be placed on a box (or other item) adjacent to the vaccine so that it is in the middle of the compartment, not on the floor of the freezer.

If the thermometer indicates a temperature outside the recommended range, remove the product to an appropriate storage unit and check that the thermometer is appropriately situated.

6. Temperature Monitoring

Relevant Reference Materials:

- Resource 3: Temperature Log for Vaccines and Biologics
- Resource 4: Storage Trouble Shooting Record

6.1. Temperature Monitoring by Assigned Personnel

Regular and accurate temperature monitoring is imperative to ensure that the products have been stored at the manufacturer's recommended storage temperatures. Refrigerators that contain vaccines or biologics must have an appropriate temperature monitoring device.

Required Actions for Daily Temperature Monitoring:

- 1. Take the fridge(s) and room temperature twice daily (including units with continuous temperature monitoring and recording devices), first thing in the morning and again at the end of the business day.
- 2. If staff do not work on the weekends some options to consider are:
 - a. Train any security that is on site, if available, to conduct the temperatures on non-work days.
 - b. Use a continuous temperature monitoring device (data logger) as it can better indicate the time and length of any exposures.
 - c. Have the refrigerator(s) hooked up to a central alarm system that will go off when temperatures are outside of the set temperatures. Designated staff or security would be required to assess the situation if an alarm goes off and know the steps required to protect the vaccines and biologics.

- 3. Document temperatures on a temperature log (*Resource 3: Temperature Log for Vaccines and Biologics*, page 25), including the:
 - Current refrigerator temperature
 - Minimum temperature since last reading
 - Maximum temperature since last reading
 - Room temperature (to establish effect of ambient temperatures on storage)

Note: If a temperature reading is missed, the log entry should remain blank.

4. Take **immediate action** when the temperature in the fridge is outside the recommended range or if there is an equipment or power failure. Actions taken should be recorded (*Resource 4: Storage Trouble Shooting Record*, page 27).

The Vaccine Coordinator or back-up will:

- 1. Review the *Temperature Log for Vaccines and Biologics* weekly to ensure proper storage temperatures are being maintained.
- 2. Review the *Temperature Log for Vaccines and Biologics* and *Vaccine Storage Trouble Shooting Records* monthly to note trends in storage temperatures and potential storage issues.
- 3. Keep the *Temperature Log for Vaccines and Biologics* and *Vaccine Storage Trouble Shooting Records* for a period of **three (3) years** (to monitor historical and seasonal patterns).

To help prevent substantial losses of vaccines and biologics, facilities storing large inventories should install **continuous monitoring temperature alarm systems** with round-theclock notification to appropriate personnel.

7. Packing, Storage and Handling for Off-Site Immunization Clinics

The following packing recommendations for the transport of vaccines and biologics to off-site clinics are based on research conducted by the BC CDC, the guidance provided by the *National Guidelines* (2007), the *BC CDC Cold Chain Guidelines*, and the *CDC Atlanta Cold Chain Guidelines*.

7.1. Basic Principles

- An insulated container should be used and temperature monitored (see page 11, *Required Actions for Temperature Monitoring at Off-site Clinics*) for frequency of temperature monitoring.
- Pack enough refrigerated and/or frozen packs to maintain cold chain (the number of packs is dependent on the container size, ambient temperature, volume of product and length of time transporting).
- During transport in a personal vehicle:
 - Do not place container in trunk
 - Avoid placing container in direct sunlight or in line with heater or air conditioner
- Only pack the quantity of vaccines and biologics that is expected to be used. Only a **brief** period out of the refrigerator can be tolerated.
- Ensure stock rotating principles are in place. Stock that has been transported and returned from clinics should be marked and used first.

7.2. Equipment for Transport to Off-Site Clinics

- Insulated Containers (Coolers)
 - Hard-sided insulated containers (with insulation of 30mm to 80mm thick) or newer Styrofoam coolers with at least two (2) inch thick walls.

- Large enough to store vaccines and biologics, insulating materials, and icepacks during transport.
- Tight-fitting lid and strong handles for carrying and/or wheels.
- Ice Packs
 - Keep enough ice packs frozen.
 - Do not place in direct contact with product as product(s) may freeze; place insulating materials and fillers, if required, between ice packs and product.
- Insulating Materials
 - Flexible insulating blankets, gel packs, shredded paper, cardboard, bubble wrap, or Styrofoam.
 - Flexible insulating blankets or gel packs conditioned to fridge temperatures can be used to wrap around the vaccines and biologics during transport.
- Temperature Monitors
 - The use of a min/max thermometer or data logger is recommended for monitoring temperature inside the cooler during all off site clinics
 - The temperature monitor should be placed next to the products and should not come into contact with the frozen packs.

7.3. Packing for Transport

The contents of the cooler should be packed as shown in the diagram below:



Diagram: Packing a Cooler for Transport to an Off-Site Clinic

Adapted from the North Carolina Vaccine Storage and Handling Guide

Note: Pack the vaccines and biologics in their original packaging between the layers of insulating material and fill spaces with crumpled paper or other filler to help prevent shifting of contents during transport. Do not remove vials from boxes and **do not** draw up vaccines or biologics in advance.

7.4. Maintaining Cold Chain at an Off-Site Clinic

The insulated container (cooler) used for transport and clinics replaces the refrigerator. The cooler should be treated in the same way as the refrigerator (i.e., only open the container when needed and monitor and document temperatures at regular intervals)

Note: There is no standard definition for a "long or mass" immunization clinic. Of coolers studied, when packed following packing guidelines, interior temperatures were acceptable for at least four to six hours under clinic simulations.

Required Actions for Temperature Monitoring at Off-site Clinics:

- Use a min/max thermometer to monitor and record temperatures on a *Temperature Log for Vaccines and Biologics* (See Section 6: *Temperature Monitoring*, page 8):
 - Before leaving the office
 - Upon arrival at off-site clinics
 - Every three (3) hours
 - At the end of the clinic
 - Upon return to the office
- 2. Each immunizer can use a separate small insulated container (cooler) at their workstation for a small quantity of product. Vaccines and biologics should be protected from freezing by placing insulating material between the product and the ice pack(s).
- 3. Keep the balance of the product in the large insulated container (cooler) used for transport.

- 4. Streamline workflow and minimize product exposure to temperatures outside of 2-8°C and mishandling, by designating one staff person to dispatch/re-pack product from the main cooler to workstations and using several small labelled coolers to differentiate products at the work stations.
- 5. Drawing up should only occur at the clinic site and every attempt should be made to minimize exposure to temperatures outside of 2-8°C. If drawing up from a multi-dose vial, the vial is to return to the insulated container as quickly as possible to avoid prolonged exposures outside of 2-8°C.

8. Managing Cold Chain Problems

Relevant Reference Materials:

- Appendix 3: Malfunctioning Refrigerator Trouble Shooting Checklist
- Appendix 4: Algorithm to Assess Problems in Temperature Readings
- Appendix 5: Cold Chain Failure Response Diagram
- Resource 5: Cold Chain Failure Response Form and Procedures
- Resource 6: DO NOT UNPLUG and WARNING Notices

Cold Chain Failures Happen...Regardless of How...Take Action!

8.1. What to do when the temperature is below +2°C or above +8°C

A temperature reading of below +2°C or above +8°C means that the vaccines and biologics have been exposed to temperatures outside of the manufacturer's storage recommendation and may have lost potency. This is referred to as a "cold chain failure."

If a cold chain failure occurs, the Vaccine Coordinator or back-up should be informed as soon as possible.

Required Actions by the Vaccine Coordinator or back-up for a Cold Chain Failure (Appendix 5: *Cold Chain Failure Response Diagram*, page 20):

Action 1	• Conduct a quick assessment of the situation to determine if the issue can immediately be identified (i.e. power disconnected, fridge door ajar or opened too frequently, temperature probe misplacement, etc.)
	• Put affected product into a separate container (ex. paper bag) marked "DO NOT USE."
	• Place product in a functioning and monitored refrigerator or cooler until clear instructions have been received about next steps.
	• The vaccines and biologics may still be viable. Don't assume the vaccines cannot be salvaged.
Action 2	• Begin completing the <i>Cold Chain Failure Response Form</i> according to the <i>Procedures for</i> <i>Completing the Cold Chain Failure Response Procedure and Form</i> (Resource 5, page 28)
	• Begin to rectify any large issues as needed to bring the refrigerator into working order.
Action 3	• Calculate the maximum length of time the stock was possibly exposed to temperatures outside the manufacturer recommended 2°C to 8°C range. If the specific time and temperature details are not available, use the time of the last temperature check as when the refrigerator malfunctioned.
Action 4	• Review the most current product monographs for stability information outside of 2-8°C.
	• If required, contact the manufacturers and provide details on the exposure and request direction regarding viability of the product. Indicate the results on the <i>Cold Chain Failure Response Form</i> .
Action 5	• If deemed useable, clearly identify on the product (e.g. with a sticker) the date of the cold chain failure and the number of hours exposed. Use at the first opportunity.
Action 6	• Fax completed <i>Cold Chain Failure Response Form</i> to Communicable Disease Control, Manitoba Health at (204) 948-2040.
Action 7	• Vaccines deemed NOT useable can be removed from the refrigerator and returned to the Provincial Vaccine Warehouse for potential cost recovery and/or destruction.
	• Consult Manitoba Health prior to ordering replacement product or returning product to the Provincial Vaccine Warehouse.
	• After approval for return is given by Manitoba Health contact the Provincial Vaccine Warehouse for return instructions at (204) 948-1333 or Toll Free: 855-683-3306.

8.2. Inventory Management of Cold Chain Failures

In most circumstances, replacement of stock can occur once the cause of the cold chain failure has been rectified and the *Cold Chain Failure Response Form* has been completed and faxed to Communicable Disease Control, Manitoba Health.

Actions for product exposed to a cold chain failure but deemed useable:

- 1. Clearly mark on the product (e.g. with a sticker) the date of the cold chain failure and the number of hours exposed. Two or more exposures may require special consideration by the manufacturer if the product can still be used.
- 2. Use up product exposed to a cold chain failure *before* using other stock.

Actions when product deemed unusable is inadvertently used:

- Contact the applicable product manufacturer(s) about appropriate actions/next steps and provide them with the following information to help with assessing the situation:
 - name of the product,
 - duration and temperature of exposure,
 - whether multi-dose vials were open at the time of exposure,
 - the number of doses, and
 - the date the dose(s) were administered.
 - any other information requested by the manufacturer.

2. People immunized with a vaccine or biologic with questionable potency may need to be tested for serologic evidence of immunity (presence of protective antibody levels) or be reimmunized. The local Medical Officer of Health within the Regional Health or First Nations Authority can be consulted on these matters.

Note: On occasion, vaccines or biologics may be required for an immediate situation. If the current supply has potentially been compromised by a cold chain failure, special arrangements can be made by contacting the Provincial Vaccine Warehouse at (204) 948-1333 or Toll-Free (855) 683-3306 during regular working hours to obtain a temporary/one week supply of replacement stock.

8.3. Refrigerator Malfunctions

When the refrigerator containing vaccines and biologics is not working it is important to determine if the malfunction can be corrected quickly. Please refer to *Appendix 3: Malfunctioning Refrigerator Trouble Shooting Checklist* (page 18) and *Appendix 4: Algorithm to Assess Problems in Temperature Readings* (page 19) for required actions during a refrigerator malfunction.

Note: If the malfunction cannot be corrected quickly (≤ 3 hours) alternative storage for the stock is required as products cannot remain in a non-functioning refrigerator for an extended period of time.

Appendices

- Appendix 1: Instructions for Refrigerator and Temperature Monitoring Maintenance
- Appendix 2: Defrosting a Refrigerator/Freezer
- Appendix 3: Malfunctioning Refrigerator Trouble Shooting Checklist
- Appendix 4: Algorithm to Assess Problems in Temperature Readings
- Appendix 5: Cold Chain Failure Response Diagram
- Appendix 6: Contact Information

Appendix 1: Instructions for Refrigerator and Temperature Monitoring Maintenance

Weekly/Monthly Maintenance

- 1. Check for Ice Build Up in Freezer
 - If you have a manual defrost freezer, it is quite normal for ice and frost to accumulate inside the compartment.
 - A thin layer of frost does not affect the cooling performance but a thick layer of frost negatively affects the efficiency of the system.
 - When frost has accumulated to a thickness of 1cm or so, the unit requires defrosting.

Quarterly Maintenance

- 1. *Clean Coils and Motor* Dust and dirt build up affects the transfer of heat from the coils and, therefore, the efficiency of the unit.
 - Unplug the unit and use a soft brush, cloth, or vacuum cleaner with an attachment hose to remove any dirt or dust from the surface of the coils.
 - After cleaning, plug in the unit and document that the power is restored and that the temperature has been maintained.
 - Avoid cleaning the coils and motor at the end of a working week. Accidentally damaging the coils will cause a problem that may not be detected until the following working day.
 - This process should only take a few minutes; therefore, it is not necessary to transfer the product to another storage unit as long as the doors remain tightly closed for the duration of the procedure.

- 2. *Clean Inside of Fridge and Freezer* quarterly or as needed.
 - Remove the vaccines and biologics from the compartments and store them in a functioning unit.
 - Unplug the unit or turn off the power and wash all inside surfaces and shelves with warm, slightly soapy water.
 - Dry thoroughly then plug in the unit or turn the thermostat back to an appropriately cold setting.
 - Wait for the unit to stabilize at the proper temperature range monitoring and recording the temperature every half-hour for the next few hours.
 - Restock each compartment with the vaccines and biologics, continuing to monitor and record the temperature every half-hour for the next few hours.
- 3. *Door Seal* check the integrity of the door seals.
 - The door seals should not be torn or brittle and there should be no gaps between the seals and the body of the unit when the doors are closed.
 - The doors should open and close properly and fit squarely against the body of the refrigerator. For this to happen, the hinges must be correctly adjusted.
 - If there are any problems with the door seals, consult a technician as necessary and monitor temperatures carefully.

Annual Maintenance

- 1. *Thermometer Check* Thermometers and other temperatures recorders must be checked annually to ensure:
 - Temperature measurement is accurate via a Slush Test.
 - Batteries are maintained and changed regularly as recommended by the manufacturer, keeping in mind warranty requirements.
 - Cables or probes are not damaged.
- 2. *Centralized Alarm System Check* External monitoring services should be tested occasionally (like a fire drill) to ensure the service is able to function properly in the event of an actual cold chain failure.

Instructions to Conduct a Slush Test

- Fill a polystyrene or plastic cup two-thirds (2/3) with cold water. Place cup in the freezer until a fine layer of ice forms on top and a small section of ice forms within the fluid (about two (2) hours). If ice is present, this ensures the mixture is 0°C.
- 2. Place the temperature probe in the middle of the cup (do not touch the sides)
- 3. Observe the temperature after two (2) minutes. Within that time, the temperature should drop to 0°C.

Most thermometers are calibrated to ±1°C or better. If the temperature reading is more than 1°C above or below 0°C after two (2) minutes, replace the battery and test again. If temperature is still not within range, contact the thermometer manufacturer for instructions on recalibration or replace the thermometer.

Appendix 2: Defrosting a Refrigerator/Freezer

Frost-free freezers do not need to be manually defrosted. They have regular defrosting cycles three or four times a day when the freezer temperature increases and melts the ice automatically.

For freezers in non-frost-free refrigerators:

- 1. Remove all products from both compartments of the unit and place them into alternate storage unit(s) in accordance with written protocols.
- 2. Turn off the power and unplug the unit.
- 3. Remove all frozen packs from the freezer (keep frozen, if possible).
- 4. Keeping the freezer door open, allow all the frost to melt.
- 5. Loose ice can be removed by hand; no sharp tools or sharp instruments should be used to remove the ice.
- A container of warm water (not greater than +50°C) inside the compartment can reduce defrosting time.
- 7. Once the frost has melted completely, clean thoroughly and wipe the unit dry. (This is also a good time to clean the refrigerator compartment).

- 8. Connect the power and ensure that the thermostat is turned to an appropriately cold setting.
- 9. Wait for each compartment of the unit to stabilize at the proper temperature range.
- 10. Monitor and record the temperature every half hour for the next few hours until stable temperatures between +2.0 and +8.0°C have been reached in the refrigerator.
- 11. Vaccines and biologics that require to be stored frozen should be in a freezer that is maintained at -15°C or colder.
- 12. Re-stock each compartment with the product.
- 13. Continue to monitor and record the temperature every half-hour for the next few hours.
- 14. If defrosting is necessary once a month or more frequently, the door may not be sealing properly, the door may have been opened too frequently, or there may be other mechanical problems with the freezer. Consult a technician and monitor temperatures carefully.

Appendix 3: Malfunctioning Refrigerator Trouble Shooting Checklist

The following checklist is designed to assist in identifying and trouble shooting issues related to possible refrigerator malfunctions.

1. Refrigerator is too warm or cold

Check for the following:

- □ Unit is plugged in, turned on, and the control knob has been set properly.
- Door is closing properly or has been opened too frequently within short time period.
- □ Temperature recording device is properly located.
- □ Freezer compartment is free of thick frost (<1 cm).
- □ Good air circulation inside and outside the unit.
- \Box Exposed coils and the motor are free from dust.
- \Box Room temperature is appropriate.

Action: Call a refrigeration technician to assess equipment, if necessary.

2. Refrigerator is too noisy (or is making an unusual noise)

Action: Call a refrigeration technician to assess equipment, if necessary.

3. Refrigerator has stopped working

Check for the following:

- □ Electrical cord is undamaged.
- \Box Unit is plugged in and turned on.
- \Box Wall outlet is operative.

Action: Appropriate personnel to check fuses and circuit breakers. Call a refrigeration technician to assess the equipment, if necessary.

Note: If a simple solution to a cold chain problem is not immediately identified (power disconnected, fridge door ajar, temperature probe misplacement, etc.) move vaccines and biologics to a back-up refrigerator or temporarily store in Styrofoam coolers.

Appendix 4: Algorithm to Assess Problems in Temperature Readings

The following algorithms summarizes actions to be taken if the refrigerator temperature reading is less than $+2^{\circ}$ C or greater than $+8^{\circ}$ C.



Temperature reading is < +2°C

Adapted from the First Nations Inuit Health Branch, Health Canada and CDC Vaccine Storage and Handling Toolkit (2005), Resources Section, National Vaccine Storage and Handling Guidelines for Immunization Providers, Appendices.

Note: If a simple solution to a cold chain problem is not immediately identified (power disconnected, fridge door ajar, temperature probe misplacement, etc.) move vaccines and biologics to a back-up refrigerator or temporarily store in Styrofoam coolers.

Appendix 5: Cold Chain Failure Response Diagram

What to do if the Temperature of the Refrigerator goes outside of 2-8°C.



Appendix 6: Contact Information

- Manitoba Health Communicable Disease Control Website: www.gov.mb.ca/health/publichealth/cdc/ index.html
- Manitoba Health Communicable Disease Control 4th floor – 300 Carlton Street Winnipeg, Manitoba R3B 3M9 Phone: (204) 788–6737 Fax: (204) 948–2040

- Provincial Vaccine Warehouse Phone: (204) 948-1333 Toll Free: (855) 683-3306 (outside Winnipeg) Fax: (204) 942-6212
- Materials Distribution Agency (MDA) Phone: (204) 945-0570 Fax: (204) 942-6212 Email: Informationresources@gov.mb.ca Website: http://www.gov.mb.ca/health/jmc/index.html

Resource Forms

- Resource 1: Magnetic Vaccine Storage Diagram
- Resource 2: Refrigerator/Temperature Monitoring Maintenance Log
- Resource 3: Temperature Log for Vaccines and Biologics
- Resource 4: Storage Trouble Shooting Record
- Resource 5: Cold Chain Failure Response Form and Procedures
- Resource 6: DO NOT UNPLUG and WARNING Notices
- Resource 7: Immunization Input Form for Facilities and Clinics

Resource 1: Magnetic Vaccine Storage Diagram – Sample

Public Health Agence de la santé Agency of Canada publique du Canada

VACCINE REFRIGERATOR



Reference: National Vaccine Storage and Handling Guidelines for Immunization Providers 2007

www.publichealth.gc.ca/storage

Canada

Storage Diagrams can be ordered from the Manitoba Materials Distribution Agency at InformationResources@gov.mb.ca

Resource 2: Refrigerator/Temperature Monitoring Maintenance Log

Year: _

Directions:

- 1. Complete activity monthly, quarterly and annually and document completion by initialling the corresponding space on the chart.
- 2. Vaccine Coordinator should ensure completion and filing of the maintenance log.

Refrigerator Type:										Year R	eceive	d:		
Maintenance		Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	
Monthly			1								1			
Ice build up in freezer has	been checked													
Quarterly														
Clean coils and motor														
Clean inside of fridge and	freezer													
Check integrity of door seals														
Temperature Gauge Type	x, data	logger	:):						Year R	eceive	d:			
Annually														
Calibrate temp gauge														
Ensure batteries are functioning or replace as recommended														
Cables and probes are not	damaged													
Repairs				1				1	1	1				1
Refrigerator repairs	Date	Completed by				What was repaired								
<u>C.1:1</u>	Data	C	1	. 1 1		D		,	T.1					
Calibrate temp gauge	Date	Cor	npiete	ed by		Kes	ults/A	ction	Taken					
Other Repair Activities	Date	Cor	nplete	ed by										

Resource 3: Temperature Log for Vaccines and Biologics

Month_____

Completing the Temperature Log:

Provider ____

- 1. Twice each working day record the time, staff initials, room temperature and place an "X" in the box that corresponds with the current refrigerator temperature where product is stored.
- 2. Check the min/max temperatures on the thermometer and indicate them on the log by writing "min" and "max" in the corresponding temperature box.

If any of the recorded temperatures are in the shaded zones: This represents an unacceptable temperature range and a cold chain failure has occured. **Immediate action is needed!**

ACTION: Contact the person at your site who is responsible for vaccine storage and handling

					Refri	gerat	or 2-8	degre	ees Ce	lsius							
					To Tak	oo Co e Act	ld ion!	Op	Optimal Temperature 2º - 8º Celsius					To Tak	o War ce Acti	m on!	
Day of Month	Time	Staff Initials	Room Temp		-10	00	10	20	30	40	50	60	70	80	90	100	110
1				am													
				pm													
2				am													
				pm													
3				am													
				pm													
4				am													
				pm													
5				am													
				pm													
6				am													
				pm													
7				am													
				pm													
8				am													
				pm													
9				am													
				pm													
10				am													
				pm													
11				am													
				pm													
12				am													
				pm							ļ						
13				am													
				pm													

					To Tak	Too Cold Take Action!		Optimal Temperature 2º - 8º Celsius						elsius	Too Warm Take Action!		
Day of Month	Time	Staff Initials	Room Temp		-10	00	10	2°	30	40	50	60	7º	80	90	10º	110
14				am													
				pm													
15				am													
				pm													
16				am													
				pm													
17				am													
				pm													
18				am													
				pm													
19				am													
				pm													
20				am													
				pm													
21				am													
				pm													
22				am													
				pm													
23				am													
- (pm													
24				am													
				pm													
25				am													
				pm													
26				am													
27				pm													
27				am													
20				pm													
28				am													
20				pm													
29				am													
20				pin													
90				am													
31				pm													
51				am													
		1	1	pm				1			1	1		1			

Resource 4: Storage Trouble Shooting Record

Use this record to keep track of temperature management problems. This information can indicate recurring problems that require intervention.

Date	Time	Fridge Temp	Room Temp	Problem	Actions Taken	Results	Initials

Resource 5: Cold Chain Failure Response Procedures and Form

Manitoba Health Cold Chain Failure Response Procedure and Form

The following document provides instruction on completing the required provincial *Cold Chain Failure Response Form* in the event of a cold chain failure involving vaccines and biologics obtained from Manitoba Health.

When a cold chain failure occurs, all sections of the *Cold Chain Failure Response Form* must be completed and faxed to Communicable Disease Control (CDC), Manitoba Health at: (204) 948-2040.

If you do not have a copy of the form, contact Manitoba Health at (204) 788-6737 to receive a copy by fax or email. The form is also available on the Manitoba Health website at: http://www.gov.mb.ca/health/publichealth/cdc/coldchain.html

Steps for Completing the Cold Chain Failure Response Form:

Section A: Contact Information and Health Care Setting Description

• Enter the date the form was completed and all contact information.

Section B: Description of Exposed Vaccines and Biologics

- Outline all vaccines and biologics that were exposed to the cold chain failure by completing the table.
- Clearly identify any vaccines and biologics that have previously been exposed to a cold chain failure, but were subsequently deemed useable. Communicate this to the manufacturer(s), as this could assist in determining if the products are useable.
- Contact the manufacturer(s) of the vaccines and biologics to explain the details of the cold chain failure and request a recommendation on the stability of the vaccines and biologics.
- All recommendations from the manufacturer(s) should be recorded on the table.
- Whenever possible ask the manufacturer(s) to provide their recommendation in writing.
- Include any written responses from the manufacturer(s) with the completed form.

Section C: Description of Occurrence and Temperatures

- Identify the date, time, current temperature, and the min/max temperatures when the cold chain failure was discovered.
- Identify the date, time, current temperature, and the min/max temperatures when the temperature was last checked and recorded.
- Indicate the estimated time of exposure outside the manufacturer's recommended storage conditions.

**This is the number of hours since the last temperature was checked and the time of discovery.

• Check the appropriate box to indicate the cause of the cold chain failure.

Section D: Temperature Monitoring/Refrigerator Information

- Complete all areas as outlined on the form to describe the temperature monitoring practices that occur at the health care facility and indicate the type of refrigerator or cooler on site.
- If the failure occurred on route to and during off-site clinics, complete the sections with the details of the type of cooler used and the results of the cold chain monitor used.

Section E: Actions Taken Following Recognition of Occurrence

• Provide details on how the situation was rectified and any steps taken to prevent further occurrences.

NOTE: Once the form has been faxed to Manitoba Health, consultation with the Manitoba Health Inventory Management Administrative Officer at (204) 788-6737 is required in order to review the occurrence, determine if products should be returned to the provincial vaccine warehouse or discarded, and for approval to order replacement product.

For additional information on cold chain maintenance of vaccines and biologics, please see the National Vaccine Storage and Handling guidelines at:

- http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php
- http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-08-eng.php

To address any specific questions or concerns, please contact Manitoba Health at (204) 788-6737.

Manitoba Health Cold Chain Failure Response Form

Page 1

Section A: Contact Information and Health Care Setting Description

Date of Report:		
Health Care Setting Name:		RHA:
Report Completed by:	Phone:	Fax:
Alternate Contact:	Phone:	Fax:

Action 1: Take action when vaccines or biologics have been exposed to temperatures < +2°C or >+8°C

Action 2: Separate affected vaccines and biologics in a separate container (paper bag) marked "DO NOT USE" and place in well functioning monitored refrigerator or cooler until clear instructions have been received on what to do with them.

The vaccines and biologics may still be viable. Do not assume that they cannot be salvaged.

Section B: Description of Exposed Vaccines and Biologics

Action 3: Record the list of vaccines and biologics exposed below.

Name of Vaccines and Biologics	Manuf.	Lot Number	Expiry Date	Qty. (in doses)	Previous Exposure (Y/N)	Recommendation from Manufacturer

** Add additional page(s) if needed.

Section C: Description of Occurrence and Temperatures

Action 4: Identify duration of exposure to undesirable storage temperatures and identify why the cold chain failure occurred.

	Date	Time	Current Temp	Min Temp	Max Temp
When Break Discovered					
When Temp. Last Checked					

Duration of Exposure (in estimated hours): ____

Cause of Occurrence:
Equipment Malfunction
Human Error
Other Specify:
Electricity Disconnected
Power Failure

Action 5: Contact specific manufacturer (in Canada) for immediate advice on whether or not the vaccines or biologics can be used. Indicate the manufacturer recommendations on the table in *Section B*. Whenever possible, ask for written responses.

Sanofi Pasteur	Grifols (formerly Talecris)	Novartis	Merck	GlaxoSmithKline	Pfizer
888-621-1146	866-482-5226	800-465-2244	800-567-2594	800-387-7374	800-463-6001

Manitoba He	ealth Cold C	hain Failure Respo	nse Fo	orm	Page 2
Section D: Tem	nperature Moni	toring/Refrigerator Inf	ormatio	n	
Is refrigerator tem If yes, type of the	perature monito rmometer used:	red? □ No □ Yes □ Household mercury t □ Continuous temp dat	hermom a logger	eter □ Min/Max thermometer	
Is temperature rec Frequency of tem	corded? p. monitoring	 No Yes Twice daily on working Daily on working day 	ng days ⁷⁸	□ From time to time □ Other specify:	
Type of fridge:	□ Lab style □ Domestic	□ Bar style □ Other Specify: _		Fridge age in years:	
Cold Chain Failu Type of cold chain	re During Trans n monitor used:	port to and During Off-	Site Clin	ics Type of carrier (cooler):	
□ Chemical temp □ Cold Mark: □ Warm Mark:	perature mark (in Clear □ Pink/0 How many rou are partially or □ 0 □ 1	dicate results): Cloudy nd indicator windows completely pink/red? □ 2 □ 3 (all)	OR	□ Continuous temperature data logge Max. Temp.: Min. Temp.: Duration of Exposure (in estimated h 	r: ours):
Section E: Action	ons Taken Follo	wing Recognition of (Occurren	nce	

Action 6: Vaccines and biologics deemed useable must be clearly identified as having been exposed to a cold chain failure and used first.

Action 7: Consultation with the Manitoba Health, Inventory Management Administrative Officer at (204) 788-6737 is required to discuss the occurrence, to review what products can be returned to the Provincial Vaccine Warehouse or discarded into an appropriate biological waste container, and for approval to order replacement product. If product can be returned contact the Provincial Vaccine Warehouse for return instructions. Phone: (204) 948-1333 or Toll-Free (855) 683-3306.

What actions have been taken to rectify the cause of the cold chain failure and/or any preventative measures that have been put into place?

Supplementary Information _____

Action 8: Fax Completed Form to: Communicable Disease Control Branch, Manitoba Health, Fax: (204)-948-2040.

For more Information: See National Vaccine Storage and Handling Guidelines for Immunization Providers (2007): http://www.phac-aspc.gc.ca/publicat/2007/nvshglp-ldemv/index-eng.php

Resource 6: DO NOT UNPLUG and WARNING Notices



Resource 7: Immunization Input Form for Facilities and Clinics

Manitoba Immunization Monitoring System Immunization Input Form for Facilities and Clinics



Provider Type:		Provider No.:	Facility/Clinic Name:		(Code:	
1	Surname	Given Name	PHIN	MHSC	$\square M$ $\square F$	Birthdate YYYY/MM/DD	
	Vaccine	Tariff Code	Date of Imm. YYYY/ MM / DD	Restriction: \Box Yes Comments:		Initial	
			YYYY/ MM / DD	Restriction: \Box Yes Reason:			
			YYYY / MM / DD	Restriction: \Box Yes Reason:			
			YYYY/ MM / DD	Restriction: \Box Yes Reason:			
2	Surname	Given Name	PHIN	MHSC	\square M \square F	Birthdate YYYY/MM/DD	
	Vaccine	Tariff Code	Date of Imm. YYYY/ MM / DD	Restriction: \Box Yes Comments:	1	Initial	
			YYYY / MM / DD	Restriction: \Box Yes Reason:			
			YYYY/ MM / DD	Restriction: \Box Yes Reason:			
			YYYY/ MM / DD	Restriction: \Box Yes Reason:			
3	Surname	Given Name	PHIN	MHSC	□ M □ F	Birthdate YYYY/MM/DD	
	Vaccine	Tariff Code	Date of Imm. YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel	Initial	
			YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel		
			YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel		
			YYYY/ MM / DD	Restriction: \Box Yes \Box Travel Reason:			
4	Surname	Given Name	PHIN	MHSC	□ M □ F	Birthdate YYYY/MM/DD	
	Vaccine	Tariff Code	Date of Imm. YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel	Initial	
			YYYY / MM / DD	Restriction: \Box Yes Reason:	□ Travel		
			YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel		
			YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel		
5	Surname	Given Name	PHIN	MHSC	□ M □ F	Birthdate YYYY/MM/DD	
	Vaccine	Tariff Code	Date of Imm. YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel	Initial	
			YYYY/ MM / DD	Restriction: \Box Yes Reason:	□ Travel		
			YYYY / MM / DD	Restriction: \Box Yes Reason:	□ Travel		
			YYYY/ MM / DD	Restriction: Ves Reason:	□ Travel		
Provider Name (Print)			Contact Info:		Date: Y	/YY/MM/DD	
MIMS Data Entry (Print Name)			Contact Info:	Contact Info: Date: Y		/YY/MM/DD	

Worksheets

- Worksheet 1: Checklist for Storage of Vaccines and Biologics
- Worksheet 2: Provider or Personnel Agreement Form
- Worksheet 3: Vaccines and Biologics Storage Tasks Roles and Responsibilities
- Worksheet 4: Routine and Emergency Contact List

Worksheet 1: Checklist for Storage of Vaccines and Biologics

Personnel	□ We have one designated person to be "in charge" of vaccines and biologics.		
	□ We have designated a back up person.		
	We train all staff who handle vaccines and biologics about the storage and handling requirements.		
Equipment	□ Our vaccines and biologics fridge is:		
	Purpose built (lab style)		
	□ Domestic (freezer compartment has a separate external door)		
	\Box The fridge temperature is maintained at 2-8 degrees Celsius.		
	\Box When the temperature is out of range we take corrective action.		
	\Box We know who to call if the fridge temperature is out of range.		
	We have DO NOT UNPLUG and Warning notices next to the refrigerator's electrical outlet and at the circuit breakers.		
Temperature	\Box We check the fridge temperature twice daily and document it on a temperature log.		
	□ We store extra bottles of water and gel packs in the unused portions of the fridge (door, crispers).		
	\Box We keep ice packs in the freezer.		
Storage and Handling	□ We only store vaccines and biologics in the refrigerator and not food, beverages or lab specimens.		
	□ When we receive product it is immediately placed in the refrigerator and follow all included delivery instructions.		
	\square We store the vaccines and biologics in the middle shelves of the fridge.		
	\square We never store product in the door or the bottom (drawers) of the fridge.		
	□ There is a sign/magnet on the door showing how the vaccine refrigerator should be organized.		
	□ We check to make sure that the door is properly closed and sealed every time after opening.		
Inventory Management	\Box We check stock expiration date and use those that will expire soonest first.		
	□ We rotate supply (newest stock is placed behind stock with the shortest expiry date).		
	\Box We use an inventory log.		
Protocols/Guidelines	□ We have protocols/guidelines for the storage and handling of vaccines and biologics.		

Worksheet 2 - Provider or Personnel Agreement Form

All staff will sign the provider agreement below.

I have read and understood the Cold Chain Protocol: Vaccines and Biologics and will support clinic/setting practices which protect the stability and efficacy of vaccines and biologics.

Name	Signature	Date	Initial of the Vaccine Coordinator

Worksheet 3: Vaccines and Biologics Storage Tasks – Roles and Responsibilities

(VC)	Ensure that vaccines and biologics storage and handling protocols are up to date, in a binder near or attached to the refrigerator.
(VC)	Keep "Contact Lists" updated.
(VC)	Provide information to new immunization providers regarding storage and handling.
(VC)	Provide information to product handlers about safe storage and handling practices.
(VC)	Ensure rescue and transport supplies (coolers, freezer packs, flashlight, protocols, etc.) are in close vicinity of the fridge.
(VC)	Review the <i>Temperature Log for Vaccines and Biologics</i> weekly to ensure proper temperature recording.
(VC)	Review the <i>Temperature Log for Vaccines and Biologics and Storage Trouble Shooting Records</i> monthly to note trends.
(VC)	Follow up on recommended actions following a cold chain failure.
	Complete Regional cold chain failure reports and report appropriately (if applicable).
	Order vaccines and biologics stock.
	Receive and process the vaccines and biologics deliveries.
	Rotate stock.
	Check and record refrigerator temperature twice daily.
	Submit the Cold Chain Failure Response Form to Manitoba Health, when necessary.
	Complete monthly inventory counts and checks.
	Weekly refrigerator maintenance.
	Quarterly refrigerator maintenance.
	Annual thermometer or data logger maintenance.

Worksheet 4: Routine and Emergency Contact List

Personnel				
Title	Name	Phone	Cell	Pager
Vaccine Coordinator				
Back-Up Person				
Program Coordinator				
After Hours Contact				
Manitoba Health				
Local Public Health Immunization Contact				
Other:				
Other Resources and Su	ppliers (insert all those that are app	licable to setting)		
Manitoba Hydro				
Generator Repair Company				
Refrigerator Repair Company				
Thermometer Manufacturer				
Alarm Company				
Weather Service				
Alternate storage location				
Other:				

Manufacturer contact information is listed on the Cold Chain Failure Response Form

