

Vaccine Storage and Handling Guidelines

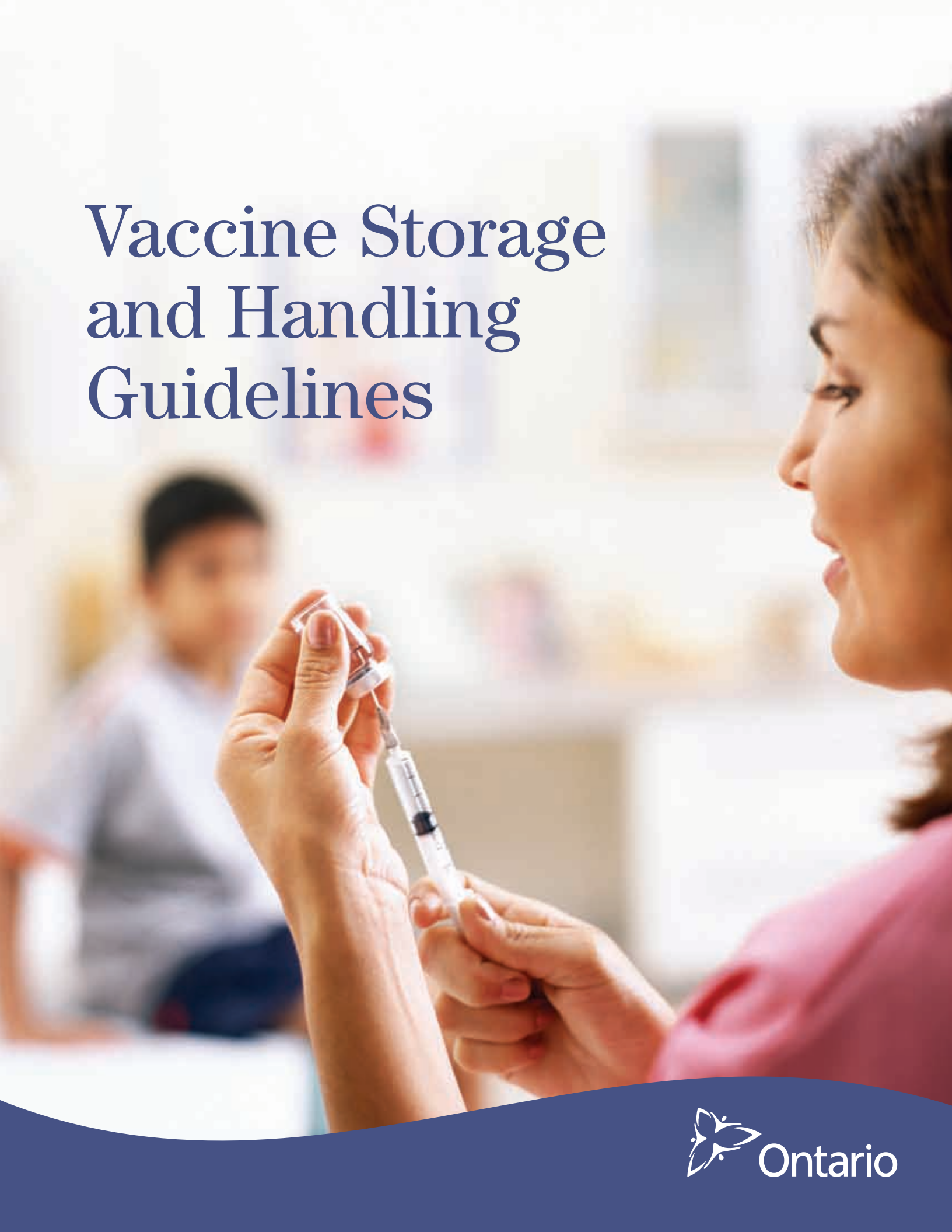


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Introduction

Immunization programs are among the most cost-effective ways to prevent disease. The success of these programs depends heavily upon the maintenance of vaccine potency and stability.

By understanding and implementing proper vaccine storage and handling practices, staff in physicians' offices and other health care facilities can play a critical role in improving the health of Ontarians by ensuring that the administered vaccines retain their potency and that vaccine wastage is reduced.

This document is intended to assist physicians' offices and other health care facilities to properly store and handle provincially funded vaccines.

Definitions

Cold Chain

The cold chain includes all of the materials, equipment and procedures used to maintain vaccines in the required temperature range of +2°C to +8°C from the time of manufacture until the vaccines are administered to individuals.

Exposed vaccine

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

Spoiled vaccine

Spoiled vaccine is vaccine that cannot be used because of exposure to temperatures below +2°C or above +8°C for a specific period of time. This will depend on the specific vaccine. The local public health unit assesses all provincially funded vaccines that have been exposed to determine whether they can be used.

Wasted vaccine

Any vaccine that cannot be used is considered to be "wasted." This includes vaccines that are spoiled and those that have expired.

The Importance of the Cold Chain

Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are exposed to heat and/or direct sunlight or fluorescent light. For example, certain vaccines lose potency when exposed to room temperature for as little as 30 minutes, or when exposed to light. Freezing damages most vaccines. Exposed vaccines can result in a reduced immune response and/or increased local reactions. The loss of vaccine potency cannot be reversed.

Protecting Ontario's Vaccine Supply

The Mandatory Health Programs and Services Guidelines, issued under the Health Protection and Promotion Act, require local public health units to inspect premises where provincially funded vaccine is stored, at least once annually. Recent inspections of refrigerators in physicians' offices and other health care facilities have shown that improper storage and handling of vaccines is still a significant problem in Ontario.

Vaccines may be wasted if they have been exposed to temperatures below +2°C or above +8°C, and are spoiled, or if they have expired before they can be used. Vaccine wastage results in increased costs (to replace the wasted vaccines). Also, with the globalization of the vaccine manufacturing industry, and intermittent global vaccine shortages, it is not always possible for Ontario to quickly obtain additional quantities of vaccines to replace vaccine that is wasted.

Patients/clients who are immunized with exposed vaccines often need to be recalled by the health care practitioner and reimmunized to ensure that they are protected against the specific vaccine preventable disease(s).



Maintaining Vaccine Potency and Minimizing Wastage

There are several key steps to ensuring that potent vaccines are administered to vaccine recipients:

- ▶ Monitor and document refrigerator temperatures twice daily (including the time the temperature was taken).
- ▶ Call your local public health unit immediately to report vaccines that have been exposed to temperatures below +2°C or above +8°C.
- ▶ Never administer or discard exposed vaccine until your local public health unit has assessed the situation.
- ▶ Spoiled or expired vaccine should always be returned to your source of supply (i.e., local public health unit or Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)).

Staff Designated to Monitor the Vaccine Storage and Handling Practices in the Office/Facility

Persons storing and handling provincially funded vaccines require knowledge of:

- ▶ The importance of the cold chain.
- ▶ Vaccine storage and handling practices.
- ▶ The appropriate action to be taken in the event of a vaccine exposure.

One person in each office/facility should be designated to monitor vaccine storage and handling practices to ensure that vaccines are kept at the required temperatures. However, all staff members should also be trained in reading the vaccine refrigerator thermometers, and documenting and monitoring the vaccine storage temperatures to provide backup in the event of staff vacations or other absences. Your local public health unit can assist you with this training.

Contingency Planning for Refrigerator Malfunctions or Electricity Disruptions

Each physician's office/facility should have a contingency plan for vaccine storage in the event of a refrigerator malfunction or electricity disruption. Arrangements should be made in advance with a facility that has a backup generator/power source.

You may wish to discuss this with your local public health unit. See page 15 for more information.

Vaccine Storage and Handling Practices

- ▶ To retain their potency and to be effective, most vaccines must be kept refrigerated between +2°C and +8°C at all times. For detailed vaccine storage and handling information, please refer to the specific product monograph.
- ▶ Always store vaccines on the middle shelves of the refrigerator. Never store vaccines in refrigerator door shelves as they may be exposed to warmer temperatures.
- ▶ Leave space between the vaccine packages in the refrigerator to allow air to circulate.
- ▶ Place vaccines of the same type together.
- ▶ Check vaccine expiry dates regularly. Always move vaccines with shorter expiry dates to the front of the refrigerator so that they can be used first. Always check expiry dates before you use vaccines. Remove expired vaccines and return them to your vaccine supply source.
- ▶ ALL VACCINES: Take vaccines out of the refrigerator only when ready to administer.
- ▶ MULTI-DOSE FORMAT: Return unused vaccine to the refrigerator immediately after the required dose has been drawn up. Mark the date on all multi-dose vials when the first dose is withdrawn. Once opened, multi-dose vials must be used within 30 days (unless otherwise indicated on the product monograph). Aseptic technique for the withdrawal of vaccines must be followed at all times.
- ▶ Protect all vaccines from sunlight and fluorescent light.
- ▶ Never leave vaccines out on the counter or the floor.

Maintaining the Required Refrigerator Temperature

- ▶ Ensure that your refrigerator capacity is large enough to store your vaccine supply. There must also be enough room to allow air to circulate around the vaccine packages.
- ▶ Do not store anything else (e.g., lunches, drinks, or laboratory specimens) in the refrigerator with vaccines.
- ▶ Minimize the number of times the refrigerator door is opened.
- ▶ Always ensure that the refrigerator door is closed tightly. Installing an inexpensive velcro latch from a hardware store can help ensure that the door is not accidentally left ajar during the day, or by cleaning staff after hours.
- ▶ Ensure that the electrical outlet and refrigerator plug are secured to prevent the refrigerator from accidentally being unplugged or turned off.
- ▶ Place a highly visible sticker by the electrical outlet to make sure that the refrigerator is not unplugged (e.g., to plug in a vacuum) OR cover outlet with a cage to prevent accidental disconnection. (See sticker provided.)
- ▶ Keep icepacks in the freezer compartment to use for transporting vaccines. In the case of a refrigerator malfunction or electricity disruption, icepacks can be put inside the refrigerator to keep the temperature from increasing.
- ▶ Defrost the refrigerator when there is more than 1 cm (1/4 inch) of ice in the freezer compartment. While defrosting the refrigerator, transfer vaccines to an insulated vaccine container (for no longer than three hours) with icepacks and a maximum-minimum thermometer OR transfer vaccines to another monitored refrigerator, and check the temperature regularly.
- ▶ Storing filled water bottles on the lower shelf and the door of the vaccine refrigerator may help maintain an even, stable temperature inside the refrigerator.



Checking, Recording and Monitoring the Required Refrigerator Temperature

- ▶ Maintaining accurate and up-to-date documentation of refrigerator temperatures is necessary to maintain vaccine potency. This information will also assist the public health unit in the assessment of cold chain exposures (determining the temperature variation and duration of exposure) should these occur. Your local public health unit staff will be able to determine whether any vaccine which has been exposed can still be used.
- ▶ Check and record the refrigerator temperature twice daily (preferably at the beginning and end of the day) to make sure that vaccines you will be using have been stored at the right temperature, and have not been exposed to temperatures below +2°C or above +8°C.
- ▶ Note: A refrigerator that feels cold may range in temperature from -5°C to +15°C, a definite risk to vaccine potency. Accurate thermometer readings are necessary to determine whether the vaccines are being kept at the required temperature to maintain their potency.

How to Use a Digital Maximum-Minimum Thermometer

There are several types of digital maximum-minimum thermometers available on the market.

Always use a digital maximum-minimum thermometer that is calibrated to within $\pm 1^{\circ}\text{C}$ accuracy. Your local public health unit can assist you in selecting an appropriate thermometer.

Each digital thermometer has slightly different operating instructions. Instructions for the use of one thermometer (Thermor brand) are included here.

- ▶ Attach the thermometer to the outside wall of the refrigerator using double-sided tape. Secure the cable to the centre of the middle shelf inside the refrigerator.
- ▶ The sensor of the digital thermometer should be placed inside the packaging of one of the vaccine packages that is stored on the middle shelf of the refrigerator. The packaging reduces the likelihood of the sensor measuring brief temperature fluctuations when the refrigerator door is opened. Do not place the sensor into fluid.

If the digital thermometer has an IN-OUT switch, make sure it is always in the **OUT** position.

- ▶ The OUT position actually reads the temperature **inside** the refrigerator, which is detected by the sensor at the end of the cable.
- ▶ The IN position reads the temperature **outside** the refrigerator, which is detected by the built-in sensor.
- ▶ You do not have to open the refrigerator door to take the temperature readings.
- ▶ Check and record the temperatures as follows:

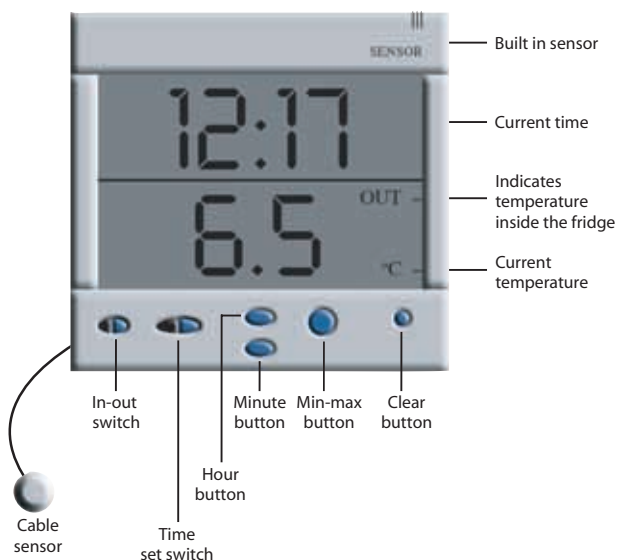
1. Check and record the current refrigerator temperature.
2. Check and record the maximum refrigerator temperature.
3. Check and record the refrigerator minimum temperature.
4. Always remember to reset the thermometer.

- ▶ To reset the thermometer, press the CLEAR button **twice: once** after the maximum temperature reading and **once** after the minimum temperature reading.
- ▶ Change the battery every six months (i.e., seasonal, with the time change) as a low functioning battery may give false temperature readings.
- ▶ Check your thermometer and always have spare batteries on hand.

Digital Maximum-Minimum Thermometer *continued*

What the Thermometer Reading Tells You

- ▶ The maximum (highest) temperature reached since the thermometer was last reset can be seen by pressing the memory maximum-minimum button. You will see the word MAX appear on the right portion of the display.
- ▶ The minimum (lowest) temperature reached since the thermometer was last reset can be seen by pressing the memory maximum-minimum button a second time. You will see the word MIN appear on the right portion of the display.
- ▶ Remember to reset your thermometer after recording the readings.



Data Loggers

Data loggers are continuous temperature recording devices, which offer a historical account of refrigerator temperatures. These devices store information which can be downloaded onto a computer. If your office/facility uses data loggers, please ensure that temperatures are monitored twice daily. Print the temperature readings out on a weekly basis and retain them for one year, or until the next inspection by your local public health unit.



Please contact your local public health unit immediately if any of the recorded temperatures are outside of the +2°C to +8°C range.

Packing a Cooler for Vaccine Transportation or Storage

- ▶ Pre-chill the insulated container (especially in the summer) by placing icepacks or coolant packs inside the cooler for at least an hour.
- ▶ Icepacks come out of the freezer at a temperature of approximately -20°C. Keeping the icepacks at room temperature for a period of time allows the ice at the core of the icepack to rise to 0°C. This process is called “conditioning.”
- ▶ An icepack is adequately conditioned as soon as beads of water cover its surface.

Note: Vaccines are vulnerable to freezing when transported in an insulated container if icepacks have not been correctly conditioned.

- ▶ Vaccines should be packed with a temperature-monitoring device (preferably a digital maximum-minimum thermometer) with the sensor placed in the centre of the vaccine package.
- ▶ The vaccine packages should be loosely wrapped in effective insulation material (e.g., bubble wrap, shredded paper). This allows for cool air circulation around the vaccines and minimizes the risk of ‘hot’ or ‘cold’ spots.

How to Transport Vaccines Outside the Office Setting

- ▶ Vaccines must be transported in insulated and monitored containers (coolers) so that they stay between +2°C and +8°C. An insulated vaccine cooler with icepacks and a thermometer is required to pick up the vaccines from the local public health unit and transport them to the office/facility. A vaccine cooler is also required to transport the vaccines from the office/facility to another location.
- ▶ Vaccines must be protected from heat, cold, sunlight and fluorescent light at all times.

An insulated container/cooler (which maintains the internal temperature within the +2°C to +8°C range with coolant packs) is used for:

- ▶ Transporting vaccine
- ▶ Temporary storage of vaccine during equipment maintenance periods (e.g., when cleaning or defrosting refrigerator)
- ▶ Emergency storage of vaccine (e.g., refrigerator malfunction or an electricity disruption)

Vaccines must never be transported in the trunk of a car due to the risk of exposure to temperature extremes.



Protecting Vaccines During Immunization Sessions/Clinics

- ▶ Only pack the amount of vaccine you expect to use during the immunization session/clinic.
- ▶ Maintaining the vaccines at the required temperature (between +2°C and +8°C) during an immunization session/clinic is important to ensure that the administered vaccine retains its potency.
- ▶ Minimize the number of times that the cooler is opened during the immunization session/clinic.
- ▶ Temperature readings in the insulated container/cooler should be recorded:

1. Before leaving the office/facility with the cooler.
2. Upon arrival at the clinic location, but prior to the immunization session/clinic.
3. Every three hours during the session/clinic (if the session/clinic is longer than three hours).
4. Upon completion of the session/clinic (before transport back to the office/facility).
5. After return to the office/facility, but before the vaccines are put back in the refrigerator.

This will ensure that the vaccines are maintained at the required temperatures throughout the process, and that the vaccines that are returned to the refrigerator have not been exposed to temperatures below +2°C or above +8°C.

During an electricity disruption, take action to protect your vaccines.

Electricity Disruptions (localized or general)

In this section, a non-functioning refrigerator refers to a refrigerator that is not functioning due to a **disruption of the electricity supply**.

Record the time and internal temperature (maximum-minimum and current) of the non-functioning refrigerator (as soon as possible after the start of the electricity disruption) in the vaccine temperature log book and reset the thermometer.

1. Electricity disruption of four hours or less:

The refrigerator door should be kept closed.

- ▶ You do not have to open the refrigerator door to take the temperature readings.

2. Electricity disruption continues for more than four hours:

Remove the vaccines from the non-functioning refrigerator, place them in an insulated container with icepacks (see page 9, “Packing a Cooler for Transport or Storage”).

If vaccines can be transported to a functioning and monitored refrigerator:

- ▶ If possible, transfer the vaccines to a functioning monitored refrigerator (i.e., in a facility that has power or a backup generator). The refrigerator should be monitored with a maximum-minimum thermometer.
- ▶ If the vaccines need to be transported, please follow the instructions on page 9 “Packing a Cooler for Transport or Storage.”

Note: If the only alternative is to transfer the vaccines to your home (which has power or a backup generator), transfer the vaccines to a separate refrigerator in your home, and monitor the refrigerator with a maximum-minimum thermometer.

Do not store the vaccines in the kitchen refrigerator, as the temperature fluctuates when the door is opened and closed.

Store the vaccines with the probe/sensor placed inside the packaging of one of the vaccine packages that is stored in the middle shelf of the refrigerator. Minimize the number of times the fridge door is opened. Continue to monitor and record the temperatures twice daily.

If vaccines cannot be transported to a functioning and monitored refrigerator:

- ▶ Keep the vaccines in the non-functioning refrigerator and place icepacks (if required and/or available) into the refrigerator to help maintain the correct temperature.
- ▶ Keep the refrigerator doors closed (opening the doors will let cool air out of the refrigerator and let warm air in).
- ▶ It is not necessary to open the refrigerator door to take the temperature readings.
- ▶ Keep the ambient temperature in the office low (i.e., close window blinds) in the summer. In the winter, protect the ambient temperature from extreme cold or freezing.
- ▶ Continue to monitor and record (maximum, minimum and current) vaccine temperatures twice daily.
- ▶ Transfer the vaccines to a functioning, monitored refrigerator as soon as possible.
- ▶ Call your local public health unit for further advice.

How to Proceed When the Electricity Supply to the Refrigerator is Restored

- ▶ Record the **time** and **refrigerator temperature** when the electricity supply is restored, and again **when the thermometer reading is within the +2°C to +8°C range**.
- ▶ Continue to read and record the temperature twice daily (a.m. and p.m.).
- ▶ Call your local public health unit immediately to report any exposures to temperatures **BELOW +2°C or ABOVE +8°C**.
- ▶ All vaccines need to be assessed to determine if the vaccine potency has been affected by storage temperatures below +2°C or above +8°C during the electricity disruption.
- ▶ **DO NOT USE OR DISCARD THE VACCINE UNTIL YOUR LOCAL PUBLIC HEALTH UNIT HAS ASSESSED THE SITUATION.**

For recurring electricity disruptions:

- ▶ Place the vaccines in a labeled container or bag marked **“DO NOT USE.”**
- ▶ Put the labeled container back in the refrigerator.
- ▶ Record the time, maximum, minimum, and current temperature (if possible) at the time of each electricity disruption in the log book.
- ▶ Record each time the electricity supply is restored and measure and document the maximum, minimum and current temperatures.

What to Do When the Temperature is Below +2°C or Above +8°C

A maximum, minimum or current temperature reading below +2°C or above +8°C means that your vaccines may have lost their potency.

In this case you should:

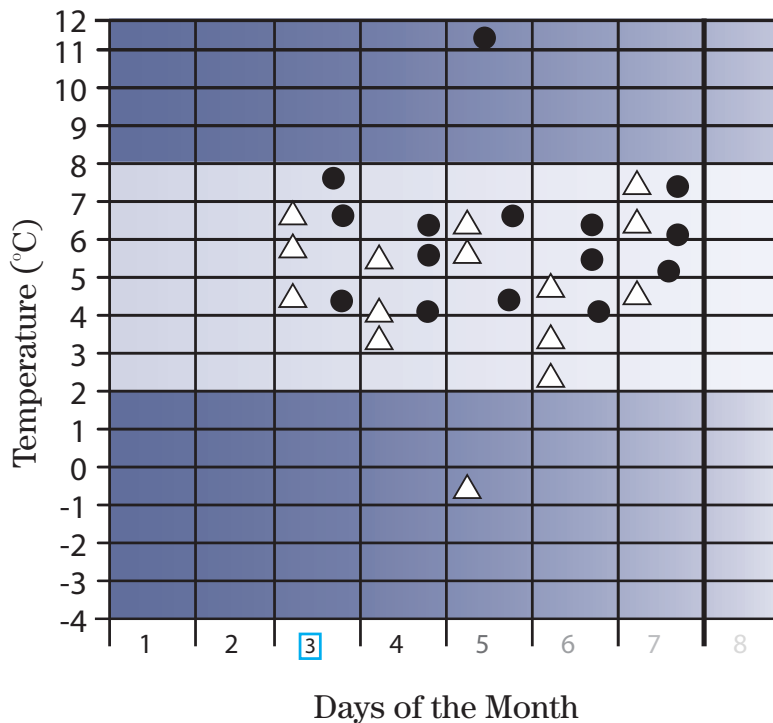
- ▶ Segregate the exposed vaccines in the refrigerator by placing these vaccines in a labeled container (or bag), marked with the date and time and **“DO NOT USE.”** Do not use any of the exposed vaccines until your local public health unit has assessed whether any of the vaccines can still be used.
- ▶ **Call your local public health unit immediately to report the vaccine exposure.**
- ▶ Check that your thermometer is working correctly (e.g., check the probe placement, check the battery). If in doubt, replace the battery.
- ▶ After checking the thermometer and the refrigerator (to make sure it is plugged in), record the date, time and temperature in your temperature log book. Always remember to reset your maximum-minimum thermometer after each recorded temperature.
- ▶ If the **current** temperature is too low or too high, move these vaccines to a properly functioning, monitored refrigerator, OR place the vaccines in a monitored insulated container with icepacks and a maximum-minimum thermometer inside the vaccine package. This will limit the number of temperature excursions outside of the +2°C to +8°C range, and help to avoid vaccine wastage.

- ▶ Insulated containers will only keep vaccines at the appropriate temperatures for a short period of time. Vaccines will need to be moved to a functioning, monitored refrigerator if the refrigerator does not stabilize at the required +2°C to +8°C range within a couple of hours.
- ▶ **Never use or discard the vaccine until your local public health unit has assessed the situation.**

Inadvertent Administration of Exposed/Expired Vaccine

If exposed/expired vaccine has been inadvertently administered, please contact your local public health unit immediately. The local public health unit staff will assist you to determine whether reimmunization is recommended.

Vaccine Temperature Log Chart



△ Morning Reading

● Afternoon Reading

Out of Range

(Contact your public health unit ASAP)

Any readings above or below the acceptable range must be reported to your local public health unit immediately.

Ordering Vaccines

- ▶ To order the hepatitis A and hepatitis B vaccines for high-risk persons, or to order post-exposure rabies vaccine and immune globulin, call your local public health unit (both within and outside Toronto).

Routine Vaccine Orders

- ▶ In Toronto, order all other routine vaccines from the OGPMS at 416-327-0837 or fax your order to 416-327-0818.
- ▶ Outside Toronto, order all other routine vaccines from your local public health unit (see list on page 15).
- ▶ Maintain no more than a one-month supply of vaccine at a time.
- ▶ Once vaccines leave the vaccine supply source, they cannot be returned for re-stocking. Ordering excess vaccine can increase the risk of wastage.
- ▶ To know how much vaccine you will need, look at the average amount of each vaccine you use each month.
- ▶ Check vaccine expiry dates regularly.

Receiving Vaccine Deliveries

- ▶ When you receive your order, check to ensure that you received your full order, and to ensure that the order matches the packing slip.
- ▶ Place vaccines in the refrigerator **right away**.
- ▶ If you did not receive everything you ordered, or your order does not match the packing slip, notify your vaccine supply source immediately.

Returning Vaccines

- ▶ Call your local public health unit for advice if you suspect that vaccine has been exposed to temperatures below +2°C or above +8°C.
- ▶ **Never discard vaccine with your office waste.**

Always return expired or spoiled vaccine to your vaccine supply source (i.e., local public health unit or the OGPMS) for disposal. The Ministry of Health and Long-Term Care may be reimbursed by manufacturers for returned vaccines.

Offices/Facilities in Toronto:

- ▶ Please ensure that you have some vaccine return forms and vaccine return labels in your office/facility. These may be obtained from the OGPMS.

Procedure for Returning Wasted Vaccines

1. Obtain a return authorization number **for wasted vaccines** from the OGPMS (see telephone number below).
2. Complete the “returned vaccines – wasted” form (pink form).
3. Affix a “returned vaccines – wasted” label (pink label) to the outside of the package. You may also obtain this label from the OGPMS driver.

Please note that the OGPMS driver will not accept returned vaccines that are not packaged/labeled properly or do not have the proper documentation (i.e., completed vaccine return form).

Offices/Facilities Outside Toronto

Return all wasted vaccines to your local public health unit.

For more information or assistance, please call the OGPMS at 416-327-0837, or your local public health unit.

List of Public Health Units in Ontario

Algoma	705-759-5287	Peel.....	905-791-7800
Brant County	519-753-4937	Perth District.....	519-271-7600
Chatham-Kent	519-352-7270	Peterborough County-City.....	705-743-1000
Durham Region.....	905-668-7711	Porcupine.....	705-267-1181
Eastern Ontario.....	613-933-1375	Renfrew County & District.....	613-732-3629
Elgin-St. Thomas.....	519-631-9900	Simcoe Muskoka District	705-721-7330
Grey-Bruce.....	519-376-9420	Sudbury & District.....	705-522-9200
Haldimand-Norfolk.....	519-426-6170	Thunder Bay District.....	807-625-5900
Haliburton, Kawartha, Pine Ridge District	905-885-9100	Timiskaming	705-647-4305
Halton Region	905-825-6000	Toronto (Immunization Line).....	416-392-1250
City of Hamilton	905-546-2424	Region of Waterloo.....	519-883-2000
Hastings and Prince Edward Counties	613-966-5500	Wellington-Dufferin-Guelph	519-846-2715
Huron County.....	519-482-3416	Windsor-Essex County	519-258-2146
Kingston, Frontenac, Lennox & Addington	613-549-1232	York Region.....	905-895-4511
County of Lambton.....	519-383-8331		
Leeds, Grenville and Lanark	613-345-5685		
Middlesex-London.....	519-663-5317		
Niagara Region.....	905-688-3762		
North Bay Parry Sound District ..	705-474-1400		
Northwestern	807-468-3147		
Ottawa.....	613-580-6744		
Oxford County	519-539-9800		