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Canadian Nursing Coalition for Immunization

National Vaccine Storage and Handling Guidelines for Immunization Providers

Canada

The Public Health Agency of Canada

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National Vaccine Storage and Handling Guidelines for Immunization Providers (2007)

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TABLE OF CONTENTS

Resources Included

Routine Vaccine Storage and Handling Protocol Checklist (Sections 2 and 9)

Contact List for Routine Vaccine Storage and Handling (Section 2)

Urgent Vaccine Storage and Handling Protocols Checklist (Sections 2 and 6)

Contact List for Urgent Vaccine Storage and Handling (Section 2)

Suspected Cold Chain Failure Exposure And Wastage Report (Sections 2 and 6)

Monthly Vaccine Inventory and Refrigerator and Thermometer Maintenance* (Sections 3 and 8)

Vaccine Tally Sheet (Sections 2 and 8)

Temperature Log for Vaccines (Celsius) (Sections 5 and 3)

Checklist for Safe Vaccine Storage and Handling (Section 4)

Algorithm to Assess Problems in Temperature Readings Outside the Recommended Ranges (Section 6)

Vaccine Storage and Handling Guidelines:

INTRODUCTION

Contents

I. BACKGROUND

The Canadian Nursing Coalition for Immunization (CNCI) is a partnership of senior public health nurse administrators/ managers/ epidemiologists from all provinces and territories, as well as representatives from the Department of National Defence (DND), First Nations Inuit Health Branch (FNIHB), Public Health Agency of Canada (PHAC), and vaccine industry. This coalition is specifically interested in enhancing the protection of Canadians from vaccine preventable diseases.

In 2005, CNCI identified a need for a national best practices document on cold chain management at the provider level. Currently only a few jurisdictions have guidelines, and the consistency and completeness of these documents are unknown. National guidelines were last updated more than 10 years ago. Through CNCI, a working group on cold chain management was established in December 2005. Representatives from the following groups participated in the working group: provinces and territories, vaccine industry, DND, Vaccine Supply Working Group, FNIHB, and PHAC.

II. INTRODUCTION

Immunization programs have had a major impact on the health status of the world population, by preventing many cases of infectious disease through immunization. Efficient vaccine storage and handling is a key component of immunization programs. It is a shared responsibility from the time the vaccine is manufactured until it is administered. The majority of vaccine storage and handling mistakes are easily avoidable.

The objectives of these guidelines are to provide recommendations for vaccine storage and handling for healthcare providers. Specific recommendations for vaccine storage and handling procedures may vary among public health offices and immunization programs, therefore, these guidelines are meant to supplement existing policies rather than replace them. If you need clarification on any process, consult your local public health office or immunization program*.

These guidelines were developed based on feasibility, available evidence base, and consistency in practice. An environmental scan was done to collect and review provincial, territorial, national, and international cold chain guidelines and/or policy statements. Standard criteria were developed and used to evaluate the current guidelines.

The content of the guidelines include general recommendations for:

- Routine and urgent storage and handling protocols
- Vaccine storage equipment and maintenance
- Temperature monitoring

- Storage troubleshooting
- Stability guideline resources
- Vaccine management
- Vaccine shipment

A Resource Section with sample templates and checklists has been included with these guidelines. You may use them as they are or revise them to suit your jurisdiction.

III. DISCLAIMER

Reference to trade names and commercial sources or manufacturers are for identification only, and do not imply endorsement by the Public Health Agency of Canada (PHAC). Photographs and resources from organizations and manufacturers found in these guidelines are provided solely as a service to our users and are not endorsements of these organizations by PHAC. The Public Health Agency of Canada is not responsible for the contents of the organizations' Web pages.

We would like to thank the US Centre for Disease Control and Prevention, National Immunization Program, for providing access to use their "Vaccine Storage and Handling Toolkit."

Strengthen Cold Chain Links By:

- Maintaining routine and urgent vaccine storage and handling protocols
- Storing vaccines in a purpose-built vaccine refrigerator
- Knowing your refrigerator
- Performing routine equipment maintenance
- Knowing how to handle inappropriate vaccine storage conditions
- Developing qualified practices in transporting vaccines to off-site clinics and monitoring temperatures at off-site clinics

*Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Vaccine Storage and Handling Guidelines:

SECTION 1 COLD CHAIN

Contents

1.1 THE COLD CHAIN

What is the Cold Chain?

"Cold chain" refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration of the vaccine to the client. The optimum temperature for refrigerated vaccines is between +2˚C and +8˚C. For frozen vaccines the optimum temperature is -15˚C or lower. In addition, protection from light is a necessary condition for some vaccines.

Cold Chain Diagram

Proper storage temperatures must be maintained at every link in the chain.

Importance of Maintaining the Cold Chain

Vaccines are sensitive biological products which may become less effective, or even destroyed, when exposed to temperatures outside the recommended range. Cold-sensitive vaccines experience an immediate loss of potency following freezing. Vaccines exposed to temperatures above the recommended temperature range experience some loss of potency with each episode of exposure. Repetitive exposure to heat episodes results in a cumulative loss of potency that is not reversible. However, information on vaccine degradation is sparse and multipoint stability studies on vaccines are difficult to perform. In addition, information from manufacturers is not always available, so it can be difficult to assess the potency of a mishandled vaccine[1].

Maintaining the potency of vaccines is important for several reasons.

- There is a need to ensure that an effective product is being used. Vaccine failures caused by administration of compromised vaccine may result in the re-emergence or occurrence of vaccine preventable disease.
- Careful management of resources is important. Vaccines are expensive and can be in short supply. Loss of vaccines may result in the cancellation of immunization clinics resulting in lost opportunities to immunize.
- Revaccination of people who have received an ineffective vaccine is professionally uncomfortable and may cause a loss of public confidence in vaccines and/or the health care system.

An estimated 17% to 37% of healthcare providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than too warm[2,3]. One study involving site visits showed that 15% of refrigeration units had temperatures of +1˚C or lower[3].

Temperatures falling outside the recommended range require immediate action to avoid loss of product.

When a cold chain break is identified after a vaccine has been administered, consult your local public health office or immunization program* for advice. The type of vaccine, duration and temperature of the exposure will be taken into account when assessing the situation. Serological testing or revaccination may be suggested[4].

Vaccines are sensitive biological products that may become less effective, or even destroyed, when exposed to temperatures outside the recommended range and/or on exposure to direct sunlight or fluorescent light.

The Effective Cold Chain

Three main elements combine to ensure proper vaccine transport, storage, and handling.

- Trained personnel
- Transport and storage equipment
- Efficient management procedures

Each of these elements will be addressed in subsequent sections.

1.2 THE SHAKE TEST

The "shake test" was one method previously used as an indicator that a liquid vaccine was inappropriately frozen. A positive shake test is the formation of granular particles which show up in the liquid upon shaking the vaccine after the vaccine was frozen and then thawed.

The shake test is not a reliable method of testing vaccine potency because a positive shake test may or may not occur after a liquid vaccine has been frozen.

1.3 REFERENCES

1. Grassby PF. *Safe storage of vaccines: problems and solutions*. Pharm J 1993;251:323–327.

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3. Bell KN, Hogue CJR, Manning C et al. *Risk factors for improper vaccine storage and handling in private provider offices*. Pediatrics 2001;107(6):1–6.

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* Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Vaccine Storage and Handling Guidelines:

SECTION 2 VACCINE STORAGE AND HANDLING PROTOCOLS

Contents

2.1 GENERAL RECOMMENDATIONS

- All health care providers who administer vaccines should evaluate their cold chain procedures to ensure that vaccine storage and handling guidelines are being followed.
- Each immunization clinic should develop detailed written protocols for:
  - **Routine Vaccine Storage and Handling** for day to day operations and
  - **Urgent Vaccine Storage and Handling** in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions.
- All staff members who administer or handle vaccines in any way should be familiar with both protocols.
- The protocols should be updated and placed in an area accessible by all staff that handle vaccines or provide immunizations, preferably near the vaccine storage units.

All immunization clinics should develop detailed written protocols for Routine Vaccine Storage and Handling and for Urgent Vaccine Storage and Handling.

2.2 ROUTINE VACCINE STORAGE AND HANDLING PROTOCOLS

Routine protocols should include all aspects of day to day vaccine management, from ordering vaccines and controlling inventory to handling vaccines and monitoring storage conditions.

Designated Vaccine Coordinators

Each site should designate one staff member to be the primary vaccine coordinator and another staff member as a backup in case the primary coordinator is unavailable. The designated person will be responsible for ensuring that all vaccines are handled correctly, that procedures are documented, and that all personnel receive appropriate cold chain training.

Designated vaccine coordinators should be fully trained in routine and urgent vaccine storage and handling protocols.

The routine protocols should include:

- Up-to-date contact information for:
  - Designated vaccine coordinators who are responsible for routine vaccine storage and handling

  - Provincial, territorial, or local public health office or immunization program*
  - Refrigerator and freezer maintenance and repair company(s)
  - Vaccine storage unit alarm company (if applicable)
  - Sources of packing materials and calibrated thermometers
- Descriptions of the roles and responsibilities of the designated vaccine coordinators and other staff members
- Summaries of the storage requirements for each vaccine and diluent in your inventory
- Protocols for:
  - Vaccine storage unit temperature monitoring
  - Vaccine storage equipment maintenance
  - Placement of vaccine within storage units
  - Responding to vaccine storage and handling problems
  - Vaccine inventory management
  - Packaging, transporting and receiving vaccine shipments
  - Disposal of vaccines and diluents as directed by jurisdictional policy or guidelines
- Samples of the forms used in your immunization program

Use the Routine Vaccine Storage and Handling Protocols Checklist and the Contact List for Routine Vaccine Storage and Handling in the Resources Section to help you organize your plan.

Each site should designate one staff member to be the primary vaccine coordinator and another staff member as a backup in case the primary coordinator is unavailable.

Other Staff

All staff members (including support staff, program manager(s), immunization coordinator(s), public health nurses, physicians, physician office staff, administration staff, janitors, security staff, etc.) should be familiar with the site's policies and procedures for vaccine storage and handling. This especially includes staff members, such as receptionists and mail handlers, who accept vaccine shipments. All policies and procedures should be available in writing and kept near the vaccine storage units for easy reference.

All staff members should be familiar with their site's policies and procedures for vaccine storage and handling

2.3 TRAINING PERSONNEL

All new staff that handle or administer vaccines should be trained in proper vaccine storage and handling practices. All other new staff should be trained to have an understanding of the importance of cold chain maintenance and basic practices so they are aware of their responsibilities to the cold chain. A refresher training session should be held annually for all staff. Staff who monitor and record vaccine storage unit temperatures should **immediately** report inappropriate storage conditions (including exposure to inappropriate temperature or light exposures) to the designated vaccine coordinator.

2.4 URGENT VACCINE STORAGE AND HANDLING PROTOCOLS

Various situations may compromise vaccine storage conditions, for example, equipment failures, power outages, or natural disasters. Ensure that all staff (current and new) has appropriate training so that they understand the urgent vaccine storage and handling protocols and their responsibility in maintaining the cold chain. Also ensure that janitorial staff and security staff are aware of the plan and know the procedures to notify designated personnel about any problems with vaccine storage equipment. Review and update the contact lists in the plan as staffing changes occur. Review and update the entire protocol **annually**.

When immunization providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might affect vaccine storage conditions, urgent procedures should be implemented **in advance of the event**.

The following personnel, equipment, information, and protocols should be in place:

- Emergency staff contact list, in order of contact preference.
- Designated vaccine coordinators, who should
  - Monitor the operation of the vaccine storage equipment and systems.
  - Track inclement weather conditions.
  - Set up and maintain a monitoring and notification system in anticipation of times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm and notification system should be considered, especially for sites with large inventories).
  - Ensure the appropriate handling of the vaccine during a disaster or power outage.
  - Ensure designated staff who will attend to after hours emergencies has 24-hour access to the building and vaccine storage unit(s).
  - Ensure that sufficient fuel and/or battery power is on hand to continuously run a backup generator for at least 72 hours if the facility has one.

When immunization providers have reasonable cause to believe that weather conditions, natural disasters, or other emergencies might affect vaccine storage conditions, urgent procedures should be implemented in advance of the event.

- Vaccine storage unit specifications and records
  - For each vaccine storage unit in your facility, identify the type of unit (e.g. refrigerator, freezer, combination refrigerator and freezer), the brand name, the model number, the serial number, and its location.
- Alternate vaccine storage facility or facilities
  - Establish working agreements with at least one alternate storage facility with a backup generator where vaccine can be appropriately and securely stored and monitored for the interim (e.g. provider offices, hospital or community pharmacies, provincial or territorial depots, local pharmaceutical warehouses or distributors that could offer or meet both refrigeration and freezer requirements).
  - Make advance arrangements with the facility to store your vaccine when weather predictions call for inclement conditions, when your vaccine storage equipment cannot be repaired, or when the power cannot be restored before the vaccine storage unit temperature rises above the recommended range.

Establish at least one alternate storage facility where vaccine can be appropriately stored and monitored. Ideally, this facility would have a backup generator.

- Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility
  - Develop written protocols for transporting vaccine to and from the alternate vaccine storage facility.
  - If the vaccine can be moved to the alternate facility before the vaccine storage temperature goes outside the recommended range, it may be transported in appropriately insulated and packaged containers or coolers within ordinary vehicles inside the passenger compartment.
  - Make advance arrangements for a primary and backup vehicle and a driver, and record the contact information.
  - If the location is far away or if you have a large quantity of vaccine, consider renting a refrigerated truck to transport the vaccine. In this case, joining with other sites to reduce costs may be advantageous.
  - Make advance arrangements with a local refrigeration company and an alternate and record the contact information.

  - Establish how to load the vehicle.
  - Have pre-selected routes to take (and alternate routes if necessary).
  - Determine the estimated time en route.
- Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours
  - These instructions should include the building security and after-hours access procedure, a floor diagram, and the locations of the following:
    - Doors
    - Flashlights
    - Spare batteries
    - Light switches
    - Keys
    - Locks
    - Alarms (including instructions for use)
    - Circuit breakers
    - Packing materials
- Appropriate packing materials to safely transport or temporarily store vaccine may include:
  - Insulated containers
  - Refrigerated packs
  - Frozen packs (may be gel or ice)
  - Dry ice if product must be frozen
  - Insulating barrier materials or materials used as barriers between the vaccine and refrigerated/frozen packs and as filler

(See Section 9—Vaccine Shipments for more details.)

In situations where an alternate vaccine storage facility with a backup generator cannot be identified within a reasonable distance, maintain the appropriate packing materials to temporarily and safely store vaccine at your facility. Record the contact information for sources of these materials.

- Written protocol for vaccine packing
  - Every facility has access to different types of shipping materials and coolers, so each facility should develop its own standard operating procedures (SOP) for packing vaccine based on their experience using the materials and/or guidance provided by their local jurisdictional immunization program*. These instructions should be readily available for staff unfamiliar with vaccine packing procedures.

- Key steps that should be reflected in all SOPs include:
  - Open the refrigerator and/or freezer doors only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to the alternate storage facility.
  - Use properly insulated containers to transport the vaccine. These containers should be qualified (previously tested resulting in a high degree of assurance that a specific process will meet its pre-determined acceptance criteria[1] by the facility using them) to ensure that they are capable of maintaining the vaccine at the correct temperatures. Shipping containers the vaccines arrive in from the manufacturer may be used if they meet your criteria. Alternatively, you may use qualified hard-sided, plastic, insulated containers or styrofoam coolers with at least 2-inch thick walls. Thin-walled recreational-use styrofoam coolers, such as those purchased to hold beverages, are not acceptable.
- Refrigerated vaccines
  - Document the vaccine storage unit temperature at the time the vaccine is removed for transport.
  - Pack the refrigerated vaccines first, using enough refrigerated and/or frozen packs to maintain the cold chain. The number and placement of refrigerated or frozen packs inside the container will depend on container size, outside temperature, and jurisdictional variations. (*See Section 9—Vaccine Shipments for more details.*) Soft-sided ice packs can be placed into plastic bags if puncture or leakage is a concern.
  - Vaccines should be packed in layers using the following materials: refrigerated or frozen packs, insulating barrier (e.g. bubble wrap, crumpled brown packing paper, styrofoam peanuts), vaccine, a temperature monitor, and filler materials (may be the same as those used as insulating barriers) to prevent shifting of the contents during transport. (*See Section 9—Vaccine Shipments for more details.*)
  - Vaccines should never be directly placed next to the ice pack or refrigerated pack. Be sure to place an insulating barrier (e.g. bubble wrap, crumpled brown packing paper, styrofoam peanuts) between the refrigerated or frozen packs and the vaccines to prevent accidental freezing.
  - Use properly placed temperature monitors to assess whether the cold chain has been broken. The temperature monitor should be placed next to the vaccine and should not come in contact with the refrigerated or frozen packs.
  - Record vaccine type(s), brand names, lot numbers, expiry date, quantity, time, and originating facility on a packing slip included inside the container.
  - Attach labels to the outside of the container to clearly identify the contents as valuable and fragile vaccines. Labels should include special instructions to refrigerate immediately upon arrival.
- Frozen vaccines
  - Document the vaccine storage unit temperature at the time the vaccine is removed for transport.
  - Pack the frozen vaccines last, using a separate insulated container.

  - Pack with dry ice immediately before they are to be transported. At least 6 pounds of dry ice should be used in the container to maintain vaccines in their frozen state.
  - Record vaccine type(s), brand names, lot numbers, expiry date, quantity, time, and originating facility on a packing slip included inside the container.
  - Attach labels to outside of the container to clearly identify the contents as valuable and fragile vaccines. Labels should include clear instructions to "keep frozen."
- Written protocol for appropriately storing vaccine at the alternate vaccine storage facility
  - Refrigerator stable vaccines should be stored in the refrigerator at +2˚C to +8˚C. Vaccines which are frozen should be stored at -15˚C or colder.
  - There should be adequate cold air circulation around the vaccines.
  - Each alternate vaccine storage unit should have a functioning calibrated temperature monitor in each compartment.
  - Temperatures inside the storage units and the room temperature should be monitored and recorded at least twice a day at the start and close of business for as long as vaccine is stored in this location.

Temperatures inside the storage units and the room temperature should be monitored and recorded at least twice a day at the start and close of business for as long as vaccine is stored in this location.

Use the Urgent Vaccine Storage and Handling Protocols Checklist and the Contact List for Urgent Vaccine Storage and Handling in the Resources Section.

2.5 EMERGENCY ACTIONS

The following emergency procedures should be implemented **in advance of the event** whenever possible.

- **Suspend immunization activities**. This will allow sufficient time for packing and transporting vaccine.
- **Notify staff at the alternate vaccine storage facility**. Before moving your vaccine, call the alternate storage facility to make them aware of the situation and to ensure that their backup generator is working.
- **Conduct an inventory of the vaccines and record the actions taken**. *Use the Vaccine Tally Sheet in the Resources Section.*
- **Follow established vaccine transport procedures for moving vaccine**.
- **If a cold chain failure occurs or is suspected** *use the Suspected Cold Chain Failure Exposure and Wastage Report in the Resources section.*

Whenever there is a question about integrity of the vaccine, contact your local public health office or immunization program* for advice.

2.6 MASS IMMUNIZATION PLANS (INCLUDING PANDEMIC)

It is important for all jurisdictions to have a mass immunization plan in the event that an outbreak or a pandemic occurs. These should be developed based on jurisdictional needs. It is beyond the scope of this document to outline further information. Also please see your local pandemic plan and/or the appropriate provincial or territorial pandemic plan for further information.

2.7 REFERENCES

1. Bishara RH. *Qualification versus validation and good cold chain management practices*. Pharmaceutical Manufacturing and Packing Sourcer 2005: 102, 104, 106.

* Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Vaccine Storage and Handling Guidelines:

SECTION 3 VACCINE STORAGE EQUIPMENT

Contents

3.1 GENERAL REQUIREMENTS

Vaccine storage units must be selected carefully and used properly. Any refrigerator or freezer used for vaccine storage must

- Be able to maintain required vaccine storage temperatures through all seasons.
- Be large enough to hold the year's highest monthly inventory, including influenza season.
- Have a calibrated thermometer or data logger inside each storage compartment.
- Be dedicated to the storage of vaccines only.
- Be placed in a secure location away from unauthorized and public access.

3.2 BACKUP EQUIPMENT

No piece of vaccine storage equipment is infallible. At some point, equipment failure will occur because of a power failure, breakdown, or normal wear and tear. Vaccine security requires that these failures be anticipated and that backup equipment and backup plans be available. Regular maintenance of all equipment is recommended to maintain optimal functioning.

3.3 ROUTINE EQUIPMENT MAINTENANCE LOGBOOKS

An equipment logbook should contain the following records of each piece of equipment:

- Date of installment
- Equipment instructions and list of routine maintenance tasks
- Dates of any routine tasks performed (e.g. cleaning)
- Dates of repairs or servicing
- The name of the person, company and contact information (operational and after hours) of the company providing service

3.4 REFRIGERATORS AND FREEZERS

Technical Requirements

There are many different types of refrigerator and freezers available. Knowing the functions and components of the refrigerators will help in understanding why certain types of refrigerators and freezers are recommended for vaccine storage. The technical features of refrigerators that can affect the safe storage of vaccines are outlined below[1].

1) Temperature regulation

The **compressor** functions to cool the inside of the refrigerator. The compressor is controlled by either a thermostat or a digital controller, depending on the type of fridge. When the temperature exceeds the set temperature of the thermostat, the compressor turns on and operates to cool the fridge. The point at which the compressor turns on depends on the design of the thermostat and fridge. Therefore, a thermostat that has a large differential between its switch points (on and off) will cause, in turn, long compressor on and off periods. This may produce large temperature fluctuations that are undesirable for the storage of vaccines.

2) Defrost mechanism

The cooling area in the refrigerator is called the evaporator. It consists of cooling coils usually located behind the surface of the wall, at the back of the refrigerator or in the exposed area at the back of the refrigerator. Heat from the warm air inside the fridge transfers to the refrigerant in the coils. As warm air passes over the evaporator, water vapor in the air condenses and freezes on the evaporator. During the process of cooling the refrigerator, an icy build up is created on the evaporator. The ice that forms may reduce the cooling capacity and efficiency of the system. Therefore, refrigerators must have a defrost cycle that allows the ice to melt off the evaporator. Ideally, the temperature remains at the set point (within the range of +2˚C to +8˚C) during the defrost cycle.

3) Spatial temperature differential

Spatial temperature differentials are the differences in temperatures within the fridge. Vaccine storage requires a uniform temperature distribution to prevent placement of vaccines outside the recommended temperature ranges.

4) Effects of changes in ambient temperature

Ambient temperature is the temperature of the environment where the fridge is kept. The aim is to have a refrigerator that can maintain a stable temperature within, even when the surrounding temperatures change.

5) Temperature recovery

Temperature recovery is the ability of the refrigerator to return to its set temperature after being exposed to elevated temperatures (e.g. after opening the door to remove vaccine).

Knowing the functions and components of different storage units will help understand why only certain units are recommended for vaccine storage.

Purpose-Built Refrigerator

A purpose-built vaccine refrigerator (also referred to as a pharmacy, lab-style or laboratory grade refrigerator) is the standard for storing large inventories of vaccines for several reasons. See Figure 1 for a picture of an example of a purpose-built vaccine refrigerator. The advantages of a purpose-built refrigerator, in terms of the technical features, are outlined below[1].

1) Temperature regulation

The temperature regulation mechanism in a purpose-built vaccine refrigerator has a very tight temperature tolerance and a quick reaction time to temperatures outside of the set range. A temperature probe for the temperature control is usually located in the path of the return airflow, thereby measuring the temperature of the warmest air in the refrigerator.

2) Defrost mechanism

Purpose-built vaccine refrigerators have a mechanism to defrost ice from the evaporator without raising the temperature in the unit. There is a small heating element wrapped around the evaporator coils that has the capacity to melt the frost off the evaporator frequently. This feature prevents the lengthy periods of time needed for defrosting in other refrigerator designs. This method of regular defrosting also prevents fluctuations of temperatures within the unit.

3) Spatial temperature differential

The spatial temperatures are tightly controlled in purpose-built vaccine refrigerators. There is constant fan-forced air circulation within the refrigerated compartments. Generally, the temperature does not vary within the storage area from the set point.

4) Effects of changes in ambient temperature

The forced air circulation helps to keep internal temperatures within a range even when the ambient temperature changes.

5) Temperature recovery

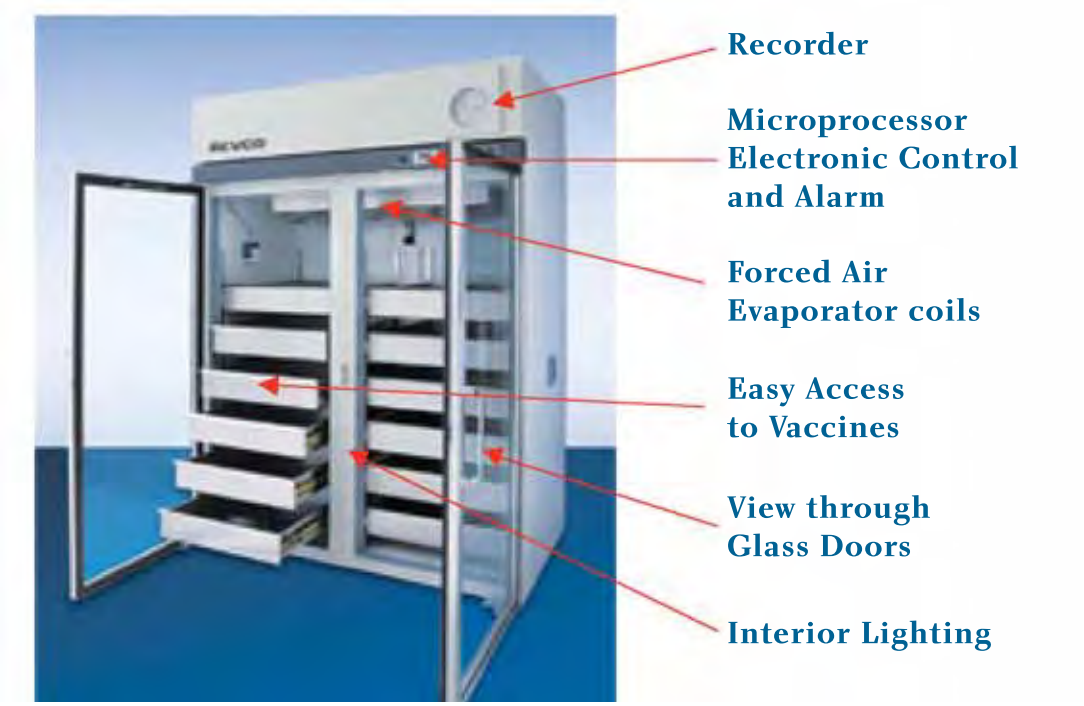
The temperature is digitally managed in purpose-built refrigerators. Any deviation in temperatures from the pre-set one is sensed very rapidly.

Note: As a result of the glass door design of the purpose built refrigerators, extra effort must be taken to protect vaccines from light exposure at all times. It is important to be aware that one limitation of purpose built refrigerators is that glass doors do not provide good insulation in the event of a power interruption, resulting in a rapid rise in temperature.

Advantages of a purpose-built vaccine refrigerator[1]

- A digital feedback system ensures narrow tolerances with internal temperatures, thus providing an excellent temperature regulation system for vaccine storage.
- On going air circulation ensures that the temperature distribution is even.
- A set-point temperature, within a +2˚C to +8˚C range, is kept.
- Evaporator operates at +2˚C, preventing vaccine from freezing.
- Air circulation is fan forced.
- Temperature recovery system is good.
- Built to handle ambient temperature changes.

Figure 1: Purpose-Built Vaccine Refrigerator Features

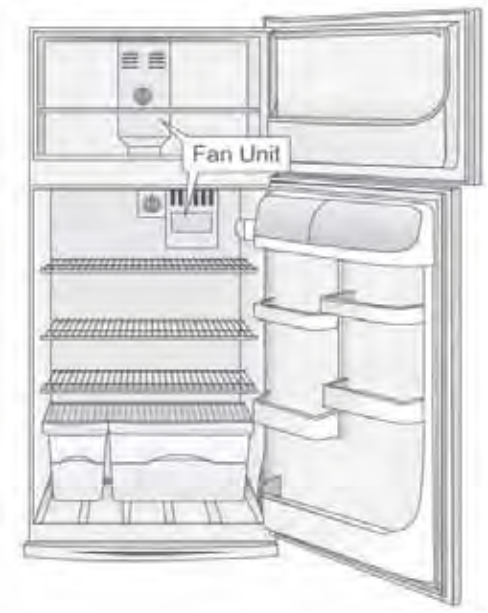


Domestic Frost-Free Versus Manual and Cyclic Defrost Refrigerators

A domestic combination refrigerator and freezer unit is acceptable, but requires significant modifications to store vaccines. The refrigerator and freezer compartments must have separate external doors and the unit must meet the criteria set out in these guidelines. There are two types of domestic refrigerators: domestic frost-free, and manual and cyclic defrost. Figures 2 and 3 illustrate examples of a domestic frost-free refrigerator and a manual and cyclic defrost refrigerator, respectively.

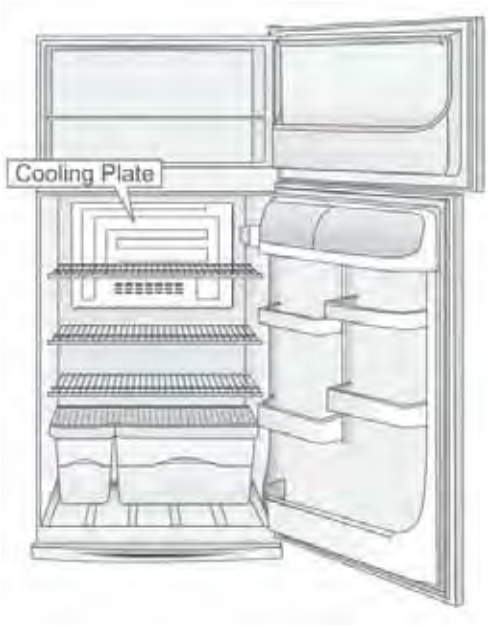
Domestic frost-free refrigerators refer to the freezer compartment where food is supposed to stay relatively frost-free. The evaporator is located in the freezer (usually behind the rear wall). The evaporator defrosts automatically with a heater that dissipates the defrost water. When the compressor is on, a fan blows the cool air through vents to the freezer and then to the refrigerator. Thus, the air being circulated to the refrigerator may be below 0°C. The cool air may damage vaccines if they are placed near the vents. Depending on the refrigerator model, some frost-free refrigerators may provide more uniform temperatures than manual and cyclic defrost models and may be more suitable for vaccine storage.

Figure 2: Domestic Frost-Free Refrigerator



Manual and cyclic defrost refrigerators refer to the refrigerator. The evaporator in the refrigerator automatically defrosts whereas the freezer needs to be manually defrosted. The evaporator is most commonly found as an exposed vertical plate at the back of the refrigerator. Manual and cyclic defrost refrigerators have not been recommended for vaccine storage because of the significant temperature variations and the risk of vaccines freezing. Generally, while the compressor is running, the area near the evaporator can be very cold whereas other areas are much warmer.

Figure 3: Manual and Cyclic Defrost Refrigerator



Domestic refrigerators are designed for food storage and not for the requirements of vaccine storage. Precautions and fridge modifications are needed in order to store vaccines.

Technical Information for Domestic Refrigerators

The technical features of domestic refrigerators that can affect vaccine storage are outlined below[1].

1) Temperature regulation

The thermostat in domestic refrigerators detects temperature changes and controls the compressor's on and off function. When the temperature exceeds the set temperature of the thermostat, the thermostat sends a signal to the compressor to cool the unit. Large fluctuations in temperatures may occur depending on the point at which the compressor turns on and the time it takes to cool the unit. This will vary depending on the specifications of the refrigerator.

Domestic refrigerators are designed to cool the unit by air blown at below 0˚C from the evaporator into the refrigerator. Products placed close to vents will experience these below 0˚C temperatures.

Finally, temperature sensors are located in various areas of the refrigerator depending on the model. The sensors may not measure the temperature where the vaccines are stored, thereby possibly exposing vaccines to temperatures outside the recommended range when the evaporator blows cold air into the refrigerator.

2) Defrost mechanism

Depending on the type of domestic refrigerator, there are two main mechanisms for defrosting. A frost-free refrigerator relies on heating coils wrapped around the evaporator in the freezer. The heating coil is controlled by a timer and/or a sensor that determines when a predetermined temperature is reached and when the heating coil should be turned off. There is a risk of temperature fluctuations that may result in higher temperatures in the freezer and sections of the refrigerator.

In a manual and cyclic defrost refrigerator, the freezer defrosts manually and the refrigerator relies on natural melting or off-cycle heating of the evaporator when the compressor is off.

The defrost mechanism in domestic refrigerators can cause temperature fluctuations within the unit. The combination of the compressor cooler, the defrost heating, as well as poor uniformity of temperatures throughout the compartments, creates temperature variations which can affect vaccine storage.

3) Spatial temperature differential

Domestic refrigerators are designed to have various temperature zones for multiple storage functions. They are designed so that there is transfer of cool air from the freezer to the refrigerator. In turn, this could result in vaccines being stored in suboptimal conditions.

4) Effects of changes in ambient temperature

In domestic refrigerators, the temperature sensor may be located in the freezer. As a result, when the ambient temperature rises, the compressor operates more frequently, and the refrigerator gets exposed to cooler air from the evaporator.

5) Temperature recovery

In domestic refrigerators, temperature recovery depends on many factors including the design of the refrigerant delivery system and temperature regulation system; the size of the compressor, evaporator and fan; and the time it takes for the temperature sensor to detect a change in temperature.

General information about a domestic refrigerator includes:

- Thermostats are generally slow to react to increase in temperatures and have a wide temperature tolerance.
- It is difficult to accurately set temperature.
- No air is circulated when the compressor is off.
- Defrost function can cause temperature fluctuations.

The vaccine coordinator must know the following information about their refrigerator if a domestic refrigerator is going to be used to store vaccines:

- The various temperature zones within compartments; vaccines can only be stored in certain areas, depending on the temperature zone.
- The air vent location; the location of air vents differ by manufacturer. Vaccines should be kept away from the air vent to avoid potential freezing. Generally the air from the evaporator is below 0˚C.
- How changes in ambient temperature affect internal temperature.

(*See Know your Refrigerator in Section 4—Vaccine Storage Practices.*)

Bar Fridge Units

Any style of small single-door (bar-style) fridge is unpredictable in terms of maintaining temperatures and should **not** be used. With combined refrigerator and freezer units, the freezer compartment in this type of unit is incapable of maintaining temperatures cold enough to store freezer-stable vaccines. Even when the freezer temperature is not adjusted, the temperature in the refrigerator compartment will fall below the recommended range, potentially freezing the refrigerated vaccines. Temperatures vary inside the compartment. The temperature-control sensor reacts to the temperature of the evaporator rather than to that of the air in the compartment, resulting in varying temperatures in the refrigerator as the ambient temperature changes[1].

Jurisdictions in Canada report **that use of bar fridges for vaccine storage is a leading cause of cold chain breaks**.

Any style of small single-door (bar-style) fridge is unpredictable in maintaining temperatures and is not recommended for vaccine storage. Jurisdictions in Canada report that use of bar fridges for vaccine storage is a leading cause of cold chain breaks.

Equipment Placement

Good air circulation around the vaccine storage unit is essential for proper heat exchange and cooling functions. The unit should be placed in a well-ventilated room and should have space around the sides, top and back. Leave at least 10 cm of space (or as recommended by the manufacturer) between the back of the unit and the wall. If the unit has coils on the back, measure 10 cm from the coils to the wall. Nothing should be blocking the cover of the motor compartment, which is normally located at the back or the side of the unit. Make sure that the unit stands firmly and level, and that the wheels or leveling legs are adjusted so that the bottom of the unit sits 2.5 to 5 cm above the floor. Do not place in direct sunlight, near a heat source, or along an outside wall where the temperature of the wall can vary, depending on the season[2].

Recommended Temperature Range

Refrigerator

The refrigerator compartment should maintain temperatures between +2˚C and +8˚C. The temperature should never fall below +2˚C or rise above +8˚C. Therefore, set the temperature mid-range to achieve an average of about +5˚C. This temperature setting will provide the best safety margin of temperature fluctuations within the +2˚C to +8˚C range.

Freezer

Vaccines that must be frozen should be maintained at a temperature of -15˚C or colder.

Setting and Stabilizing the Temperature

Who should adjust the temperature?

Only the designated vaccine coordinators should adjust the temperature of a vaccine storage unit. Limiting access to the thermostat reduces the risk that the temperatures will be adjusted inappropriately. If the thermostat requires adjustment, alert the designated vaccine coordinator.

A warning sign should be posted on the storage unit that says, “Do not adjust refrigerator or freezer temperature controls. Notify primary vaccine coordinator or the back-up coordinator if adjustments are necessary.”

Thermostats

Refrigerator and freezer thermostats are marked in various ways, depending on the brand. In general, thermostats do not show temperatures but rather the levels of coldness. For example, some have a series of numbers or letters on the control knob. Others may have “MIN,” “MED,” and “MAX” marked on the knob. The only way to know the temperature inside the unit is to measure it with a thermometer. In combination refrigerator and freezer units, the thermostat actually controls the volume of cold freezer-temperature air that goes into the refrigerator. Consult the manufacturer’s guidelines for instructions on how to operate the thermostat.

Only the vaccine coordinators should adjust the temperature of a vaccine storage unit.

How to adjust the temperature

To adjust the temperature:

- Be sure the unit is plugged into the power source.
- If necessary remove all vaccines and store appropriately.
- Check the temperatures inside the refrigerator and freezer compartments.
- Adjust the temperature indicator slightly toward a warmer or colder setting as necessary. Adjust the thermostat slowly so as not to exceed the recommended temperature range.
- Allow the temperature inside the unit to stabilize for **half an hour** then recheck the temperature. Adjust the thermostat again as necessary. If the refrigerator is newly installed or newly repaired it should be preconditioned to the set point temperature and stabilized. Allow one week of twice daily refrigerator and freezer temperature recordings before using the unit to store vaccines.
- Always strive for +5˚C to stabilize the refrigerator temperature. Make sure the temperature does not fall below the lower limit or rise above the upper limit of the recommended refrigerator temperature range of +2˚C to +8˚C.
- Aim to stabilize the freezer temperature at -15˚C or colder.
- Be sure the temperature in the refrigerator has stabilized before returning vaccines that have been removed.

Combined refrigerator and freezer units use a cooling system that directs cold air from the freezer compartment into the main refrigerator compartment. Therefore, be careful when adjusting the freezer temperature because this will affect the temperature of the air venting into the refrigerator compartment. Without careful and frequent temperature monitoring inside the refrigerator compartment, there is a danger of freezing the refrigerated vaccines.

Frequent temperature monitoring of both the freezer and refrigerator compartments throughout the day, as well as at the beginning and end of the workday, is required whenever thermostats are adjusted. **The temperature in a newly installed or newly repaired refrigerator may take 2 to 7 days to stabilize within the recommended range of +2˚C to +8˚C. The temperature in a newly installed or newly repaired freezer unit may take 2 to 3 days to stabilize within the recommended range of -15˚C or colder. Allow one week of twice daily refrigerator and freezer temperature recordings before using the unit to store vaccines**.

Consider re-loading the refrigerator with vaccines at the beginning of a work week. Monitor newly adjusted fridge temperatures closely after loading with vaccines. The presence of vaccines has a major impact on the temperature of the refrigerator, especially when using domestic models[3].

To maintain the cold chain during any period when the refrigerator or freezer is out of service, vaccines should be temporarily stored in a temperature monitored alternate vaccine storage unit until the temperature in the original unit can be stabilized within the recommended range. Another option is to store the vaccines in an appropriately packed cooler if the storage unit will be out of service for a short time and vaccine-appropriate temperatures can be maintained in the cooler for the time required. (*See Section 9—Vaccine Shipments for more details.*)

Allow 1 week of twice daily refrigerator and freezer temperature recordings before using a newly installed or newly repaired refrigeration unit to store vaccines.

Factors Affecting Temperature Variations

Temperatures can vary in a vaccine storage unit based on the contents/load, seasonal temperature variation, how often the door is opened and power interruptions. The only way to be sure the temperature in the storage unit has remained within the recommended range is to frequently monitor and record the temperature using a min/max thermometer or data logger. (*See Know Your Refrigerator in Section 4—Vaccine Storage Practices for more details.*)

Opening the door

Limit the number of times the vaccine storage unit doors are opened and avoid letting the doors stand open unnecessarily. Not only does this affect the temperature in the unit, it also exposes the vaccines to light (which can affect the potency of some vaccines). Routinely check the doors throughout the day and at the end of the day to ensure they are tightly closed.

Avoid unnecessarily opening the refrigerator door. The World Health Organization recommends door openings be minimized to not more than four times a day.

Stabilizing the temperature with water bottles and frozen packs

You can help stabilize the temperature in the refrigerator by keeping two or more large containers of water inside. Store the water bottles in the crisper area, in the door racks, and/or against the inside walls of the refrigerator. You can help stabilize the temperature in the freezer by keeping frozen packs or ice trays inside. Store the frozen packs along the walls, back, and bottom of the freezer compartment and inside the racks of the freezer door. Not only will water bottles and frozen packs help maintain an even temperature in the compartments with opening and closing of the doors, they will also help keep the temperatures stable longer in the event of a power failure.

Vegetable bins ("crispers")

Consider removing the vegetable bins from the refrigerator. Removing the bins not only provides extra space for storing containers of water, but it also removes the temptation to use the bins for storage of food, beverages, or vaccines. Vaccines should never be stored near the floor of the refrigerator in the vegetable bins because the temperature in this area is different from that in the body of the refrigerator. (*See Know Your Refrigerator in Section 4—Vaccine Storage Practices for more details*.)

When to Adjust the Temperature

The refrigerator and freezer temperatures should be adjusted if outside the recommended range or if, over time, the temperature appears to be moving toward the upper or lower temperature limit. (*See Section 6—Storage Troubleshooting for more details*.)

In some situations, the thermostat may need to be reset in summer and winter, depending on the ambient temperature.

3.5 REFRIGERATOR AND FREEZER MAINTENANCE

General Principles

Regular maintenance is required to ensure proper operation, to maintain required temperatures, and to extend the useful life of the appliance.

The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply. Move the vaccine to a properly functioning storage unit with appropriate temperatures. After this is accomplished, attempt to find the cause of the problem and correct it. (*See Section 6—Storage Troubleshooting for more details*.)

The most important action to take if the vaccine storage unit is not working properly is to protect the vaccine supply.

Daily Maintenance Tasks

Check the internal temperature

The minimum and maximum temperature inside each compartment of the vaccine storage unit must be checked with a calibrated thermometer and recorded numerically on a temperature log at least twice each day: once in the morning when the door is first opened and once at the end of the clinic day just before the door is closed for the last time. *(See Section 5—Temperature Monitoring and use the Temperature Log for Vaccines (Celsius) in the Resources Section.)* More frequent temperature monitoring is required following thermostat adjustments. The temperatures should be recorded on a temperature log and charted on a graph for visual focus when it is outside the optimal temperature range. If the temperature is outside the recommended range, the designated vaccine coordinator should be notified without delay. **Immediate action** must be taken. (*See Steps in Handling Inappropriate Vaccine Storage Conditions (Light and Temperature) in Section 6—Storage Troubleshooting for more details.*)

The temperature inside each compartment of the vaccine storage unit must be checked with a calibrated thermometer at least twice each day.

Check that the doors are closed

To maintain internal temperatures within the recommended ranges, the vaccine storage unit doors must fit securely and tightly against the unit. The rubber-like seals that run around the inner edges of the doors contain magnets that help hold the doors closed and create tight seals, keeping cold air inside. Check that the doors are properly sealed by giving a gentle tug on the door handles. The doors should also be checked at the end of each clinic day to make sure that they are properly closed and sealed. Installing an inexpensive Velcro™ latch from a hardware store can help ensure that the door is not accidentally left ajar.

Check that doors are properly sealed each time they are closed and at the end of each day.

Weekly Maintenance

Check ice buildup in the freezer (manual and cyclic defrost units only)

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.

Check the inside walls of the freezer compartment **weekly**. When frost has accumulated to a thickness of 1cm or so, the unit requires defrosting. **Follow the manufacturer's guidelines for specific recommendations for defrosting the freezer**.

General guidelines for defrosting a manual and cyclic defrost refrigerator include:

1) Remove all vaccines 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.
6) 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.
11) Re-stock each compartment with vaccine.
12) Continue to monitor and record the temperature every half-hour for the next few hours.

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. (*See Refrigerator and Freezer Door Problems in Section 6—Storage Troubleshooting for more details*.) Consult a technician and monitor temperatures carefully.

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

Quarterly Maintenance

Clean the coils and motor

The vaccine storage unit coils should be examined and cleaned quarterly. 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 Friday. Accidentally damaging the coils will cause a problem that may not be detected until the following Monday.

This process should only take a few minutes; therefore, it is not necessary to transfer the vaccine to another storage unit as long as the doors remain tightly closed for the duration of the procedure.

Clean the refrigerator and freezer compartments

Clean the refrigerator and freezer compartments quarterly or as needed. Remove the vaccines 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 reach and stabilize at the proper temperature range monitoring and recording the temperature every half-hour for the next few hours. Restock each compartment with vaccine, continuing to monitor and record the temperature every half-hour for the next few hours.

Check the door seals

Quarterly, check the integrity of the rubber-like door seals. They 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. (*See Refrigerator and Freezer Door Problems in Section 6—Storage Troubleshooting for more details.*)

Use the Monthly Vaccine Inventory and Refrigerator and Thermometer Maintenance in the Resources Section as a summary of maintenance completed.

3.6 THERMOMETERS AND TEMPERATURE MONITORS

All thermometers are calibrated (given a temperature scale) during manufacturing. Not all models of minimum and maximum (min/max) thermometers are calibrated with the same scale and may have different accuracies and resolutions. Please check with the manufacturer for the accuracy of your thermometer.

Calibration should be accurate within ±1˚C. Avoid using thermometers that have not been calibrated to be accurate within ±1˚C. (*See "Thermometer Maintenance" later in this section for more details.*)

Always use a thermometer that has been calibrated within ±1˚C.

Types of Temperature Monitoring Devices

Overview

Immunization providers must be familiar with their jurisdiction's requirements for temperature monitoring equipment.

The only thermometers and temperature recording devices recommended for monitoring the temperatures within vaccine storage units are thermometers that provide continuous

recording or min/max thermometers that are properly monitored. These types of thermometers are preferred because they provide an indication of the length of time a storage compartment has been operating outside recommended temperature ranges when a cold chain break occurs. The min/max thermometer must be reset regularly (after properly recording temperatures) for meaningful readings.

The only thermometers and temperature recording devices recommended for monitoring the temperatures within vaccine storage units are thermometers that provide continuous recording or min/max thermometers that are properly monitored.

1) Data Loggers

Digital data loggers are miniature, battery-powered, stand-alone temperature monitors that record hundreds or thousands of temperature readings. These are the ideal temperature monitors because they can **indicate when the exposure occurred and how long the vaccines were exposed to the min/max temperatures**. Data loggers may be single use and used only in transport, or they may be multiple use. Single-use data loggers have external lights (or symbols) that alert the user to out-of-range temperature events; a green light indicates the cold chain was properly maintained and a red light indicates inappropriate temperature exposure occurred. If a red light is seen, the vaccine shipment must await approval for use, and the device must be sent back to the manufacturer to interpret the temperature data.

Multiple-use digital data loggers are accompanied by special software that is installed in a computer. This software allows the user to set the frequency of the temperature readings, download data from the device, and calculate temperature averages, minimums, and maximums, as well as the time spent at each temperature. Data loggers should be replaced or re-calibrated annually.

Document the temperatures twice a day. Monitor for visual alarm whenever going into the fridge. Download data each morning because the data logger will detect any out of range temperature overnight.

2) Strip monitors

Strip monitors are battery-powered single-use units that record continuous temperature readings on a paper strip and may be used to monitor vaccine temperatures during transport.

3) Chart recorders

Chart recorders consist of a graph wheel with replaceable graph paper and ink pens. The pens mark the temperature on the graph paper as the wheel turns. Temperatures are recorded continuously, 24 hours a day. The graph paper has a Fahrenheit or Celsius scale

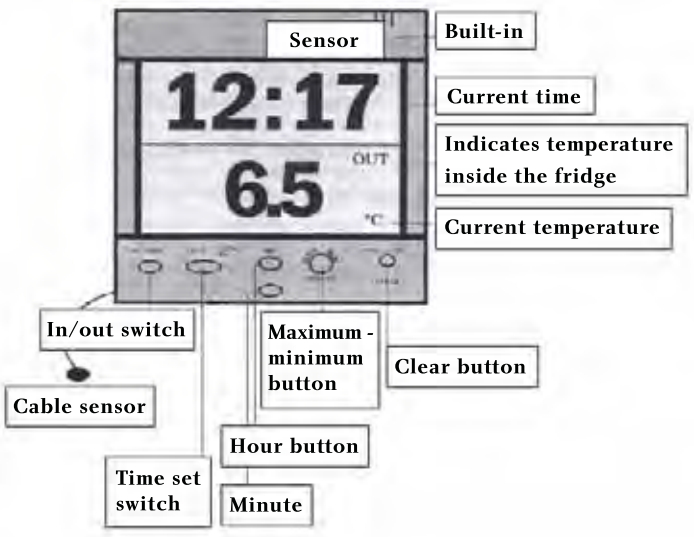
on it, and the temperature is read where the ink line falls on the scale. The graph paper must be changed when it completes a full circle, usually weekly. Record the date on the graph paper when it is fitted and when you remove or change the graph paper. Keep old graphs as a permanent record of the performance of the vaccine storage unit. As with other thermometers, temperature readings should be checked and recorded at least twice daily.

Some chart recorders have temperature probes. (*See "Temperature Probes" later in this section for more details.*) Chart recorders are more difficult to read than digital thermometers because they require interpretation of the temperature graph.

4) Minimum and maximum thermometers

Min/max thermometers are available in fluid-filled and digital forms. They show the current temperature and the minimum and maximum temperatures that have been reached since the last time the thermometer was reset. Temperature fluctuations outside the recommended range can be detected by referring to the minimum and maximum temperature readings. It is important to manually reset the minimum and maximum temperatures to the current temperature each time the temperatures are recorded. The min/max thermometer must be reset regularly (after properly recording temperatures) for meaningful readings.

Figure 4: Min/Max Thermometers



5) Digital thermometers

Digital thermometers have a screen in which the temperature is displayed in Fahrenheit and/or Celsius. Choose a model that displays the minimum and maximum temperatures. Some models have a temperature probe and an alarm that can be set to ring at a specified temperature. An alarm that rings outside the storage unit is preferable to one that rings inside the unit. Some digital thermometers have two components: a display that mounts to the outside of the unit and a probe on a cord (usually 1 to 3 meters long) that is placed inside a vaccine or a diluent box inside the unit. This arrangement allows the temperature to be read without opening the door of the storage unit.

Digital thermometers with a min/max feature are easy to read because they display a number indicating the temperature and do not require interpretation. Temperature fluctuations outside the recommended range can be detected by referring to the minimum and maximum temperature readings. The digital thermometer must be reset regularly (after properly recording temperatures) for meaningful readings.

A limitation of min/max thermometers is that readings do not indicate when the exposure occurred and the exact length of time the vaccines were exposed to the out of range temperatures.

6) Thermometers that are not recommended for monitoring temperatures inside vaccine storage units: Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, and household mercury thermometers

Fluid-filled biosafe liquid (bottle) thermometers, bi-metal stem thermometers, and household thermometers are not recommended for temperature monitoring in vaccine storage units. They can be difficult to read and only indicate the temperature at the precise time they are read, therefore, temperature fluctuations outside the recommended range may not be detected.

Fluid-filled biosafe liquid thermometers, bi-metal stem thermometers, and household mercury thermometers are NOT recommended for monitoring temperatures.

Thermometer Placement

The thermometer should be placed in the center of the compartment away from the coils, walls, door, floor, and fan, and the temperature probe should be placed in the vaccine box. In the refrigerator compartment, the thermometer should be placed on the middle shelf adjacent to the vaccine. 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 vaccine to an appropriate storage unit and check that the thermometer is appropriately situated.

Temperature Probes

Some chart recorders and digital thermometers have temperature probes. Probes are available in two forms: a standard probe and a biosafe liquid-encased probe. Probes should be placed in the center of the compartment. Fluid probes can give a more relevant reading because they do not react to short fluctuations in air temperature and mimic vaccine temperatures [1]. To standardize procedures for domestic refrigerator temperature monitoring it is recommended that the temperature probe be placed in a diluent or vaccine box to reduce the risk of measuring short air fluctuations when opening the refrigerator door.

3.7 THERMOMETER MAINTENANCE

Checking the Accuracy of the Thermometer

Thermometers should be checked annually to ensure:

- Temperature measurement is accurate.
- Batteries are functioning. Maintain and change batteries as recommended by the manufacturer, keeping in mind warranty requirements.
- Cables or probes are not damaged.
- An adequate supply of graph paper and ink pens for chart recorders.

All of these may affect accuracy in temperature readings.

Slush test

The accuracy of a thermometer can be checked using the following test. This test should be done at least once a year.

1) Fill a polystyrene or plastic cup two-thirds with cold water. Place the cup in the freezer until a fine layer of ice forms on top and a small section of ice forms within the fluid (about 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 2 minutes. The temperature should drop to 0˚C within 2 minutes.

Most thermometers are calibrated to be accurate to ±1˚C or better. If the temperature reading is more than 1˚C above or below 0˚C at 2 minutes, replace the battery and test again. If the thermometer is still not within range, contact your thermometer manufacturer for instructions regarding recalibration procedures or replace the thermometer.

Another method of testing thermometer accuracy is to test the accuracy of a thermometer against a reference thermometer but this is less reliable.

If the calibrated thermometer indicates an out-of-range temperature and if it is properly positioned assume it is accurate and take immediate steps to safeguard the vaccine. Once the vaccine is safely stored under proper conditions, the accuracy (and batteries) of the thermometer can be checked. However, always check other causes of inappropriate storage temperatures first.

Use the Monthly Vaccine Inventory and Refrigerator and Thermometer Maintenance in the Resources Section to summarize maintenance completed.

Thermometers should be checked annually to ensure:

- Temperature measurement is accurate.
- Batteries are functioning. Maintain and change batteries as recommended by the manufacturer, keeping in mind warranty requirements.
- Cables or probes are not damaged.

3.8 COLD CHAIN MONITORS

General Principles

There are two basic types of cold chain monitors (CCMs): those that indicate whether packages have reached temperatures that are too warm and those that indicate whether packages have reached temperatures that are too cold. These types of monitors are designed to be irreversible indicators of inappropriate temperatures once a temperature excursion has occurred above or below the activation set points. In general, CCMs are for single use only and should not be re-used.

Cold chain monitors are not a substitute for twice-a-day temperature reading and recording. They should only be used to monitor the temperature of vaccine during transport.

Types of Cold Chain Monitors

Heat indicators

Heat indicators, also known as time and temperature indicators are made for single use only. Heat indicators that are appropriate for vaccine shipping have an activation temperature of +10°C and a run-out time of 48 hours to 7 days.

A heat indicator releases a coloured dye into the windows of the device when the temperature has exceeded the threshold or activation temperature (indicated on the device). The dye gradually moves through the windows over time. Once activated, the process is irreversible. If the temperature drops below the threshold again, the dye stops moving but does not disappear. Therefore these indicators also show the length of time in hours or days that the temperature has exceeded the desired range. Response cards are used to interpret the time and temperature relationship for each indicator.

The heat indicator must be preconditioned **below** its threshold response temperature before use; check manufacturer specifications for the length of conditioning time and the appropriate conditioning temperature.

In general, heat indicators are preconditioned in the refrigerator. This ensures that the dye inside the indicator is in a solid state when the activation tab is pulled. The activation strip needs to be removed to start the monitor—this allows for the coloured marker to melt and stain the porous wick as it undergoes temperature excursions above its threshold temperature. If the dye is not in a solid state, it will start moving down the track of the indicator and through the windows, producing an inaccurate reading.

Always attach the indicator to a vaccine vial or box; do not attach it to the transport box. If the surface to which the indicator is attached is at a temperature above the threshold of the indicator, the indicator will activate prematurely. Once the indicator is preconditioned, pull the activation tab, and place it and the vaccine into the environment to be monitored. This allows the indicator strip and reservoir pad to come in direct contact with each other and begins the temperature monitoring process. Like vaccines, heat indicators will have an expiration date and should be checked for these dates routinely.

Freeze indicators

Freeze indicators are made for single use only. Unlike warm indicators, freeze indicators do not indicate the length of time vaccine has been exposed to temperatures outside the recommended temperature range. Freeze indicators appropriate for vaccine shipping have an activation temperature of 0°C.

A freeze indicator uses coloured liquid to indicate exposure to freezing temperatures. In some models, the freeze indicator has a clear indicator bulb; when the temperature drops below the threshold freezing point, the indicator bulb irreversibly changes colour. The indicator does not require preconditioning and may be attached to any clean dry surface in the environment being monitored. There is no activation tab to pull; the indicator is working at all times.

Other freeze indicators use a specially designed ampoule filled with dye; when the temperature drops below the freezing threshold, the ampoule breaks and releases the dye that irreversibly stains the paper behind the ampoule. This type of freeze indicator requires preconditioning in a temperature above the freezing threshold; check the manufacturer's specifications for the duration of this preconditioning period. Leaving it out at room temperature will meet this requirement.

For freeze indicators that require preconditioning, attach the indicator to any clean dry surface in the environment being monitored, after the preconditioning. There is no activation tab to pull. To determine if the product has been exposed to freezing temperatures, observe the paper behind the ampoule. If it is stained with colour, the product being monitored was exposed. If there is no colour, remove the indicator from the surface to which it is attached and vigorously tap the bottom edge of the device three times on a hard surface. If the paper becomes stained, the product being monitored was exposed. Tapping will not cause colour staining in an unexposed indicator.

Like vaccines, freeze indicators have an expiration date that should be checked routinely.

Using cold chain monitors

Cold chain monitors are primarily used to monitor temperature thresholds when vaccine is shipped by manufacturers, commercial vaccine distributors, and government-managed vaccine depots. When the vaccine arrives at its destination, the CCMs should be checked immediately and the temperature inside the transport unit should be documented. If the CCM has been activated, the product should be quarantined in the fridge. **Do not assume that the exposed vaccine CANNOT be salvaged**. (*See Section 6—Storage Troubleshooting for more details*.)

Cold chain monitors should only be used during transport.

3.9 VACCINE SECURITY

Protecting the Power Supply

To protect vaccine supply within the proper range, the unit must be in good working condition and have power at all times.

To prevent problems with the power supply

- Avoid using power outlets with built-in circuit switches and outlets that can be activated by a wall switch.
- Use a safety-lock plug or an outlet cover.
- Post a warning sign at the plug and on the storage unit alerting others not to unplug the unit.
- Label the fuses and circuit breakers to alert others not to turn off the power to the vaccine storage unit.
- Consider installing a temperature alarm with 24 hour and 7 days a week monitoring, especially for large vaccine inventories.

Temperature Alarms

A continuous-monitoring temperature alarm or notification system should be considered, especially for vaccine storage units with a large inventory, to help prevent substantial financial loss in the event of a cold chain break. These systems help alert staff to after hours emergencies. Simple systems sound audible alarms when the temperatures inside the storage units exceed the recommended ranges. A system that sounds an audible alarm and alerts one or more designated person(s) at a specified phone or pager number is preferable. For larger or centralized depots, alarms should be monitored 24 hours a day and 7 days a week by external sources that maintain a fan-out list of contacts. 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 break. This drill should be done outside of operational hours, for example, during a weekend when regular staff is unavailable.

Backup Generators

Facilities storing large vaccine inventories should install backup generators that automatically provide power to the storage units to maintain the recommended storage temperatures in the event of power outages.

Backup generators should be tested quarterly and should receive maintenance at least annually (check the manufacturer's specifications for test procedures and maintenance schedules). Backup generators should be of a sufficient capacity to run continuously for 72 hours if necessary. Plans should be made to ensure that an adequate supply of fuel is on hand. (*See both Routine and Urgent Vaccine Storage and Handling Protocols in Section 2—Vaccine Storage and Handling Plans and Section 6—Storage Troubleshooting for more details.*)

3.10 REFERENCES

1. Miller N, Watts M, Albances S et al. *Technical issues with refrigerators.* In: Langley A, Grant S, eds. *Proceedings of the National Vaccine Storage Workshop*. 1st ed. Brisbane: Queensland Health, 2004:15-42.

2. Australian Government, Department of Health and Ageing. *National vaccine storage guidelines: strive for 5*. 3rd ed. Australia, 2005:7-23.

3. Grassby PF. *Safe storage of vaccines: problems and solutions*. Pharm J. 1993; 251:323–327.

Vaccine Storage and Handling Guidelines:

SECTION 4 VACCINE STORAGE PRACTICES

Contents

4.1 APPROPRIATE VACCINE AND DILUENT STORAGE CONDITIONS

Proper vaccine storage and handling procedures include but are not limited to the following:

- A minimum of twice daily minimum and maximum temperature monitoring of the refrigerator(s) and freezer(s), as well as the room temperature.
- A minimum of twice daily recording on the temperature logs.
- Responding to storage temperatures outside the recommended range.
- Maintaining storage and handling equipment and records.
- Rotating vaccine stock so that vaccine closer to its expiration date will be used first.
- Monitoring expiration dates on vaccines and ensuring that expired vaccine is not administered to clients.
- Ordering vaccines to maintain no more than a one month supply (or quantity sufficient to meet seasonal or outbreak demands).
- Overseeing proper receipt, storage, and transport of vaccine.

All vaccines should be stored with the caps on in their original boxes until they are needed. Light exposure may cause loss of potency in vaccines and other biologics. Therefore, these products should be protected from light exposure at all times.

Live Vaccines

Certain live vaccines must be stored in a continuously frozen state at -15˚C or colder until administration. In Canada, most live vaccines are licenced as refrigerator stable products. However, if the vaccine is received frozen from the vaccine supply source, it may be stored in the freezer. Do not refreeze vaccines. Always refer to the product monograph for the most up-to-date information on storage information.

Inactivated Vaccines

Inactivated vaccines are sensitive to both excessive heat and freezing. They should be stored in a refrigerator at +2˚C to +8˚C, with a desired average temperature of +5˚C (mid-point that allows for ±3˚C buffer). Exposure to temperatures outside this range may result in decreased vaccine potency and increased risk of vaccine-preventable diseases.

Lyophilized (Freeze-Dried) Vaccines and Diluents

Diluent that is packaged separately from its corresponding lyophilized (freeze-dried) vaccine can be stored at room temperature or in the refrigerator. To conserve space, these diluents may also be stored in the door of the refrigerator. Use only the diluent accompanying the vaccine for reconstitution as specified by the manufacturer.

Diluent which has been frozen should not be used because of the risk of fractures in the vial that may cause contamination. Appropriate actions should be taken to isolate and dispose of the vials according to your local public health office or immunization program* recommendations.

4.2 ORGANIZING YOUR REFRIGERATOR AND FREEZER

Organization of your refrigerator and freezer must take into account convenience for staff, technical features of the refrigerators, and vaccine requirements. Figure 1 summarizes how your refrigerator should be organized.

Ideally, frozen vaccines should be stored in a separate designated freezer unit. However, for domestic refrigerators having a separate freezer compartment, frozen vaccine may be stored in the middle of the compartment away from the walls, coils, and floor. Vaccines should not be stored in the freezer door. The temperature in the door is not stable because door openings subject products in this location to frequent temperature fluctuations.

Frozen vaccines may be stored in either a manual defrost or a frost-free freezer at -15˚ C or colder. Vaccine products must not be stacked or placed so closely together that air circulation inside the freezer compartment is impeded.

In the refrigerator, vaccine should be stored in the middle of the compartment away from the coils, walls, floor, and cold-air vent. The temperature near the floor of the refrigerator is not stable and differs from that in the middle of the compartment. For this reason, vaccine should never be stored in the vegetable bins. Vaccines should not be stored in the refrigerator door. The temperature in the door is not stable because door openings subject products in this location to frequent temperature fluctuations. Refrigerated vaccines should always be stored far enough away from the air venting from the freezer compartment to avoid freezing.

Organization of your refrigerator and freezer must take into account convenience for staff, technical features of the refrigerators, and vaccine requirements. In the refrigerator, vaccine should be stored in the middle of the compartment away from the coils, walls, floor, and cold-air vent. In the freezer, vaccine should be stored in the middle of the compartment away from the walls, coils, and peripheral areas.

Figure 1: Organizing the Refrigerator

Know Your Refrigerator

Refrigerator technology can vary, so it is not possible to make generalized statements on how to manage vaccines for all refrigerators. It is important that you "know your refrigerator." The following suggestions are summarized from the Australian Government, Department of Health and Ageing,[1] and Grassby[2].

Most refrigerators have a temperature gradient, meaning that there is a gradual difference in temperature from one part of the refrigerator to another, for example, from top to bottom, side to side, and front to back. It is important to know each refrigerator's temperature gradients. Do not assume that the top part of the refrigerator is coldest and the bottom part is warmest. The gradients will depend on how the refrigerator is cooled and/or where the plate evaporator is located.

To determine the gradients within your refrigerator, a recording device, such as a data logger, should be placed in each position for a minimum of 24 hours, preferably with at least two other recorders simultaneously placed in other parts of the unit. Depending on the type and number of recorders available, this could take some time and is best done when there is no vaccine in the fridge but with some sort of "cold mass" to simulate a batch of vaccine (e.g. cooled water bottles). Knowing the temperature gradients will help you to place your vaccines properly within the refrigerator.

Temperatures for each location of the refrigerator can also fluctuate at any given time. For frost-free refrigerators, the defrost cycle can affect the temperature. Environmental factors may also affect the temperature, for example, the surrounding room temperature and the location of the refrigerator in reference to windows, heat sources, or air conditioning. It is also important to know what happens when there are changes in the weather, or a decrease or increase in use compared to usual daily activities.

It is important to know your refrigerator. Knowing the temperature gradients will help you to place your vaccines properly within the refrigerator. It is also important to know the factors that affect fluctuations in temperatures in the refrigerator.

Vaccine Spacing

Vaccine should be grouped by product, taking note to place short-dated products near the front of the group for more immediate use and with space between the vaccine and the compartment wall, and with space between each large box, block, or tray of vaccine to allow for cold air circulation around the vaccine. Adequate cold-air circulation helps each vaccine to reach a consistent temperature throughout its mass and is necessary for the storage unit to maintain a consistent temperature inside the compartment. Packing any vaccine storage unit too tightly will affect the temperature. Likewise, packing too much vaccine in one unit will affect the temperature (e.g. during peak flu season). No more than 50% of the internal volume of the refrigeration unit should be filled with vaccine[2].

Packing any vaccine storage unit too tightly and/or packing too much vaccine in one unit will affect the temperature.

Vaccine Packaging

Vaccine products that have similar packaging should be stored in different locations to avoid confusion and medication errors. For example, if you have pediatric and adult versions of the same vaccine, storing them in different locations lessens the chance that someone will inadvertently choose the wrong vaccine.

Likewise, vaccines that have similar sounding names should be stored in different locations. For example, DT and Td vaccines might be easily confused, as could Hib and hepatitis B vaccines.

Like antigens of different brands are also best kept separate to avoid administration of an incorrect dose if the dosing schedule or series differs among brands of the same antigen.

4.3 ORGANIZING VACCINE INVENTORY

The location of each specific vaccine inside the storage unit should be clearly labeled. Storing each vaccine in its own specifically labeled section of the refrigerator or freezer helps decrease the chance that someone will mistakenly select the wrong vaccine.

In addition to labeling the location of vaccines, mark each opened multidose vial with the **date** it was **first punctured**. Mark reconstituted vaccine with the **date and time** it was reconstituted. Dating these vials is important for two reasons.

1) Some vaccines expire within a certain time after puncturing or after reconstitution. This may not correspond to the expiration date printed on the vial by the manufacturer. Follow manufacturer recommendations or jurisdictional guidelines for use of multidose vials and reconstituted vaccine.
2) Dating punctured or reconstituted vials helps manage vaccine inventory by identifying vials that should be used first. Whenever possible, use all the vaccine in one multidose vial before opening another vial. Use all the reconstituted vaccine in one vial before reconstituting another vial to reduce vaccine waste.

Store punctured multidose vials in a designated, labeled container so that they are easily recognized. Remember to store these vials in their original boxes to prevent light exposure.

Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the boxes of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This avoids confusion and helps to ensure that you use only the specific diluent provided by the manufacturer for each type of lyophilized (freeze-dried) vaccine. This is particularly important if you store two or more lyophilized vaccines using different diluents.

Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator.

4.4 STORAGE CONTAINERS

Vaccine Boxes

Vaccine and diluent should be stored in their original packaging. Storing loose vaccine vials makes inventory management more difficult, administration errors more likely, and exposes the vaccines to light.

Trays and Containers

Trays and containers may be used to organize vaccine boxes. Each tray or container should only store vaccine of the same type. Other medications and biological products, if they **must** be stored in the vaccine storage unit, must not be stored on the same trays or containers as the vaccines to avoid medication errors. Clearly label trays or containers.

Trays and containers must not be stacked or placed so closely together that air circulation inside the vaccine storage unit compartment is impeded. Trays and containers should be vented to allow air circulation. Never use air-tight containers.

4.5 STORAGE OF NON-VACCINE PRODUCTS

Never store food or beverages inside vaccine storage units. As well, whenever possible, medications and/or other biological products should not be stored with vaccines. Storing non-vaccine items results in frequent opening of the storage unit door. This results in a greater chance for temperature instability and excessive exposure to light. It may also result in spills and contamination inside the compartment. Introduction of other items also impedes airflow and introduces varying temperatures to the unit.

Never store food or beverages inside vaccine storage units.

Use the Checklist for Safe Vaccine Storage and Handling in the Resources Section to summarize ways to safeguard vaccines.

4.6 REFERENCES

1. Australian Government, Department of Health and Ageing. *National vaccine storage guidelines: strive for 5*. 3rd ed. Australia, 2005:3-23.

2. Grassby PF. *Safe storage of vaccines: problems and solutions*. Pharm J 1993;251:323–327.

* Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Vaccine Storage and Handling Guidelines:

SECTION 5 TEMPERATURE MONITORING

Contents

5.1 CHECKING AND RECORDING TEMPERATURES

1) Post a temperature log on the vaccine storage unit door. *Use the Temperature Log For Vaccines (Celsius) in the Resources Section.*

2) Read the thermometers in both the refrigerator and freezer at least **twice a day** for all storage units, including those with continuous temperature monitoring and recording devices: once in the morning when the door is opened for the first time, and again at the end of the clinic day just before the door is closed for the last time. Remember: Min/max thermometers must be reset regularly (after properly recording temperatures) for meaningful readings. (*See Section 3—Vaccine Storage Equipment for more details.*) The room temperature should also be read at the same time to establish awareness of how ambient temperature affects the vaccine storage. Room temperatures may be read with a standard household thermometer.

3) Record the temperatures in numerical values on the temperature log each time the thermometers are read for the refrigerator, freezer and the room. Remember to record the minimum and maximum temperatures for the refrigerator and freezer.

Also include:

- Date and time
- Initials of the person recording
- Comments, if appropriate

4) If a temperature reading is missed, the log entry should remain blank.

5) **Take immediate action** when the temperature in either the refrigerator or freezer is outside the recommended range for vaccine storage. Document the action taken. *(Use the Temperature Log for Vaccines (Celsius) and the Vaccine Storage Troubleshooting Record in the Resources Section.)*

Record the temperature in the refrigerator, freezer and room twice daily. Remember to record the minimum and maximum temperatures for the refrigerator and freezer.

Take immediate action when the temperature in either the refrigerator or freezer is outside the recommended range for vaccine storage.

5.2 REVIEWING TEMPERATURE LOGS

If other staff are monitoring and recording the temperatures, the designated vaccine coordinator should review the log weekly to ensure proper temperature recording and to note trends in refrigerator and freezer temperatures. In some jurisdictions log books must be submitted prior to ordering vaccine.

The designated vaccine coordinator should review the log weekly to ensure proper temperature recording and to note trends in refrigerator and freezer temperatures.

5.3 NOTING EQUIPMENT FAILURES AND ROOM TEMPERATURES

When a mechanical malfunction or power outage occurs, record the following:

- Date and time
- Storage unit temperature
- Room temperature where the vaccine storage unit is located
  - A standard household thermometer may be used.
  - Do not use the thermometer from the vaccine storage unit.
  - Do not rely on the temperature displayed by the room thermostat.
- Problem
- Actions taken
- Results
- Initials

Record the information on the temperature log or on a jurisdictionally determined document.

Use the Temperature Log for Vaccines (Celsius) and the Vaccine Storage Troubleshooting Record in the Resources Section.

If a mechanical malfunction or power outage has occurred, the room temperature where the vaccine storage unit is kept should also be recorded.

5.4 MAINTAINING TEMPERATURE LOGS

Maintaining an ongoing file of temperature logs and equipment failures will help to track recurring problems for vaccine storage units. It will also contribute to quality assurance assessment. Completed logs should be stored for legal purposes for the period of time determined by the local jurisdiction.

5.5 USING ALARM SYSTEMS

Facilities storing large vaccine inventories should consider installing continuous monitoring temperature alarm systems with round-the-clock notification of appropriate personnel to help prevent substantial financial loss. Even if alarm systems are used, temperatures must be checked and recorded twice a day.

Vaccine Storage and Handling Guidelines:

SECTION 6 STORAGE TROUBLESHOOTING

Contents

6.1 STEPS IN HANDLING INAPPROPRIATE VACCINE STORAGE CONDITIONS (LIGHT AND TEMPERATURE)

If you become aware of inappropriate vaccine storage conditions, the following steps should be taken immediately:

1) Notify the designated vaccine coordinator.

2) Record the following information:

- Date and time of incident
- The issue (e.g. inappropriate temperature and/or exposure to light)
- Length of time the vaccine may have been exposed to inappropriate conditions
- The room temperature where the vaccine storage unit is located
  - A standard household thermometer may be used.
  - Do not use the thermometer from the vaccine storage unit.
  - Do not rely on the temperature displayed by the room thermostat.
- Current temperature inside the vaccine storage unit (and freezer)
- Minimum and maximum temperature readings inside the vaccine storage unit (and freezer)
- Presence of water bottles in the refrigerator
- Presence of frozen packs in the freezer
- Action that has been taken to protect the vaccines
- Action that has been taken to correct the issue

Use the Suspected Cold Chain Failure Exposure and Wastage Report in the Resources Section.

3) Document the inventory of the vaccines affected by this event. Include vaccine name, lot number, expiry date, and quantity. *Use the Suspected Cold Chain Failure Exposure and Wastage Report in the Resources Section* to help you organize your response. Consult your local public health office or immunization program* for any special instructions or forms.

4) Isolate and quarantine the affected vaccines and mark them as "DO NOT USE."

5) Store the affected vaccines under appropriate conditions until the integrity of the vaccine is determined. If your vaccine storage unit is not maintaining the appropriate storage conditions, activate the Urgent Vaccine Storage and Handling Protocols. (*See Section 2—Vaccine Storage and Handling Protocols for more details and use the Urgent Vaccine Storage and Handling Protocols Checklist in the Resources Section.*)

Do not assume that vaccine inappropriately exposed to light or to excessive temperatures cannot be salvaged. Contact your local public health office or immunization program* for further guidance.

6.2 DEALING WITH MALFUNCTIONING VACCINE STORAGE UNITS

General Instructions

The most important step to take if the vaccine storage unit is not working properly is to protect the vaccine supply. **Do not allow the vaccine to remain in a non-functioning unit for an extended period of time while you attempt to correct the problem**. If you are not sure that the problem can be corrected in time to maintain an appropriate temperature, activate the Urgent Vaccine Storage and Handling Protocols. (*See Urgent Vaccine Storage and Handling Protocols in Section 2—Vaccine Storage and Handling Protocols and the Urgent Vaccine Storage and Handling Protocols Checklist in the Resources Section for more details*.)

The most important step to take if the vaccine storage unit is not working properly is to protect the vaccine supply.

Vaccine Storage Unit Problems

Vaccine storage unit is too warm

- Check for the following (*see Section 3—Vaccine Storage Equipment for more details*):
  - Unit is plugged in, turned on, and the control knob has been set properly.
  - The door is closing properly.
  - The thermometer is properly located.
  - The freezer compartment is free of thick frost (< 1 cm).
  - There is good air circulation inside and outside the unit.
  - Exposed coils and the motor are free from dust.
  - The room temperature is appropriate.
- Call a refrigeration technician to assess equipment if necessary.

Vaccine storage unit is too cold

- Check for the following (*see Section 3—Vaccine Storage Equipment for more details*):
  - The control knob is properly set.
  - The thermometer is properly located.
  - The freezer compartment is free of thick frost (< 1 cm).

  - There is good air circulation inside and outside the unit.
  - The room temperature is appropriate.
- Call a refrigeration technician to assess equipment if necessary.

Vaccine storage unit is too noisy

- If the unit is making an unusual noise, contact a refrigeration technician to assess the equipment.

Vaccine storage unit has stopped

- Check for the following:
  - The electrical cord is undamaged.
  - The unit is plugged in and turned on.
  - The wall outlet is operative.
    (Appropriate personnel should check fuses and circuit breakers.)
- Call a refrigeration technician to assess the equipment if necessary.

Document all the checks you made and the actions taken in the vaccine storage unit logbook. (*See Routine Equipment Maintenance Logbooks in Section 3—Vaccine Storage Equipment for more details.*)

Use the Algorithm to Assess Problems in Temperature Readings Outside the Recommended Range in the Resources Section. There are two algorithms that summarize actions to take if the refrigerator temperature reading is less than +2˚C or greater than +8˚C.

6.3 REFRIGERATOR AND FREEZER DOOR PROBLEMS

Checking the Door Seal

To check that the vaccine storage unit door is sealing properly:

1) Place a thin paper strip against the cabinet front.
2) Close the door.
3) Pull the paper strip. If it moves easily or falls away by itself, the door and the rubber-like seal need to be adjusted.
4) Check all the way around the door. Pay particular attention to the corners.

Adjusting the Door Seal

If you have checked the door seal and determined that the refrigerator door is not closing properly, call a technician.

6.4 THERMOMETER PROBLEMS

Checking Thermometer Placement

If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated in the center of the storage unit compartment, adjacent to the vaccine. If the thermometer is placed near the coils, walls, floor, door, or fan, it may indicate colder or warmer temperatures than a thermometer appropriately placed in the center of the compartment where the vaccines should be kept.

Checking if the Thermometer Works

A slight variation in temperature is often seen from one thermometer reading to another, even when the vaccine storage unit thermostat is set at a particular temperature. If the thermometer reading does not fluctuate at all over several readings, temporarily remove the thermometer from the storage unit and place it outside the unit at room temperature. Check whether the temperature reading rises. If no change in the temperature reading occurs, check the batteries. Batteries should be changed at least once a year. If there continues to be a problem with the thermometer, call the manufacturer. The thermometer may be faulty and need to be replaced. (*See Section 3—Vaccine Storage Equipment for more details.*)

Thermometers should be checked annually to ensure:

- Temperature measurement is accurate
- Batteries are functioning
- Cables or probes are not damaged
- Adequate supplies of graph paper and ink pens for chart recorders

Checking if the Thermometer Is Accurate

If the thermometer appears to be working but there is concern regarding the accuracy of the reading, the slush test should be used to test the accuracy of the thermometer. (*See Section 3—Vaccine Storage Equipment for more details.*)

6.5 POWER OUTAGES

Advance Preparations

When there is reasonable cause to believe that a power outage may occur, emergency procedures should be implemented **in advance of the event**. (*See Urgent Vaccine Storage and Handling Protocols in Section 2—Vaccine Storage and Handling Protocols and the Urgent Vaccine Storage and Handling Protocols Checklist in the Resources Section for more details*.)

When there is reasonable cause to believe that a power outage may occur, emergency procedures should be implemented in advance of the event.

Temperature Considerations

Most refrigerated vaccines will remain stable at elevated temperatures for limited periods of time. Knowledge of a vaccine's stability, especially the rate of decline in potency at a given temperature, can be helpful in determining impact on expiry date and use of product after a temperature excursion has occurred. The World Health Organization[1] provides general information on vaccine potency. Consult your local public health office or immunization program* for product specific up-to-date stability data.

Power Outage Procedures

The information below is provided as a guideline. Consult your local public health office or immunization program* for any special instructions or forms.

If there is an ongoing power outage, take the following steps:

1) Do not allow the vaccine to remain in a nonfunctioning unit for an extended period of time. If you are unsure that the problem can be corrected in time to maintain an appropriate temperature, activate the Urgent Vaccine Storage and Handling Protocols. (*See Urgent Vaccine Storage and Handling Protocols in Section 2—Vaccine Storage and Handling Protocols and the Urgent Vaccine Storage and Handling Protocols Checklist in the Resources Section for more details*.)

Note: Even purpose-built fridges, especially those with glass doors, may not be able to maintain temperatures for longer than 30 minutes (anecdotal experience). Knowing the technical details of the refrigerator will help in the assessment. (*See Section 3—Vaccine Storage Equipment and Section 4—Vaccine Storage Practices for more details*.)

2) If it is a **scheduled, time-limited** power outage and you are **certain** the power will be restored before the vaccine storage unit temperature rises above the recommended range, take the following steps:

- Do not open the refrigerator or freezer door until the power is restored. Staff should be aware of the specific defrost timeframe of their refrigerator and/or freezer.
- Continue to monitor the temperatures inside the vaccine storage unit if the thermometer allows temperature monitoring **without** opening the storage unit doors.
- Record the room temperature and the temperature(s) inside the unit(s) at the time the problem is discovered, as well as the minimum and maximum temperatures reached inside the unit(s) during the power outage.
- Record the room temperature and the temperatures inside the vaccine storage units as soon as possible after power has been **restored**. Note the length of time the power has been off and the maximum temperature observed.
- If the temperature inside the refrigerator has exceeded the recommended +8˚C or if the temperature inside the freezer has risen above -15˚C, record the duration of inappropriate temperature exposure and follow the procedures in *"Steps in Handling Inappropriate Vaccine Storage Conditions (Light and Temperature)" earlier in this section.*

6.6 REFERENCES

1. World Health Organization. *Thermostability of vaccines*. Geneva, World Health Organization, 1998. (WHO/GPV/98.07)

* Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs

Vaccine Storage and Handling Guidelines:

SECTION 7 STABILITY GUIDELINES AND RESOURCES

Contents

7.1 STABILITY GUIDELINE RESOURCES

New vaccine development has increased dramatically in recent years. The increasing number of and changes in licensed products makes it very difficult to keep a table of vaccines and their stability guidelines current. Availability of specific recommendations may vary at any given time.

- For the latest information about product storage and handling, vaccine providers are encouraged to consult the manufacturer's product monographs, and your local public health office or immunization program.*
- The following resources are also recommended:
  - The current *Canadian Immunization Guide*[1]
  - *Compendium of Pharmaceuticals and Specialties*[2]
  - *Thermostability Guidelines*[3]
  - *Vaccine Identification Database System* (VIDS), is an on-line database that will be available in the near future. It provides up-to-date information on all vaccines licensed in Canada.

Maintaining and Updating Information

It is recommended that all facilities maintain a binder or charts that outline the basic shipping and handling information for each vaccine provided by the facility. The information should be updated when new information and products become available. This information should be readily accessible to all providers.

Basic information on each vaccine should include the following:

- Shipping requirements
- Storage requirements
- Shelf life
- Instructions for reconstitution (if applicable)
- Shelf life of multi-dose vaccines after opening
- Special instructions

It is recommended that all facilities maintain a binder or charts that outline the basic shipping and handling information for each vaccine provided by the facility. The information should be updated regularly.

7.2 A WORD OF CAUTION

Do not discard vaccines or diluent prior to determining their integrity. **When a cold break is suspected**, consult your local public health office or immunization program* because jurisdictions may maintain more detailed and jurisdictionally approved stability guidelines to aid in the assessment of cold chain breaks.

Do not discard vaccines or diluent prior to determining their integrity. WHEN A COLD CHAIN BREAK IS SUSPECTED consult your local public health office or immunization program*.

7.3 REFERENCES

1. National Advisory Committee on Immunization. *Canadian immunization guide*. 7th ed. Ottawa, Ont.: Public Health Agency of Canada, 2006. (Minister of Public Works and Government Services Canada. Cat. No. HP40-3/2006E)

2. Canadian Pharmaceutical Association. *Compendium of pharmaceuticals and specialties*. 41st ed. Ottawa, Ont.: Canadian Pharmaceutical Association, 2006.

3. World Health Organization. *Thermostability of vaccines*. Geneva, World Health Organization, 1998. (WHO/GPV/98.07)

* Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Vaccine Storage and Handling Guidelines:

SECTION 8 VACCINE MANAGEMENT

Contents

8.1 VACCINE MANAGEMENT

Limit access to the vaccine supply to authorized personnel only. This will help protect the vaccine supply by avoiding inappropriate removal of vaccine or inappropriate handling of vaccine and vaccine storage units by untrained personnel.

8.2 EXPIRATION DATES

Interpreting Expiration Dates

All vaccines and diluents have expiration dates. The expiration date is the date by which the vaccine or diluent should be used. This date is labeled on all vaccine and diluent containers (e.g. vials, syringes, ampoules) and their package boxes.

Expiration dates vary by the type of vaccine or diluent, and by the lot number. The vaccine or diluent may be used up to and including this date. **When the expiration date is marked with only a month and year, the vaccine or diluent may be used up to and including the last day of the month indicated on the vial**.

What to Do with Expired and Mishandled Vaccine or Diluent

Expired vaccine and diluent, even if they are only one day past the expiration date, should **never** be administered. Likewise, vaccines that have been mishandled should not be administered. If expired vaccine is inadvertently given, contact your local public health office or immunization program* for advice. Record the lot number and expiry date of the immunizing agent. Promptly remove expired or mishandled vaccine and diluent from the refrigerator or freezer and place in a container marked "DO NOT USE." Return it or dispose of it according to public health guidelines or policies. Consult your local public health office or immunization program* for specific policies regarding the disposition of mishandled or expired vaccine.

Expired vaccine and diluent, even if they are only one day past the expiration date, should never be administered.

Exceptions to the Expiration Date

The expiration date labeling each vial or box is valid only if proper storage and handling conditions are observed at all times. If vaccine has been inappropriately exposed to excessive heat, cold, or light, its potency may be reduced **before** the expiration date is reached.

The only way to determine if proper transport and storage conditions have been maintained is to monitor vaccine and diluent temperatures during every link in the cold chain and to safeguard light sensitive vaccines from exposure to light. The manufacturer-labeled expiration date may also be invalidated after the vial is opened or reconstituted. (*See "Expiration of multidose, single dose, and select vaccine products" later in this section for details*.)

Transferring Vaccine or Diluent that Cannot Be Used Before Expiration

If you determine that a product cannot be used prior to expiry date, contact your local public health office or immunization program* for guidance. You may be able to transfer the product under appropriate cold chain conditions to another facility where it can be used before it expires.

Expiration of Multidose, Single Dose, and Select Vaccine Products

Some multidose premixed vaccine vials contain bacteriostatic agents that prevent the growth of bacteria. Once punctured, multidose vials should be marked with the date of puncture, maintained under appropriate storage conditions, and should be used within the timeframe specified by the manufacturer.

Single-dose vials are meant for one-time use only. To avoid needless waste of vaccine, **always** check the vial or syringe before removing the cap to make sure you have the correct vaccine type, and remove the cap only when you are ready to draw up and administer the vaccine. Single-dose vials without their protective caps should be discarded at the end of the clinic day even if there is residual volume.

Following reconstitution of vaccines, consult the package insert for the most up-to-date information about expiration times and dates. Unused reconstituted vaccines kept beyond recommended limits should not be administered. The best way to avoid such waste is to reconstitute and draw up vaccines immediately before administration.

Once punctured, multidose vials should be marked with the date of puncture and should be used within the timeframe specified by the manufacturer.

8.3 INVENTORY MANAGEMENT

General Recommendations

Inventory management is important for vaccine quality management. Proper inventory management means knowing the following:

- Quantities of vaccines and diluents that have been received
- Quantities of vaccines and diluents that have been administered, wasted, or spoiled
- Vaccines and diluents, and the quantities that are currently in stock and are available for administration
- Vaccines and diluents, and the quantities that are currently in quarantine awaiting follow-up directions
- Vaccine and diluent vials that should be used first
- Vaccine and diluent vials that are expired and that must not be administered
- Vaccines and diluents that need to be ordered

The vaccine coordinator should arrange the vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives. The vials and boxes with the earliest expiration dates should be placed in front of other vials and boxes of the same type with later expiration dates. This practice avoids waste by ensuring that short-dated vaccine and diluent are easily accessible and will be used first, thereby limiting the amount of unused vaccine that has passed its expiration date.

The vaccine coordinator should arrange the vaccine and diluent supplies according to the expiration dates on a weekly basis and each time a vaccine shipment arrives.

Vaccine Inventory Calculations and Vaccine Ordering

In general, there are three main principles to keep in mind when calculating the amount of vaccine supplies needed and when placing vaccine orders.

- **Order and stock enough vaccine to ensure that there is an adequate supply to meet the needs of the population served**. An adequate supply for most practices would normally be enough vaccine to last 30 days. Consult your local public health office or immunization program* for recommendations on different supply levels, depending on local use.
- **Do not over order vaccines**. This practice leads to vaccine waste if unused vaccine expires. It also results in unnecessarily large volumes of vaccine being stored, which increases the risk of losing a large quantity of vaccine should there be a cold chain break.

- **Alert office staff** that an order has been placed. The designated vaccine coordinator should be notified immediately upon arrival of a vaccine shipment so that the vaccine is stored under appropriate conditions and the cold chain is maintained. (*See Receiving and Unpacking Vaccine Shipments in Section 9—Vaccine Shipments for more details.*) Vaccine shipments must also be documented in the appropriate inventory record.

Use the Monthly Vaccine Inventory and Refrigerator and Thermometer Maintenance in the Resources Section.

The three main principles to keep in mind when calculating the amount of vaccine supplies needed and when placing vaccine orders are:

- Order and stock enough vaccine to ensure that there is adequate supply to meet the needs of the population served
- Do not over order vaccines
- Alert office staff that an order has been placed.

Inventory Records

Maintaining complete and accurate inventory records is a critical component of inventory management to prevent over- or under-stocking of supplies and disruption to the immunization program. This also contributes to planning for seasonal fluctuations in inventory, such as during an influenza program or school-based program. The balance of doses remaining in stock as indicated on the inventory records should be updated weekly, using a tally of doses administered, wasted, spoiled, or expired that week.

Quantities of vaccine and corresponding diluent must be equal at all times.

Each inventory record should contain the following:

- Date each shipment arrived at the facility
- Initials of the person who unpacked and checked the shipment upon arrival (This person should also record the shipment on the inventory record.)
- Condition of the shipment upon arrival (i.e. Did the vaccine arrive in good condition at the proper temperature or was there a reason to question its integrity?)
- For each vaccine and diluent:
  - Manufacturer and lot number
  - Quantity of units received per lot number (or the balance of doses carried forward)
  - Expiration date for each lot (including the new expiration dates for punctured multi-dose vials and times for vaccines that have been reconstituted)
  - Type of container (i.e. single-dose vial, multidose vial, or manufacturer-filled syringe)

- Number of doses used (i.e. administered, wasted, spoiled, or expired)
- Balance remaining (in **doses**) after subtracting the amount used (i.e. administered, wasted, spoiled or expired)

If you receive multiple vials of the same vaccine in the same type of container (i.e. single-dose vial, multidose vial, or manufacturer-filled syringe) from the same lot with the same expiration date, these **doses** may be recorded as one entry on the inventory record. Simply indicate the total number of doses of that particular vaccine (regardless of the number of vials or syringes those doses came in).

Use the Monthly Vaccine Inventory and Refrigerator and Thermometer Maintenance sheet that can be found in the Resources Section. It shows the components that you may include on your own inventory record.

Maintaining complete and accurate inventory records is a critical component of inventory management to prevent over- or under-stocking of supplies and disruption to the immunization program.

Tally Sheets

A running tally sheet must be used to record vaccine doses and diluent that were removed from or returned to the vaccine storage unit. These include doses that were administered, wasted, spoiled, or expired. Each time a dose of vaccine is removed or returned, it should be marked on a tally sheet that is placed on the outside of the storage unit door or in some other convenient location. Tick marks can be used to record doses that have been removed from the storage unit. Alternatively, the initials of the person removing the dose may be used.

The tally sheet(s) can be used to keep inventory records updated. For example, place a tally sheet on the storage unit door and record the doses removed from the unit during the week. At the end of the week, the vaccine coordinator or a designated person should add up the number of doses of each vaccine used and update the inventory records accordingly to determine the new inventory balance at the end of the week. Store used tally sheets in a file for future reference for the length of time determined by your jurisdiction.

Use the Vaccine Tally Sheet in the Resources Section. It shows the components that you may include on your own tally sheet.

A running tally sheet must be used to record vaccine doses and diluent that were removed from or returned to the vaccine storage unit. The tally sheet(s) can be used to keep inventory records updated.

Recording New Shipments

See Receiving and Unpacking Vaccine Shipments in Section 9—Vaccine Shipments for details.

Recording Administered, Wasted, Spoiled and Expired Doses

Consult pertinent local policy for vaccine inventory management requirements for recording and reporting of vaccine use or reasons for not using the vaccine. Maintaining a tally sheet where each dose of vaccine is accounted for will help with inventory management.

Counting Inventory

An actual count of the number of doses of vaccine and diluent in inventory is an important component of inventory management and is the responsibility of the designated vaccine coordinator.

- At the end of every month, make a summary of the amount of each vaccine and diluent used during that month and the amount of inventory still available at the end of that month. This information is useful in determining how much vaccine to order and can be used to monitor the seasonality of vaccine use.
- At the end of every year, total the amount of each vaccine and diluent received and the amount used. This information is useful for determining the annual vaccine needs of the practice.

*Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Vaccine Storage and Handling Guidelines:

SECTION 9 VACCINE SHIPMENTS

Contents

9.1 STANDARD OPERATING PROCEDURES

It is important to establish a routine, systematic process for handling vaccine shipments and vaccine transport. Each facility should develop its own written standard operating procedures (SOP), covering every aspect of vaccine shipping: receiving, storing, packing, and transportation. Written SOPs are useful for reference, training, and evaluation and should be included in the Routine Vaccine Storage and Handling Protocols. (*See Section 2—Vaccine Storage and Handling Protocols and the Routine Vaccine Storage and Handling Protocols Checklist in the Resources Section for more details.*)

9.2 RECEIVING AND UNPACKING VACCINE SHIPMENTS

Receiving Vaccine Shipments

All staff members who accept vaccine deliveries must be aware of the importance of maintaining the cold chain and of the need to **immediately notify** the designated vaccine coordinator of the arrival of the vaccine shipment so that it can be handled and stored appropriately.

Checking and Documenting the Condition of a Shipment

When the vaccine shipment is received, it should be examined and refrigerated immediately.

- Open and examine the shipping container and its contents for temperature monitoring device/indicators and for any signs of physical damage.
- Read and/or stop the recording of the temperature monitoring device upon receipt to determine if they have been activated or alarmed.
- Determine if the shipping time was less than 48 hours. If the interval between shipment from the supplier and arrival at its destination was more than 48 hours, the chance of a cold chain break is greater.
- Crosscheck the contents with the packing slip to be sure they match. Remove **all contents** of the shipping container before returning or storing the shipping container to ensure that all vaccines have been removed and stored appropriately. If there are any discrepancies with the packing slip immediately notify the designated vaccine coordinator.
- Check the vaccine expiration dates to ensure that you have not received any vaccine or diluent that is already expired or that is short dated.
- Examine the vaccine and diluent for heat or cold damage.
  - Check the cold chain monitor(s) or data loggers to see if the vaccine or diluent has been exposed to temperatures outside the recommended range during transport.

  - Check that inactivated vaccines are cold but not frozen. Refrigerated packs should still be cold. Frozen packs can be melted but the package should still be cold. Vaccines should not be in direct contact with refrigerated or frozen packs. There should be an insulating barrier between the vaccine and the refrigerated or frozen packs, such as crumpled brown packing paper or bubble wrap.
  - Check that diluent is cool or at room temperature. Diluent should not be in direct contact with refrigerated or frozen packs. There should be an insulating barrier between the diluent and the refrigerated or frozen packs.
  - Check that frozen vaccines are frozen.
- If there are any concerns about the shipment, mark the vaccine and diluent as "DO NOT USE" and store it under appropriate conditions apart from other vaccine supplies until the integrity of the vaccine and diluent is determined.

When the vaccine shipment is received, it should be examined and refrigerated immediately.

9.3 TRANSPORTING VACCINE TO OFF-SITE CLINICS

General Recommendations

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

When transporting vaccines using a personal vehicle, do not place vaccine inside the trunk of the vehicle. The temperature inside the trunk cannot be regulated. Avoid placing the vaccine in direct sunlight, or directly in line with air from the vehicle's heater and air conditioner. Vaccine should not be left unattended in the vehicle. Staff should be instructed to deliver the vaccine directly to the appropriate personnel as soon as possible.

Ensure you are aware of jurisdictional guidelines on transporting open multidose vials. Before transporting open multidose vials to a hospital or health centre, always ensure you know their regulations. Many facilities do not accept open multidose vials due to potential contamination.

The best assurance of vaccine efficacy is to minimize the number of times vaccines are handled and transported. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

Transporting Diluent

Those diluents that can be stored at room temperature may be transported either at room temperature or inside the same insulated cooled container as its corresponding vaccine. If transported inside cooled containers with vaccine, diluent must not be in direct contact with refrigerated/frozen packs and must be refrigerated at least 24 hours in advance so as to not raise the temperature of the cooler and the refrigerated vaccines.

If transporting diluent inside an insulated container with vaccine, diluent must not be in direct contact with refrigerated/frozen packs and must be refrigerated at least 24 hours in advance so as to not raise the temperature of the cooler and thus refrigerated vaccines.

Packing Vaccine for Transport to Off-Site Clinics

Packing vaccines for transportation is an art unto itself with many variables to consider, including the ambient temperature, the distance and time in transit, the mode of transportation, and the amount of vaccine being packaged.

Qualification is the process of testing material resulting in a high degree of assurance that a specific process will meet its pre-determined acceptance criteria[1]. It is important to test and qualify the method of packing vaccines in order to maintain the cold chain during transportation. The container and packing materials tested should take into account the variables mentioned above.

A consistent approach to packing vaccines must be developed and qualified. Some of the basic principles include:

- An insulated and temperature monitored container must be used when transporting vaccines.
- Pack enough refrigerated or frozen packs to maintain the cold chain.
- Do not use loose or bagged ice.
- The number and placement of refrigerated or frozen packs inside the container will depend on container size, the ambient temperature, and the volume of vaccine.

Vaccines should be transported in insulated containers that have been internally qualified (tested to meet the specific transportation requirements of the region or jurisdiction) to ensure they are capable of maintaining the vaccine at the correct temperatures for the necessary duration. The shipping containers the vaccine arrived in from the manufacturer may be used to transport vaccine if they meet the criteria. Alternatively, use hard-sided plastic insulated containers or newer styrofoam coolers with at least 2-inch thick walls. Banged-up old styrofoam containers and thin-walled styrofoam coolers, such as those purchased to hold beverages, are not acceptable because they cannot consistently maintain appropriate temperatures.

Summer and winter packing configurations will vary by jurisdiction. Consult your local public health office or immunization program* for more information. For example, summer configurations might include insulated material on the bottom of the insulated container, ice packs (preconditioned according to manufacturer's recommendations), gel packs preconditioned to +5˚C, insulating barrier, temperature-monitoring device and vaccine, insulating barrier, gel pack preconditioned to +5˚C, ice pack (preconditioned according to manufacturer's recommendations), insulating material on top, and frozen ice packs on top with an insulated cover. A winter configuration may include the same materials as the summer configuration, except top packs are not frozen but refrigerated packs, preconditioned to +5˚C. In extreme conditions, frozen ice packs may not be used at all.

There are two main types of cooling packs: refrigerator-conditioned (refrigerated at +2˚C to +8˚C) and frozen packs available for packing vaccines. The use of these packs for transporting vaccines will depend on the ambient temperature, the amount and type of vaccine, and the size of the container.

Packing vaccines for transportation is an art unto itself with many variables to consider, including the ambient temperature, the distance and time in transit, the mode of transportation, the size of the container and the amount of vaccine being packaged.

It is very important to qualify a consistent approach to packing vaccines in order to maintain vaccines at the appropriate temperatures during transport.

Ice packs

An ice pack is a flat rectangular plastic container designed to be 7/8 filled with water, frozen, and then used to keep vaccines at the recommended temperatures. Ice packs may have a removable lid for filling or be pre-filled and sealed. Ice packs that are filled with tap water and frozen are the safest type for maintaining the recommended vaccine storage temperature of +2˚C to +8˚C inside a cold box[2].

Commercial coolant packs

There are many different types of gel packs that contain coolants that depress the melting point and ensure the coolant remains cooler than 0˚C for longer than water-filled ice packs[2].

Caution: There are coolant packs that have freezing points below 0˚C and may present a risk of freezing vaccines unless they are properly conditioned before use in the cooler[2].

Before purchasing coolant products, request the following information from the manufacturer:

- Validation of their claim about the product's cold life
- Clear instructions on how to freeze and condition the product before use, and how to use them to pack vaccines

Note: Insulating and filler material should not be stored in the same refrigerator as vaccines (whenever possible), since placing room temperature items in the refrigerator may affect the fridge's operating temperature and take up too much space.

Basic principles for packing vaccines

1) Vaccines should be packed in layers using the following materials: refrigerated and/or frozen packs, insulating barrier (e.g. bubble wrap, crumpled brown packing paper, styrofoam peanuts), vaccine, a temperature monitor, and filler materials (may be the same as those used as insulating barriers) to prevent shifting of the contents during transport. The number and placement of refrigerated or frozen packs inside the container will depend on container size, outside temperature, and jurisdictional variations in storage and handling materials.

2) Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, styrofoam peanuts) between the refrigerated or frozen packs and the vaccines to prevent accidental freezing.

3) Pack vaccines in their original packaging on top of the barrier. Do not remove vaccine vials from boxes. Be sure to fill any spaces between vaccine boxes with crumpled paper or other filler to prevent shifting of contents in the insulated container.

4) Use a properly placed min/max thermometer, data logger, or cold chain monitor near the vaccine. The temperature-monitoring device should be placed in the middle of the vaccines and should not come in contact with the refrigerated or frozen packs.

5) Record vaccine type(s), lot numbers, brand names, quantity, date, time, and originating facility on a packing slip on the inside of the container.

6) Attach labels to the outside of the container to clearly identify the contents as being valuable, fragile, and temperature sensitive vaccines that require refrigeration immediately upon shipment arrival.

9.4 MAINTAINING TEMPERATURES DURING OFF-SITE CLINICS

Vaccine must be maintained between +2˚C and +8˚C during an off-site clinic and should be stored in an insulated container. Pack enough refrigerated or frozen packs to maintain the cold chain. The number and placement of refrigerated or frozen packs inside the container will depend on container size, the ambient temperature, the volume of vaccine and jurisdictional variations. The combination of insulated container and packing material should be qualified to take into account these variables in order to maintain vaccines between +2˚C and +8˚C, during an off-site clinic.

Keep the container closed as much as possible. A thermometer must be kept in the container with the vaccines, and temperatures checked and recorded periodically to ensure that the cold chain is not broken.

Record temperatures before leaving the facility, periodically during the clinic and upon return to the office, as per jurisdictional recommendations.

9.5 REFERENCES

1. Bishara RH. *Qualification versus validation and good cold chain management practices*. Pharmaceutical Manufacturing and Packing Sourcer 2005: 102, 104, 106.

2. Kempe A. *Bulk storage and transport of vaccines including outreach clinics*. In: Langley A, Grant S, eds. *Proceedings of the National Vaccine Storage Workshop*. 1st ed. Brisbane: Queensland Health, 2004: 67-86.

National Vaccine Storage and Handling Guidelines for Immunization Providers: Resources Section

Routine Vaccine Storage and Handling Protocols Checklist* (Sections 2 and 9)

The following is a suggested checklist of items that may be included in the routine vaccine storage and handling protocols. The protocol should be available in an accessible area near the vaccine storage unit. See Section 2 for details.

Checklist

- ❑ Up-to-date contact information for the:
  - ○ Designated vaccine coordinators
  - ○ Provincial, territorial, or local health department immunization program
  - ○ Refrigerator and freezer maintenance and repair company(s)
  - ○ Vaccine storage unit alarm company (if applicable)
  - ○ Sources of packing materials and calibrated thermometers
- ❑ Descriptions of the roles and responsibilities of the designated vaccine coordinators
- ❑ Descriptions of the roles and responsibilities of other staff members
- ❑ Summaries of the storage requirements for each vaccine and diluent in your inventory

Protocols for:

- ❑ Vaccine storage unit temperature monitoring
- ❑ Vaccine storage equipment maintenance
- ❑ Placement of vaccine within storage units
- ❑ Responding to vaccine storage and handling problems
- ❑ Vaccine inventory management
- ❑ Transporting and receiving vaccine shipments
- ❑ Disposal of vaccines and diluents as directed by jurisdictional policy or guidelines
- ❑ Samples of the forms used in your immunization program

*Adapted from CDC Vaccine Storage and Handling Toolkit (2005)

Contact List for Routine Vaccine Storage and Handling (Section 2)

Designated Vaccine Coordinators					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Primary Coordinator					
Backup Coordinator					
Program Resource Contact List					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Provincial or Territorial Immunization Program					
Local Immunization Program					

Supplier Resource Contact List					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Electric power company					
Refrigerator repair company					
Thermometer supplier					
Security alarm company (if applicable)					
Insulated containers or coolers					
Refrigerated or frozen cold packs					
Dry ice vendor (if applicable)					
Fillers (i.e. bubble wrap, styrofoam)					
Other					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**

Urgent Vaccine Storage and Handling Protocols Checklist* (Sections 2 and 6)

The following is a suggested checklist of the items that may be included in the urgent vaccine storage and handling protocols. The protocols should be available in an accessible area near the vaccine storage unit. See Section 2 for details.

Checklist

- ❑ Emergency staff contact list in order of contact preference
- ❑ Designated vaccine coordinators
- ❑ The designated vaccine coordinators outlined roles, including:
  - ○ Monitor the operation of the vaccine storage equipment and systems.
  - ○ Track inclement weather conditions.
  - ○ Set up and maintain a monitoring and notification system during times of inclement weather or other conditions that might cause a power outage (a continuous-monitoring temperature alarm and notification system should be considered, especially for sites with large inventories).
  - ○ Ensure the appropriate handling of the vaccine during a disaster or power outage.
  - ○ Ensure 24-hour access to the building and vaccine storage unit(s).
  - ○ Ensure that sufficient fuel and/or battery power is on hand to continuously run the generator for at least 72 hours if the facility has a backup generator.
- ❑ Up-to-date contact information for the:
  - ○ Designated vaccine coordinators
  - ○ Drivers to transport vaccines to alternate facility
  - ○ Provincial, territorial, or local health department immunization program
  - ○ Electric power company
  - ○ Refrigerator and freezer maintenance and repair company(s)
  - ○ Emergency generator repair company
  - ○ Vaccine storage unit alarm company (if applicable)
  - ○ Sources of packing materials and calibrated thermometers
  - ○ Weather service
- ❑ Vaccine storage unit specifications (type, brand, model number, serial number)
- ❑ Alternate vaccine storage facility or facilities

*Adapted from CDC Vaccine Storage and Handling Toolkit (2005)

- ❑ Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility
- ❑ Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours
  - ○ These instructions should include the building security/after-hours access procedure, a floor diagram, and the locations of the following:
    - Doors
    - Flashlights
    - Spare batteries
    - Light switches
    - Keys
    - Locks
    - Alarms (including instructions for use)
    - Circuit breakers
    - Packing materials
- ❑ Appropriate packing materials to safely transport or temporarily store vaccine
- ❑ Written protocol for vaccine packing
- ❑ Written protocol for appropriately storing vaccine at the alternate vaccine storage facility

*Adapted from CDC Vaccine Storage and Handling Toolkit (2005)

Contact List for Urgent Vaccine Storage and Handling (Section 2)

Designated Vaccine Coordinators					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Primary Coordinator					
Backup Coordinator					
Driver of Vehicle					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Primary Driver					
Backup Driver					

Emergency Staff Contact List					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Emergency Resource Contact List					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Provincial or Territorial Immunization Program					
Local Immunization Program					

Supplier Resource Contacts					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**
Electric power company					
Emergency generator repair company					
Refrigerator repair company					
Temperature alarm monitoring company					
Security alarm company (if applicable)					
Weather service					
Alternate vaccine storage facility					
Other					
Title	**Name**	**Phone #**	**Cell #**	**Pager #**	**Email**

Suspected Cold Chain Failure Exposure and Wastage Report* (Sections 2 and 6)

Health Unit, Region Name: _____

Section A : Health Unit or Facility Information	
Date of report:	
Report completed by:	
Fax #:	
Phone #:	

Facility Name:

Contact Name, if other than reporter:

Telephone #:

Fax #:

Detected on Annual inspection: Yes ☐ No ☐
Date of most recent inspection: _____

Section B: Incident Description	
Discovery date:	
Discovery time:	

Date and time of last known temperature consistently between +2°C and +8°C

Date:_____ Time: _____

Temperature at time of discovery:

Min:_____ Max:_____ Current:_____

Estimated duration of exposure: _____hours

_____days _____weeks

Was there any expired vaccine discovered at facility?

Yes ☐ No ☐

Please check the box that applies to the cold chain failure and describe the event briefly.

☐ Equipment malfunction: (e.g. thermometer, alarm)

☐ Fridge malfunction: (i.e. sensor, compressor)

☐ Power failure:
How long was the power disrupted? _____
What time of day was the disruption? _____
What was the cause of disruption? _____

☐ Human error:
(e.g. fridge door left open, fridge unplugged)

☐ Other: (Describe)

Complete if transportation involved

Date _____ and time _____products were packed. Air ☐ Land ☐

Date _____ and time _____products were unpacked.

Describe container : _____

Describe transport (i.e. car, courier, bus): _____

Temperature exposed to during transport: _____

Condition of gel or ice packs on arrival (i.e. number, frozen, cold or warm, left on counter):

_____

_____

Describe filler used: _____

Temperature monitoring device(s) used: _____

☐ Products labeled "DO NOT USE" and moved to appropriate storage conditions

☐ Determine vaccine stability using charts and report finding to office or facility

☐ Advise facility to mark vaccine to indicate single exposure and to use vaccine first

Comments: _____

_____

*Adapted from Alberta Health and Wellness (2006)

Vaccine Inventory: Cold Chain Failure

Health Unit, Region:_____ **Facility:** _____

Vaccine	# Packages	# Un-opened doses	# Open multi-dose vials	Lot #	Expiry date	Previous exposure		Can be used and mark as exposed	**Do not use, return vaccine**	Approximate value of returned vaccine (s)
						Yes	No			
Other										

Approximate Value of Returned Vaccine:	**$**

*Adapted from Alberta Health and Wellness (2006)

Monthly Vaccine Inventory and Refrigerator and Thermometer Maintenance* (Sections 3 and 8)

Date: _____

Health Centre: _____

Primary Vaccine Co-ordinator: _____

Back-up Vaccine Co-ordinator: _____

Refrigerator and Thermometer Maintenance

Refrigerator Maintenance

Refrigerator Type: _____ Year Received: _____

a) Cleaning

Motor and coils Date: _____ Completed by _____

Fridge and freezer Date: _____ Completed by _____

b) Door seals checked Date: _____ Completed by _____

c) *Manual defrost refrigerators only*:

Defrosting Date: _____ Completed by _____

d) Refrigerator Repairs Date: _____ Completed by _____

Details:

_____

_____

_____

_____

Min/Max Thermometer (circle one)

Thermometer Type: _____ Year Received: _____

a) Battery replaced or changed Date: _____ Completed by_____

b) Probes/cables checked Date: _____ Completed by_____

c) Calibration (slush test) Date: _____ Completed by_____

Results/Action taken:

_____

_____

_____

*Adapted from the First Nations Inuit Health Branch, Health Canada

Vaccine Inventory

Date: _____ Completed by: _____

Note: Record the vaccine and diluent together in the inventory sheet.

VACCINE	DATE RECEIVED	LOT NUMBER	EXPIRY DATE		CURRENT NUMBER OF DOSES
			SINGLE DOSE	MULTI-DOSE	
Diphtheria, Tetanus, acellular Pertussis, and inactivated Polio virus vaccine (DTaP-IPV)					
Haemophilus influenzae type b conjugate vaccine (HiB)					
Measles, Mumps, and Rubella vaccine (MMR)					
Varicella vaccine (Var)					
Hepatitis B (Hep B)					
Pneumococcal conjugate vaccine (Pneu-C)					
Meningococcal C conjugate vaccine (Men-C)					
Diphtheria, Tetanus, acellular Pertussis vaccine (adult) (dTap)					
Influenza vaccine (Flu)					
Other					

*Adapted from the First Nations Inuit Health Branch, Health Canada

Vaccine Tally Sheet* (Sections 2 and 8)

Instructions: The following information should be recorded for each vaccine inventory when it arrives. At the end of each week, doses used should be recorded. At the end of the month the balance should be recorded.

Vaccine Type: _____ **Month and Year: _____**

Date received or usage tallied	Person receiving shipment*	Arrival condition**	Vaccine or diluent name	Manufacturer	Vial type (S,M,Y)***	Lot number	Expiration date	Expiration date after reconstitution	Doses received or balance forward	Doses used§	Balance
	Beginning balance for the month									**NA**	
								Vaccine Total			**§§**

* The initials of the person who unpacked or checked the vaccine and/or the diluent upon arrival.
** Vaccines arrived in good condition
X Condition of vaccine questionable; document details on reverse.
*** S Single-dose vial.
M Multidose vial.
Y Pre-filled syringe
§ Include the number of doses administered, wasted, spoiled, expired or transferred.
§§ Enter the total of "total doses received or balance forward" minus "total doses used"
NA Not applicable

*Adapted from CDC Vaccine Storage and Handling Toolkit (2005)

Temperature Log for Vaccines (Celsius)* (Sections 3 and 5)

Month/Year:_____ Days 1–15

Completing this temperature log: Check the min/max temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for as long as your jurisdiction requires.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. **Store the vaccine** under proper conditions as quickly as possible. 2. Notify the designated **vaccine coordinator**. 3. **Document the action taken**.

Day of Month	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Staff Initials																														
Room Temp.																														
Exact Time																														
°C Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Too warm* +11°																														
+10°							Take immediate action if temperature is in shaded section*																									
+9°																														
Refrigerator temperature +8°																														
+7°																														
+6°																														
+5°																														
+4°																														
+3°																														
+2°																														
Too cold* +1°																														
0°							Take immediate action if temperature is in shaded section*																									
-1°																														

Too warm* • -12°																														
Freezer temp -13°							Take immediate action if temperature is in shaded section*																							
-14°																														
-15°																														
-16°																														
• -17°																														

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

www.immunize.org/news.d/celsiusp.pdf • Item #P3039A (1/07)

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

*Adapted from the Immunization Action Coalition

Temperature Log for Vaccines (Celsius)* (Sections 3 and 5)

Month/Year:_____ Days 16–31

Completing this temperature log: Check the min/max temperatures in both the freezer and the refrigerator compartments of your vaccine storage units at least twice each working day. Place an "X" in the box that corresponds with the temperature and record the ambient (room) temperature, the time of the temperature readings, and your initials. Once the month has ended, save each month's completed form for as long as your jurisdiction requires.

If the recorded temperature is in the shaded zone: This represents an unacceptable temperature range. Follow these steps: 1. **Store the vaccine** under proper conditions as quickly as possible. 2. Notify the designated **vaccine coordinator**. 3. **Document the action taken**.

Day of Month	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Staff Initials																																
Room Temp.																																
Exact Time																																
°C Temp	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm
Too warm* / Refrigerator temperature +11°							Take immediate action if temperature is in shaded section*																									
+10°																																
+9°																																
+8°																																
+7°																																
+6°																																
+5°																																
+4°																																
+3°																																
+2°																																
Too cold* / +1°							Take immediate action if temperature is in shaded section*																									
0°																																
-1°																																
Too warm* / Freezer temp • -12°							Take immediate action if temperature is in shaded section*																									
-13°																																
-14°																																
-15°																																
-16°																																
• -17°																																

Adapted by the Immunization Action Coalition courtesy of the Michigan Department of Community Health and the California Department of Health Services.

Technical content reviewed by the Centers for Disease Control and Prevention, Jan. 2007.

www.immunize.org/news.d/celsiusp.pdf • Item #P3039A (1/07)

Vaccine Storage Troubleshooting Record

Date	Time	Storage Unit Temp	Room Temp	Problem	Action Taken	Results	Initials

*Adapted from the Immunization Action Coalition

Checklist for Safe Vaccine Storage and Handling (Section 4)

Are you doing them all?

Yes	No	Checklist for Safe Vaccine Storage and Handling
		1. We have a designated vaccine coordinator.
		2. We have a designated back-up vaccine coordinator.
		3. All staff receives ongoing training.
		4. All new staff is trained at an appropriate level in proper storage and handling practices.
		5. A vaccine inventory log is maintained that documents:
		5a) Vaccine name and number of doses received
		5b) Date the vaccine was received
		5c) Arrival condition of vaccine
		5d) Initials of person unpacking shipment
		5e) Vaccine manufacturer and lot number
		5f) Vaccine expiration date
		5g) Type of container of each vaccine
		5h) Number of doses used
		5i) Number of doses remaining
		6. Our refrigerator for vaccines is either a purpose-built or a domestic frost-free style, NOT a bar-style. The freezer compartment has a separate exterior door.
		7. We do NOT store any food, drink or specimens in the refrigerator or freezer.
		8. We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.

Yes	No	Checklist for Safe Vaccine Storage and Handling
		9. We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.
		10. We check vaccine expiration dates and use those that will expire soonest first.
		11. We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.
		12. We always keep a min/max thermometer or data logger in the refrigerator and freezer.
		13. The temperature in the refrigerator is maintained between + 2°C and + 8°C.
		14. We keep extra containers of water in the refrigerator in appropriate areas.
		15. The temperature in the freezer is maintained at -15°C or colder.
		16. We keep ice packs and other ice-filled containers in the freezer.
		17. We record the minimum and maximum temperatures for the refrigerator and freezer, and the room temperature twice daily, first thing in the morning and at clinic closing time.
		18. We know whom to call if the temperature is out of range.
		19. We calibrate the thermometer using the slush test at least once a year and change batteries in thermometer or data loggers on a regular basis.
		20. We defrost the refrigerator regularly.
		21. We have a **Do Not Unplug** sign next to the refrigerator's electrical outlet.
		22. We check that the door is properly closed and sealed.
		23. In the event of a refrigerator failure, we take the following steps:
		23a) We assure that the vaccines are maintained under appropriate conditions

Yes	No	Checklist for Safe Vaccine Storage and Handling
		23b) We mark vaccines as having been exposed and separate them from undamaged vaccines.
		23c) We note the refrigerator or freezer temperature and the ambiant temperature and then always contact the local public health office or immunization program* to determine how to handle the affected vaccines.
		23d) We follow the local public health office or immunization program* instructions. If useable, we mark the vials with the revised expiration date provided by the program.
		24. We have a detailed written protocol for routine and urgent vaccine storage and handling.

If all above answers are **Yes** we are patting ourselves on the back.
If not, we will contact our local public health program for assistance in protecting our vaccine supply.

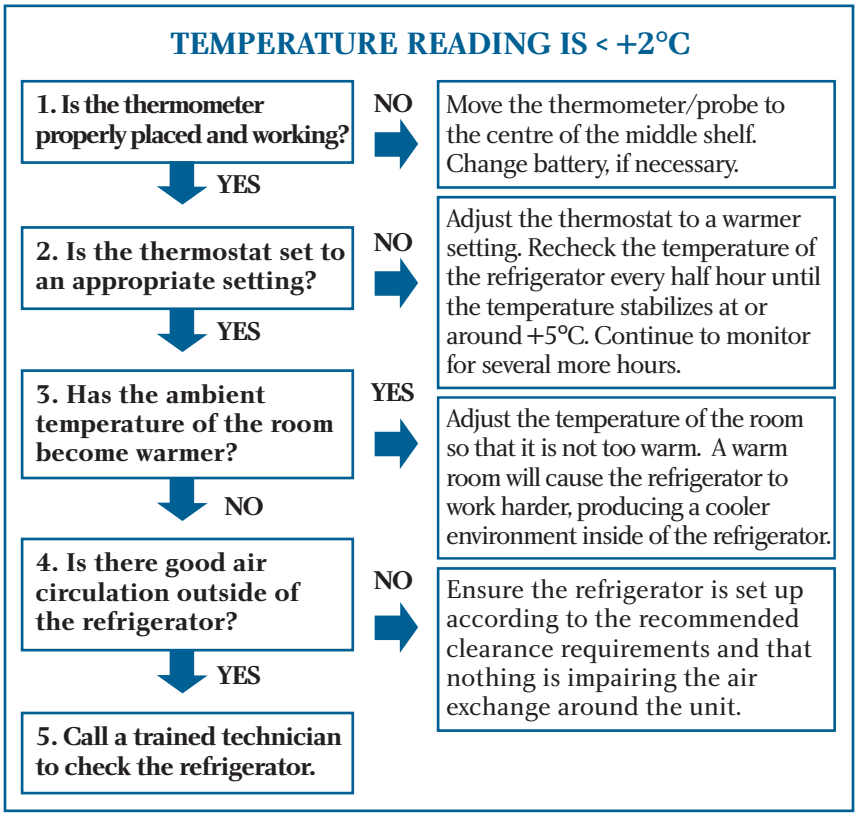
For more information, contact our local public health office or immunization program* at:

_____

* Including local, regional, provincial, territorial, or federal health departments, or other jurisdictional immunization programs.

Algorithm to Assess Problems in Temperature Readings Outside the Recommended Ranges* (Section 6)

Prior to assessment of the problem, move vaccine to a backup refrigerator or activate the Urgent Vaccine Storage and Handling Protocols.



Prior to assessment of the problem, move vaccine to a backup refrigerator or activate the Urgent Vaccine Storage and Handling Protocols.