

Vaccine Storage and Handling Guidelines

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Introduction

Immunizations help save lives, prevent serious illnesses, and are recognized as one of the most effective public health interventions available today. Immunization programs are among the most cost-effective ways to prevent disease. The success of these programs depends heavily upon the high immunization coverage of the target group and vaccine inventory management, including proper storage and handling of vaccines.

By understanding and implementing proper vaccine storage and handling practices, staff in health care provider premises 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 all health care providers with how to properly store and handle provincially funded vaccines. Prior to storing vaccine, health care providers are required to understand and meet the vaccine storage and handling requirements indicated in this document.

Glossary

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.

Cold chain incident

Occurs when vaccine is exposed to a temperature outside the required temperature range of +2 °C to +8 °C for any period of time and the potency of the vaccine is potentially compromised.

Cold chain incident inspection

Cold chain incident inspections investigate the cause of the cold chain incident, determine whether vaccine can be used by the health care provider or returned to the public health unit, provide follow-up education in order to prevent the occurrence of future incidents and ensure that adequate cold chain conditions can be maintained prior to continuing the vaccine supply to the health care provider.

Exposed vaccine

Vaccine that is stored or handled at temperatures below +2 °C and/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." Depending on the length and type of exposure some vaccines may still be viable. Your public health unit will assist you in determining the vaccines that remain suitable for use.

Insulated container

An insulated container is a solid walled container with a tight lid. The container must be able to store and transport vaccines at the required temperatures for the necessary duration of time.

Routine (annual) inspection

Routine inspections assess the health care providers' level of compliance with vaccine storage and handling requirements, including cold chain requirements. Routine inspections

enable public health unit staff to provide information and resources regarding the proper storage and handling of vaccines and the proper temperature monitoring device that should be in place to optimize vaccine potency.

Spoiled vaccine

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

Temperature monitoring device

An electronic device that measures temperatures. This can include devices such as a digital maximum-minimum thermometer or a data logger.

Vaccine Cold Chain Incident Exposure/Wastage Report form

This report form is used by public health units to document when provincially funded vaccines are exposed to a cold chain incident. This report provides details of the incident and the vaccines that were wasted and/or exposed during the cold chain incident. This form (#4575-64) is available on the Ontario Central Forms Repository at www.forms.ssb.gov.on.ca

Vaccine Cold Chain Maintenance Inspection Report form

This report form is used by public health units when conducting routine (annual) inspections. This form assesses a health care provider's compliance with all vaccine storage and handling requirements. This form (#4574-64) is available on the Ontario Central Forms Repository at www.forms.ssb.gov.on.ca

Wasted vaccine

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

Public Health Units

- Recent inspections of refrigerators in health care provider premises have shown that improper storage and handling of vaccines is still a significant problem in Ontario.
- Public health units are required by the *Vaccine Storage and Handling Protocol* under the Ontario Public Health Standards, issued under the authority of the *Health Protection and Promotion Act* to respond to reports of all cold chain incidents and to inspect premises, at least once annually, where provincially funded vaccines are stored.
- The purpose of cold chain incident and routine (annual) inspections is to:
 - Ensure the proper management of vaccine inventories;
 - Provide education strategies to minimize vaccine wastage;
 - Reduce provincially funded vaccine wastage; and
 - Promote vaccine safety and effectiveness.

Public health units must conduct cold chain incident and annual routine inspections.

Contact your public health unit for assistance with vaccine storage and handling practices.

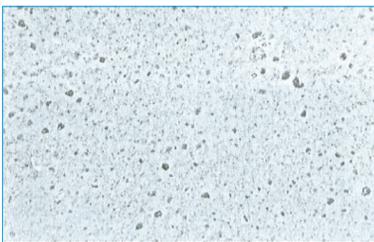


Importance of the Cold Chain

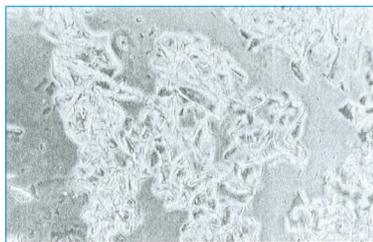
- Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are exposed to temperatures (heat and/or cold) outside the required temperature range of +2 °C to +8 °C or when exposed to light.
- Freezing refers to a situation where vaccines experience temperatures at or below 0 °C. Vaccines may not appear frozen but may have been damaged at these temperatures. Most vaccines are considered to be damaged at 0 °C.
- Failure to adhere to cold chain requirements may reduce vaccine potency, resulting in lack of protection against vaccine preventable diseases.
- The loss of vaccine effectiveness due to cold chain exposures to adverse conditions is cumulative, permanent and irreversible.
- Individuals who are immunized with exposed vaccines often need to be recalled by their health care provider and reimmunized to ensure that they are protected against the specific vaccine preventable disease(s).
- Vaccines may be wasted if they have been exposed to temperatures below +2 °C and/or above +8 °C or if they are not used prior to the expiry date.
- Vaccine wastage results in increased costs (to replace the wasted vaccines, human services and specialized transportation).
- 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.

Diphtheria, tetanus and acellular pertussis vaccine affected by freezing showing large conglomerates of massed precipitates with crystalline structure

Vaccine stored between +2 °C to +8 °C



Vaccine stored at -18 °C



World Health Organization, Department of Immunization, Vaccines, Biologicals. Temperature sensitivity of vaccines. Geneva, Switzerland: World Health Organization; 2006.

- Vaccines must be stored and transported within the required temperature range of +2 °C to +8 °C at all times.
- Most vaccines are considered to be damaged at 0 °C. Frozen or damaged vaccine may not visually appear solid or change in appearance.
- Failure to adhere to cold chain requirements may reduce vaccine potency, resulting in lack of protection against vaccine preventable diseases.
- The loss of vaccine effectiveness due to exposures to adverse conditions is cumulative, permanent and irreversible.

Staff Designated to Monitor Vaccine Storage and Handling Practices in the Premises

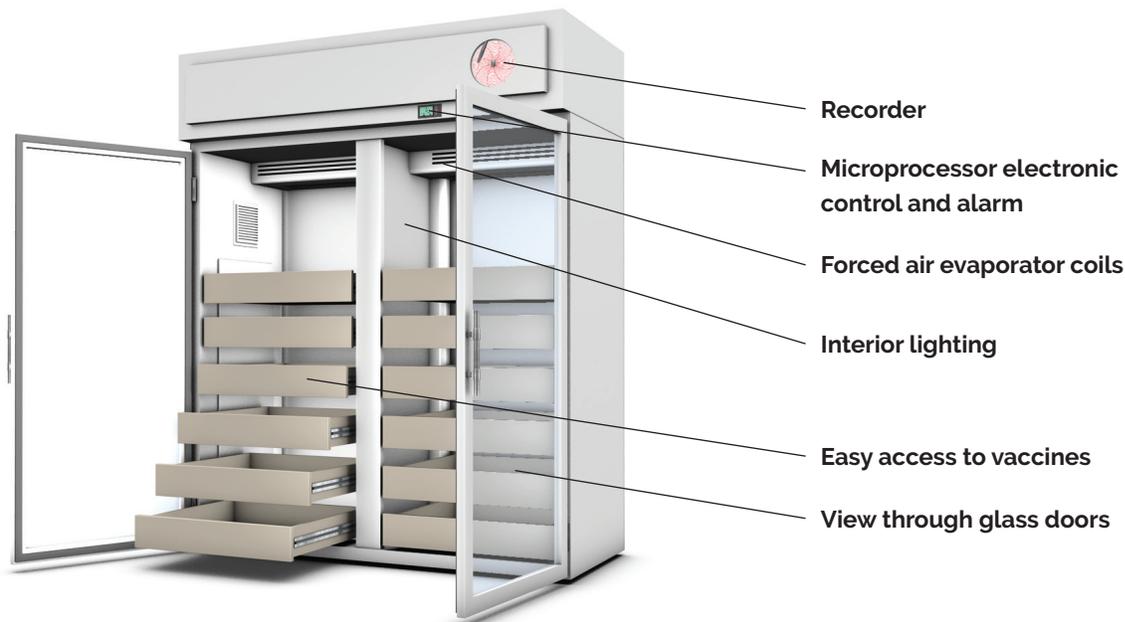
- It is important that staff handling vaccines understand the reason behind what they are doing and why they are doing it.
- One person in each premises should be designated as the lead and one person assigned as back-up to monitor vaccine storage and handling practices.
- Talk to your public health unit for training opportunities.

- Staff handling provincially funded vaccines require knowledge of:
 - The importance of the cold chain;
 - Vaccine storage and handling practices;
 - Equipment maintenance and repair procedures;
 - The appropriate action to be taken in the event of a vaccine exposure; and
 - Contingency plans and ensure that they are in place in the event of premises closure during staff vacation, equipment failure and/or electrical disruptions.
- One person in each premises should be designated as the lead and one person assigned as back-up (when the lead person is not available) to monitor vaccine storage and handling practices and ensure that vaccines are kept at the required temperatures.
- All staff members should also be trained in reading the vaccine temperature monitoring device(s), and documenting and monitoring the vaccine storage temperatures to provide backup in the event of staff vacations or other absences.
- Your public health unit can assist you with vaccine storage and handling training.



Refrigerators Used for Vaccine Storage

Purpose-built refrigerators



- Purpose-built refrigerators are the preferred refrigerators for vaccine storage for health care providers and are required for vaccine storage at public health units.
- It is recommended that purpose-built refrigerators are used when storing large inventories of vaccines.
- Although purpose-built refrigerators are considerably more expensive than domestic (kitchen) and bar refrigerators, they have the advantage where modifications are not required for vaccine storage.
- The main features of a purpose-built refrigerator include:
 - The temperature regulation mechanism ensures narrow tolerances with internal temperatures. This provides appropriate temperature regulation;
 - Ongoing air circulation ensures that the temperature is distributed evenly;
 - An internal temperature between +2 °C to +8 °C is maintained;
 - An evaporator operates at +2 °C, preventing the vaccine from freezing;
 - The temperature recovery system is very quick; and
 - The forced air circulation helps to keep internal temperatures between +2 °C to +8 °C even when the ambient temperature changes.

- **Management of a purpose-built refrigerator is less demanding than a domestic or bar refrigerator.**
- **In a purpose-built refrigerator nearly all of the internal space can be used for storing vaccines.**

Note: Domestic (kitchen) and bar refrigerators do not have any of these features.

■ Domestic or bar refrigerators are not recommended for vaccine storage.

■ It is complicated to manage domestic and bar refrigerators for vaccine storage.

■ Domestic and bar refrigerators are unsuitable for vaccine storage if appropriate vaccine storage and handling practices are not diligently undertaken.

■ Contact your public health unit for assistance on domestic and bar refrigerator modifications that are required prior to vaccine storage in order to ensure that vaccines will be safely stored.

Domestic (kitchen) and bar refrigerators

- Domestic and bar refrigerators are designed and built for food and drink storage – not for the special temperature requirements of vaccines.
- Although it is not recommended, it is possible (although very complex) to manage kitchen and bar refrigerators to reduce the risk of heating and/or freezing the vaccines.
- Health care providers using domestic and/or bar refrigerators to store vaccine should contact their public health unit regarding the modifications that will be required in order to safely store provincially funded vaccines.



- Check and log temperature twice a day.
- Stock only a one month supply.
- Never leave vaccine outside the refrigerator.
- Open the door only when necessary.

■ A temperature monitoring device is an essential requirement for vaccine temperature monitoring.

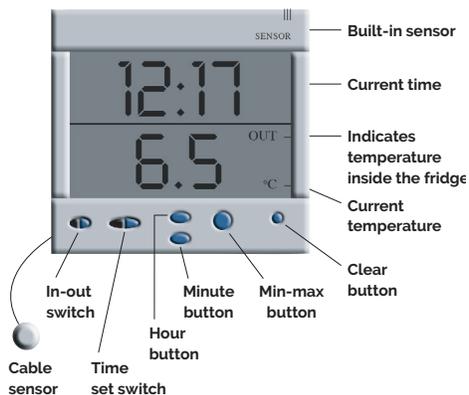
■ Each vaccine refrigerator and insulated container used for vaccine storage and transport must have a temperature monitoring device.

■ Temperature monitoring devices need to be accurate. Check the accuracy of the devices once annually and change the battery every 6 months.

Temperature Monitoring Devices

- A temperature monitoring device is an essential requirement for temperature monitoring of vaccines.
- Always use a temperature monitoring device that is calibrated to within $\pm 1^\circ\text{C}$ accuracy. Your public health unit can assist you in selecting an appropriate temperature monitoring device.
- Temperature monitoring devices should be checked for accuracy on an annual basis, as they lose their accuracy over time. Your public health unit can assist you with checking the accuracy of your temperature monitoring device during your routine (annual) inspection.
- The temperature monitoring device may also become less accurate (which may result in wastage of potent vaccine) if the batteries are low. To ensure optimum function of the device, the batteries should be changed every 6 months.

Digital Maximum-Minimum Thermometers



- Digital maximum-minimum thermometers measure the current temperature and the minimum and maximum temperatures that have been reached over a period of time.
- Maximum-minimum thermometers provide three readings: the current temperature, the maximum temperature reached since it was last reset and the minimum temperature since it was last reset.
- Digital maximum-minimum thermometers should have a display screen so the temperature can be visually checked whenever going into the refrigerator and will allow for troubleshooting if temperatures are at +3 °C or +7 °C.
- Maximum-minimum thermometer should record temperature increments by 0.1 °C.
- The maximum-minimum thermometer sensor should be placed on the middle refrigerator shelf inside an empty vaccine box to help stabilize the temperature readings and to protect the sensor from exposure to sudden breezes of cold or warm air.

- Always reset your maximum-minimum thermometer after recording the temperature readings.
- Place the maximum-minimum thermometer probe on the middle refrigerator shelf inside an empty vaccine box.

Data Loggers



- Data loggers are continuous temperature recording devices, which offer a historical record of refrigerator temperatures.
- These devices store temperature readings which can be downloaded onto a computer.
- Print the temperature readings out on a weekly basis (or more often if required) and retain them for 1 year, or until the next inspection by your public health unit.
- Data loggers do not replace the need for a twice daily observation and documentation of the current, maximum and minimum refrigerator temperatures in the *Temperature Log Book*.
- The data logger display should be equipped with a digital display screen so the temperature can be visually checked whenever going into the refrigerator. This will also allow for troubleshooting if temperatures are at +3 °C or +7 °C.
- The data loggers should record temperature increments by 0.1 °C.

- Data loggers are continuous temperature recording devices, which offer a historical account of refrigerator temperatures.
- When using a data logger, the minimum, maximum and current temperatures still need to be recorded manually as a timely alert to any breach in the cold chain.

Vaccine Storage and Handling Practices

- To retain their potency and to be effective, provincially funded vaccines must be kept refrigerated between +2 °C and +8 °C at all times.
- Strive to maintain vaccine refrigerator temperature at +5 °C, as this gives a greater leeway for protection from temperature fluctuation. For detailed vaccine storage and handling information, please refer to the specific vaccine product monograph.
- The internal refrigerator temperatures must be stabilized between +2 °C to +8 °C for a recommended period of 7 consecutive days prior to stocking vaccine.
- To ensure appropriate vaccine storage and handling practices are in place, potent vaccine is administered and wastage is minimized, it is important that the following practices are in place.

■ **Strive to maintain vaccine refrigerator temperature at +5 °C, as this gives a greater leeway for protection from temperature fluctuation.**

■ **Stabilize the temperature of the vaccine refrigerator before stocking vaccine.**

1. Vaccine refrigerator temperatures and readings

- Maintaining accurate and up-to-date documentation of refrigerator temperatures is necessary to maintain vaccine potency.
- Maximum, minimum and current temperatures must be checked twice daily and documented (at the beginning and end of each day) in the *Temperature Log Book* (see page 20 for an example). This will ensure that vaccines have been stored at the right temperature, and have not been exposed to temperatures below +2 °C and/or above +8 °C.
- Check and record the maximum, minimum and current temperatures twice daily in the *Temperature Log Book* at the beginning and the end of each day.
- The *Temperature Log Book* is the written record that enables you and your staff to monitor and take action if temperatures go outside the required range. Temperature log books are available from your vaccine supply source (i.e., public health unit or Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)).
- The temperature should be viewed every time the refrigerator is opened. This will allow for troubleshooting if required.
- Temperature readings documented in the *Temperature Log Book* will also assist your public health unit in the assessment of cold chain exposures (determining the temperature variation and duration of exposure) should these occur.

- Your public health unit will be able to determine whether any vaccine which has been exposed to a cold chain incident can still be used.
- Temperature monitoring and recording devices (e.g., data loggers) and equipment (e.g., temperature alarm systems) do not eliminate the need for staff intervention and monitoring of the cold chain.

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.

■ **Check and record the maximum, minimum and current temperatures twice daily in the *Temperature Log Book* at the beginning and end of each day.**

■ **Contact your public health unit immediately if vaccines have been exposed to temperatures below +2 °C or above +8 °C.**

■ **Temperature monitoring and recording devices (e.g., data loggers) and equipment (e.g., temperature alarm systems) do not guarantee safety of vaccines and are not to be considered a substitute for the manual recording of minimum, maximum and current temperatures twice daily.**

2. Ministry of Health cold chain material

- In addition to this document, additional ministry cold chain material is available from your public health unit to assist you with vaccine storage and handling requirements.
- Materials include: temperature log books, equipment log books, posters, stickers and insulated containers (including packaging material).
- These materials should be accessible at all times and staff should be knowledgeable regarding the material contained in all vaccine storage and handling documents provided by the ministry and your public health unit.

3. Refrigerator organization

- Vaccines should be away from the refrigerator walls, floors and cold-air vents; storage of vaccine against refrigerator walls, floors and cold air vents increases the risk of exposing vaccines to temperatures below +2 °C.
- When storing vaccine in domestic or bar style refrigerators, always store vaccines on the middle internal shelves. Never store vaccines in refrigerator door shelves or drawers as they may be exposed to warmer temperatures.
- Organize vaccine by product. Place vaccines of the same type together.
- Leave space between the vaccine packages in the refrigerator to allow air to circulate.
- Protect vaccines from light. Storage of vaccines in their original packaging will protect vaccines from light.
- Check vaccine expiry dates regularly and after every vaccine order. 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 (i.e., public health unit or OGPMS).
- Vaccine refrigerator must be dedicated for storage of vaccines only. Food, beverages or medical/laboratory specimens should not be stored in a vaccine storage unit because this practice results in frequent door openings and destabilization of the temperature.
- Storing filled water bottles on the lower shelf and the door of a kitchen or bar refrigerator used to store vaccines will help maintain an even, stable temperature inside the refrigerator.
- Diluents should be stored with vaccines and be kept within +2 °C to +8 °C.

- **Speak to your public health unit regarding vaccine storage and handling resources.**

- **Do not store food, beverages or medical/laboratory specimens in the vaccine refrigerator.**
- **Fill the lower drawers and the door with water bottles.**
- **Vaccines should be stored in the refrigerator in their original packaging.**
- **Vaccines must never be stored in the door of the refrigerator.**

■ Do not overstock your refrigerator with vaccines. Ordering excess vaccine can increase the risk of wastage.

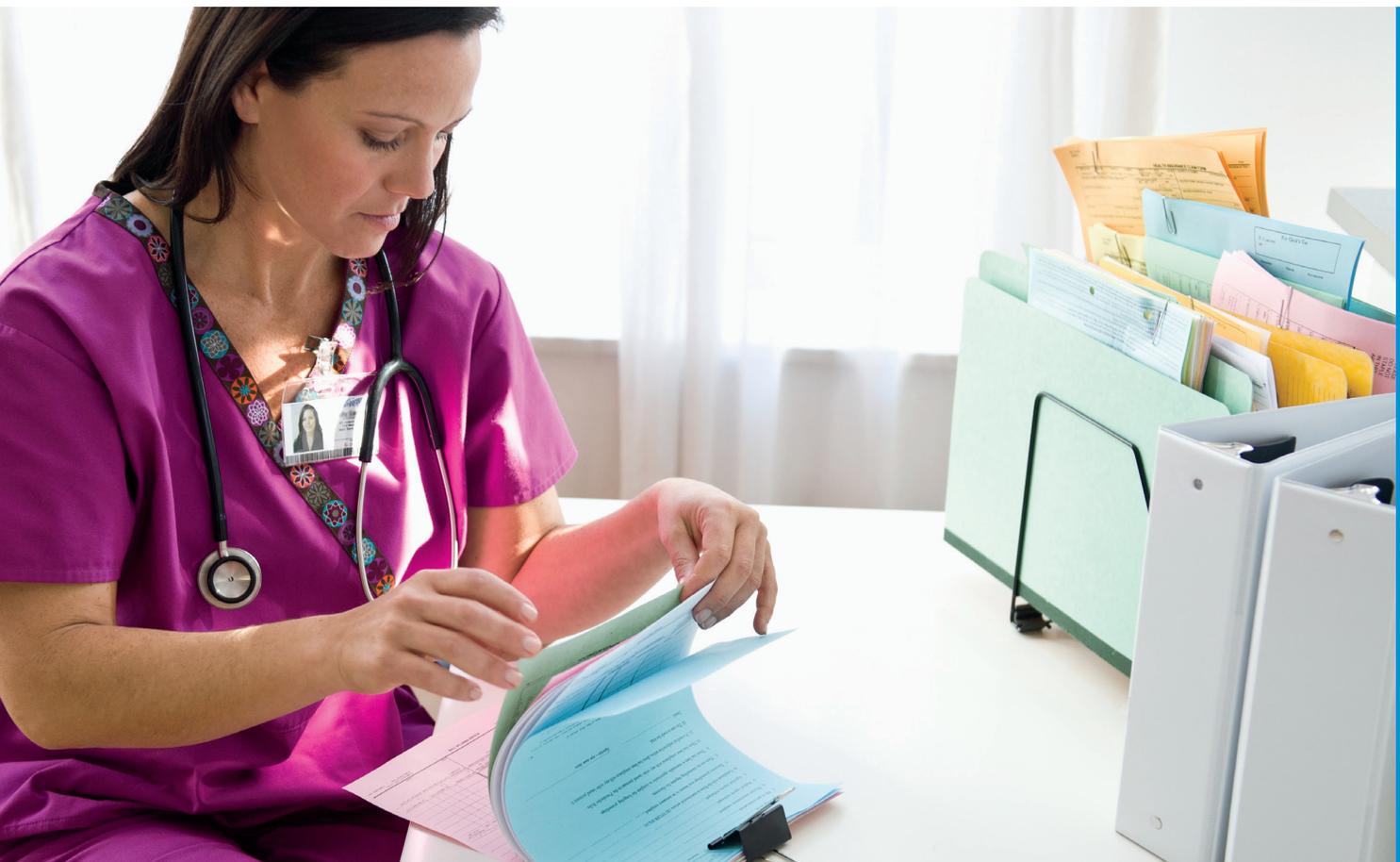
■ Rotate stock so vaccines with the shortest expiry date are used first.

4. Inventory management

- 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.
- Maintain no more than a one-month supply of vaccine at a time. However, depending on the size of your vaccine refrigerator, inventory may need to be reduced to a 1-2 week supply to prevent overcrowding.
- Once vaccines leave the vaccine supply source (i.e., public health unit or OGPMS), 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.
- Rotate stock with every vaccine order and check vaccine expiry dates regularly.

5. Vaccine handling

- **All vaccines:** Take vaccines out of the refrigerator only when ready to administer and protect vaccines from light.
- **Multi-dose format vaccines:** 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 the time indicated on the product monograph. Aseptic technique for the withdrawal of vaccines must be followed at all times.



6. General tips

- Refrigerator should be optimally placed in an area that is well ventilated, out of direct sunlight and away from external walls.
- Vaccines must be secured away from public access. Vaccine refrigerators should be equipped with a lockable door or the vaccine refrigerator should be stored in a room with a lockable door. Designated staff must lock the refrigerator and/or the room that vaccine is housed in after office 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 (plug sticker is available from your public health unit).
- For kitchen and bar refrigerators defrost the refrigerator when there is more than 1 cm (¼ inch) of ice in the freezer compartment. While defrosting the refrigerator, transfer vaccines to an insulated vaccine container (for no longer than 3 hours) with icepacks and temperature monitoring device or transfer vaccines to another monitored refrigerator, and check the temperature regularly.
- 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.
- Perform refrigerator maintenance as required, including cleaning and dusting the back (including coils, top and sides) and ensuring the door is sealed tightly and properly (has adequate door seals and tight door hinges).
- Never leave vaccines out on the counter or the floor.
- Minimize the number of times the refrigerator door is opened.
- 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.
- Keep equipment log books for each piece of vaccine storage and handling storage equipment. This log book should be a record of the serial numbers of each piece of equipment, the date each piece of equipment was installed, the dates of routine maintenance tasks and the dates of any repairs or servicing. Equipment log books are available from your vaccine supply source (e.g., public health unit or OGPMS).

■ Place the refrigerator out of direct sunlight.

■ Mark the plug clearly so the refrigerator is not unplugged or turned off accidentally.

■ Keep icepacks/gel packs in your freezer.

■ Keep your refrigerator door openings to a minimum.

■ Ensure your refrigerator is in good working order.

Insulated Containers

- **Vaccines should be maintained within +2 °C to +8 °C inside properly packaged insulated containers during storage and transport.**
- **Insulated containers can maintain the required temperature for 3-4 hours; however, this is subject to environmental and physical conditions.**
- **Do not place insulated containers with vaccines in the trunk of a car.**

- An insulated container is a solid-walled container with a tight lid. The required temperatures inside the insulated container are maintained by icepack(s) and/or gel pack(s).
- Vaccines should be stored and transported in insulated containers with the appropriate packaging material and packing configuration to ensure that vaccines are maintained within the +2 °C to +8 °C temperature range for the maximum length of time that might be required for transport and/or storage.
- Insulated containers are not adequate for the transport and/or storage of vaccines for prolonged periods as their cold life (the container's ability to maintain the required temperature range) is limited.
- Most insulated containers can maintain the required temperatures for a maximum of 3-4 hours. However, the external temperature, the number of times the insulated container is opened and closed, the amount of vaccine that is being stored and the type of packaging material used may reduce the amount of time vaccines can be stored in the insulated container.
- If vaccines will be stored and/or transported for more than 3-4 hours in the insulated container, the icepack(s) and/or gel pack(s) should be removed and replaced with a new set of conditioned frozen and/or refrigerated icepack(s) and/or gel/pack(s).
- When transporting vaccines in an insulated container, the temperatures must be continued to be monitored during vaccine transport. The frequency of the checking and the recording of temperatures are dependent on the amount of time the vaccine is stored and transported in the insulated container.
- The number of insulated containers and packing material that the premises should maintain must accommodate the entire vaccine inventory.
- Insulated containers storing vaccines should not be transported in the trunk of a vehicle due to the extreme temperatures that can occur.
- Speak with your public health unit if you require an insulated container.

- **Use insulated containers for:**
 - • **Transporting vaccine;**
 - • **Temporary storage of vaccine (e.g., during clinics or cleaning the refrigerator); and**
 - • **Emergency storage (e.g., power outage).**

When to use an Insulated Container

- An insulated container, temperature monitoring device and appropriate packaging material is used for:
 - Transporting vaccine;
 - Storing vaccine during immunization sessions/clinics;
 - Temporary storage of vaccine during equipment maintenance periods (e.g., when cleaning or defrosting refrigerator); and
 - Emergency storage of vaccine (e.g., refrigerator malfunction or an electricity disruption).

1. Transporting vaccine from the public health unit to the office

- Monitor and record temperature readings in the insulated container:
 - a. Before leaving the public health unit with the insulated container;
 - b. After 1 hour of travel; and
 - c. Upon arrival at the office/facility but before the vaccines are placed back into the refrigerator:
 - i. Place vaccine into inventory for use if the temperature monitoring device(s) indicates that the cold chain was maintained between +2 °C to +8 °C.
 - ii. If the temperature monitoring device(s) indicates an out-of-range reading, place the vaccine under quarantine in the refrigerator and immediately report the incident to your public health unit. The vaccines must be kept refrigerated and should not be used until your public health unit provides further direction.

- **Record temperature in the insulated container:**
 - Before leaving the public health unit;
 - After 1 hour of travel; and
 - Upon arrival at office.

2. Storing vaccines during immunization sessions/clinics

- Monitor and record temperature readings in the insulated container:
 - a. Before leaving the office/facility with the insulated container;
 - b. Upon arrival at the session/clinic, but prior to the immunization session/clinic;
 - c. At 1 hour intervals during the immunization session/clinic;
 - d. Upon completion of the session/clinic, but before transport back to the office/facility; and
 - e. Upon arrival to the office/facility:
 - i. Place vaccine into inventory for use if the temperature monitoring device(s) indicates that the cold chain was maintained between +2 °C to +8 °C.
 - ii. If the temperature monitoring device(s) indicates an out-of-range reading, your public health unit should be contacted and vaccines should place the vaccine under quarantine in the refrigerator until your public health unit has assessed the cold chain incident.
- In addition, to the above required temperature monitoring and recordings in the insulated container, the temperature monitoring device should be visually inspected each time the insulated container is opened.
- Only pack the amount of vaccine you expect to use during the immunization session/clinic.
- Minimize the number of times that the cooler is opened during the immunization session/clinic.
- Remove vaccines from the insulated container only as they are required.

- **Record temperature in the insulated container:**
 - Before leaving the office;
 - Upon arrival at clinic;
 - Every hour during the session;
 - Upon completion of the session at the clinic; and
 - Upon arrival back to office.
 - Visually inspect the temperature every time the insulated container is opened.

Steps to prepare an insulated container (and related material) prior to transportation or storage

1. Pre-chill the insulated container by placing icepacks inside the insulated container for at least 1 hour. After the hour, remove all icepacks.
2. Precondition icepacks. Vaccines are vulnerable to freezing when transported in an insulated container if icepacks have not been correctly conditioned. 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. The conditioning process usually takes approximately 20 to 30 minutes.
3. Prepare your temperature monitoring device. (See details on page 8.)
4. Ensure that all other items necessary to pack the insulated container are ready and easily accessible.

■ **Ice and/or gel packs must be correctly conditioned before use. The risk of freezing vaccines increases if the icepacks/gel packs are not correctly conditioned.**

■ **Incorrect use of gel packs is even riskier than icepacks because the gel packs remain colder than 0°C for longer than icepacks.**

■ **Freezing episodes happen very easily in all coolers, usually in the first 2 hours after packing.**

■ **Pre-chill the cooler before use.**

Steps to packing an insulated container (and related material) prior to transportation or storage

Freezing episodes happen very easily in all insulated containers, usually in the first 2 hours after packing.

To ensure vaccines arrive at the destination safely:

1. Place 1 or 2 icepacks at the bottom of the insulated container.
2. Place a pre-conditioned ($+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$) ice blanket(s) on top of the icepacks.
3. Place the vaccine package on top of the ice blanket(s).
4. Position the temperature monitoring device or the sensor in the centre of the vaccine package.
5. Insulation material (e.g., bubble wrap, newspaper) may be loosely wrapped around the vaccine packages. This allows for cool air circulation around the vaccines and minimizes the risk of "hot" or "cold" spots.
6. Place another pre-conditioned ice blanket(s) over the vaccine.
7. Place 1 or 2 pre-conditioned icepacks on top of the ice blanket(s).
8. Add newspaper or bubble wrap as necessary to fill vertical void.
9. Clearly mark all insulated containers storing vaccine with the following label: "VACCINES – STORE BETWEEN $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$."

■ **Correctly packing a cooler reduces the risk of freezing.**

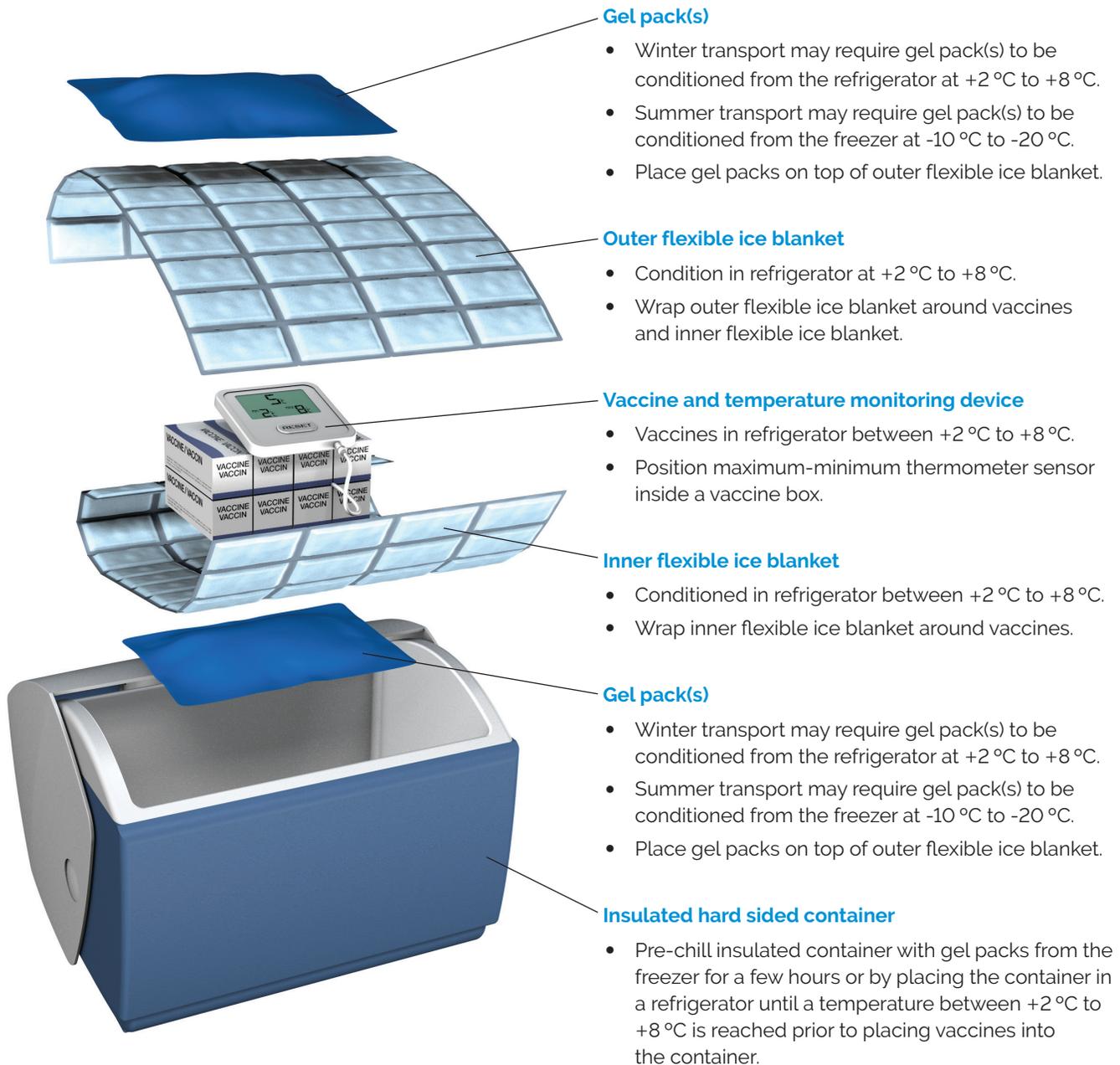
Experiment to find the correct combination of icepack(s) and/or gel pack(s) to ensure the insulated container is able to maintain the required temperatures for:

1. The maximum length of time the vaccine might have to be in the insulated container;
2. The amount of vaccines to be transported; and
3. The external temperatures (e.g., winter climate vs. summer climate).

■ **Experiment to find the correct combination of icepack(s) and/or gel pack(s) to ensure the insulated container is able to maintain the required temperatures.**

Ministry of Health

Detailed instructions on how to pack an insulated container:



Note: Additional icepacks may be required depending on cold-life needed for the length of transport. Additional insulating material (e.g., bubble wrap, Styrofoam chips, crumpled or shredded newspaper) should be placed inside (bottom, top and sides) the insulated container to allow for cool air circulation.

Contingency Planning

Each health care provider's premises should have a contingency plan for vaccine storage in the event of a refrigerator malfunction and electricity disruptions. If there is no access to a backup power supply (i.e., generator) at the premises, arrangements should be made in advance with an alternate storage site (e.g., hospital, long-term care home) that has an emergency backup power supply and appropriate vaccine storage capacity. However, if this cannot be arranged, insulated containers and packaging materials should be made available to temporarily and safely store the vaccines at the premises. Please discuss this with your public health unit.

- **During an electricity disruption, take action to protect your vaccines.**
- **Always have an alternative means of vaccine storage available.**

Electricity disruptions (localized or general)

During an electricity disruption

- When an electricity disruption occurs, document the time and the maximum, minimum and current temperature inside of the non-functioning refrigerator in the *Temperature Log Book* and reset the maximum-minimum thermometer (if applicable).
- Contact your public health unit for information concerning the estimated time before electricity should be restored.
- Factors including the amount of vaccine being stored in the refrigerator, the external temperatures (e.g., summer vs. winter) and the type, model and age of the refrigerator will affect the duration of time vaccines within the refrigerator will be kept within +2 °C to +8 °C. It is therefore important to "know your vaccine refrigerator" to facilitate a timely response and minimize potential vaccine loss.
- Do not allow the vaccine to remain in a non-functioning unit for an extended period of time. If it is unsure that the problem can be corrected in time to maintain the required temperatures, initiate your contingency plan, which should include:
 1. Transferring vaccines to alternative storage facility. See the instructions on how to use an insulated container to transport vaccines on page 17.
 2. If an alternative storage facility cannot be identified within a reasonable distance, place the vaccine in insulated containers with appropriate packaging material and temperature monitoring devices and record the temperature. See the instructions on how to use an insulated container to on page 17.

- **When an electricity disruption occurs, document the time and the maximum, minimum and current temperature inside of the non-functioning refrigerator in the *Temperature Log Book*.**
- **Factors including the amount of vaccine being stored in the refrigerator, the external temperatures and the refrigerator will affect the duration of time vaccines within the refrigerator will be kept within +2 °C to +8 °C.**
- **Do not allow the vaccine to remain in a non-functioning unit for an extended period of time.**

If it is a **scheduled or a time-limited** power outage and you are **certain** the power should be restored before the vaccine refrigerator temperature rises above +8 °C, take the following steps:

1. Keep the vaccines in the non-functioning refrigerator and place icepacks (if required and/or available) into the refrigerator to help maintain the required temperatures for as long as possible.
2. Keep the refrigerator doors closed (opening the doors will let cool air out of the refrigerator and let warm air in).
3. It is not necessary to open the refrigerator door to take the temperature readings.
4. 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.
5. 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.
6. Call your public health unit for further advice.

Recurring electricity disruptions

- Determine if the vaccines can be maintained in the refrigerator, transferred to insulated containers or transferred to an alternative storage facility.
- If possible, record each time when the electricity supply is restored and document the maximum, minimum and current temperatures inside the non-functioning refrigerator, without opening the refrigerator door.

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 +2 °C to +8 °C.
- Continue to read and record the temperature twice daily (a.m. and p.m.).
- Call your public health unit immediately to report any exposures to temperatures below +2 °C and/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 and/or above +8 °C during the electricity disruption.
- Do not use or discard the vaccine until your public health unit has assessed the situation.

■ **Record the time and refrigerator temperature when the electricity supply is restored, and again when the thermometer reading is within +2 °C to +8 °C.**

■ **Call your public health unit immediately to report any exposures to temperatures below +2 °C and/or above +8 °C.**

What to do when the temperature is below +2 °C and/or above +8 °C

- Vaccines may lose potency if the maximum, minimum or current temperature readings are below +2 °C and/or above +8 °C.
- In this case you should:
 - Segregate the exposed vaccines in the refrigerator by placing these vaccines in a labelled container (or bag), marked with the date and time and **"DO NOT USE."**
 - Call your public health unit immediately to report the vaccine exposure. Do not use or discard any of the exposed vaccines until your public health unit has assessed whether any of the vaccines can still be used.
 - Check to ensure your temperature monitoring device is working correctly (e.g., check the probe placement, check the battery). If in doubt, replace the battery.
 - After checking the temperature monitoring device 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 (if applicable) 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 temperature monitoring device inside the vaccine package. This will limit the number of temperature excursions outside of the +2 °C to +8 °C, 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 between +2 °C to +8 °C within a couple of hours.
- If you are experiencing any difficulties maintaining the required temperatures, your public health unit can assist you with troubleshooting.

Call your public health unit for advice if you suspect that vaccine has been exposed to temperatures below +2 °C or above +8 °C.

Segregate the exposed vaccines in the refrigerator by placing these vaccines in a labelled container (or bag), marked with the date and time and "DO NOT USE."

Never use or discard the vaccine until your public health unit has assessed the situation.

Vaccine Temperature Log Book

Month: January 2021 Office/Facility: ABC Family Practice

Week 1	Mon	3	Tue	4	Wed	5	Thurs	6	Fri	7	Sat	8	Sun	9
Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Current Temp	5.8	7.0	3.4	5.6	5.7	6.8	3.2	5.3	5.3	5.2	7.0	6.5	6.0	6.7
Max Temp	6.8	6.5	6.0	6.8	6.7	7.1	10.4	6.9	6.3	6.4	5.6	5.2	4.5	5.5
Min Temp	3.4	3.5	2.9	3.3	3.4	4.0	2.5	3.0	-0.2	3.6	7.0	7.5	6.5	7.8
Initials	AB	AB	AA	AA	AA	AA	AA	AA	AA	AA	AB	AB	AB	AB
Week 2	Mon		Tue		Wed		Thurs		Fri		Sat		Sun	
Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Current Temp														

Out-of-Range Temperatures

Any temperature readings below +2 °C and/or above +8 °C must be reported to your public health unit immediately.

Inadvertent Administration of Exposed and/or Expired Vaccine

- If exposed vaccine deemed non-usable and/or expired vaccine has been inadvertently administered, please contact your public health unit immediately. Public health unit staff will assist you to determine whether reimmunization is recommended.

Ordering routine vaccines

- Outside Toronto, order all routine vaccines from your public health unit.
- In Toronto, order all routine vaccines from the OGPMS by faxing the *Toronto Clients Requisition for Biological Supplies* form to 416-327-0818. This form (#2203-64E) is available on the Ontario Central Forms Repository at www.forms.ssb.gov.on.ca

Ordering non-routine vaccines

- To order hepatitis A vaccine, hepatitis B vaccine, meningococcal C-ACWY-135 and/or multicomponent meningococcal B vaccine for high-risk persons, post-exposure rabies vaccine and/or immune globulin, call your public health unit.

Receiving vaccine deliveries

- When you receive your order, check that you received your full order and ensure that the order matches the packing slip.
- Place vaccines in the refrigerator immediately.
- If you did not receive everything you ordered, or your order does not match the packing slip, notify your vaccine supply source (i.e., public health units or OGPMS) immediately.

Returning vaccines

- Always return expired or spoiled vaccine to your vaccine supply source for disposal. The ministry may be reimbursed by manufacturers for returned vaccines.
- Outside Toronto, return expired or spoiled vaccine to your public health unit.
- In Toronto, ensure the following steps are followed:
 1. Obtain a return authorization number for wasted vaccines from the OGPMS at 416-327-0837.
 2. Complete the vaccine return form – *Non-Reusable Vaccine (spoiled or expired) Return Record – Toronto Clients*. This form (#3296-64) is available on the Ontario Central Forms Repository at www.forms.ssb.gov.on.ca
 3. Affix a "Non-Reusable Vaccines" label (pink label) to the outside of the package. You may also obtain this label from the OGPMS driver.

Note: OGPMS drivers will not accept returned vaccines that are not packaged and/or labelled properly or do not have the proper documentation (i.e., completed vaccine return form).

Place vaccines in the refrigerator immediately

Always return expired or spoiled vaccine to your vaccine supply source for disposal.

For more information or assistance regarding the Publicly Funded Immunization Schedules for Ontario, please contact your public health unit.

Public Health Units in Ontario

Algoma	705-942-4646	1-866-892-0172
Brant County	519-753-4937	
Chatham-Kent	519-352-7270	
Durham	905-668-7711	1-800-841-2729
Eastern Ontario	613-933-1375	1-800-267-7120
Grey-Bruce	519-376-9420	1-800-263-3456
Haldimand-Norfolk	519-426-6170	905-318-6623
Haliburton, Kawartha, Pine Ridge District	905-885-9100	1-866-888-4577
Halton	905-825-6000	1-866-442-5866
Hamilton	905-546-2424	
Hastings Prince Edward	613-966-5500	
Huron Perth	1-888-221-2133	
Kingston, Frontenac, and Lennox & Addington	613-549-1232	1-800-267-7875
Lambton	519-383-8331	
Leeds, Grenville and Lanark District	613-345-5685	1-800-660-5853
Middlesex-London	519-663-5317	
Niagara	905-688-3762	1-800-263-7248
North Bay Parry Sound District	705-474-1400	1-800-563-2808
Northwestern	807-468-3147	1-800-830-5978
Ottawa	613-580-6744	1-866-426-8885
Oxford County	519-539-9800	1-800-755-0394
Peel	905-791-7800	1-888-919-7800
Peterborough	705-743-1000	1-877-743-0101
Porcupine	705-267-1181	1-800-461-1818
Renfrew County and District	613-732-3629	1-800-267-1097
Simcoe Muskoka District	705-721-7520	1-877-721-7520
Southwestern	1-800-922-0096	
Sudbury and Districts	705-522-9200	
Thunder Bay District	807-625-5900	1-888-294-6630
Timiskaming	705-647-4305	1-866-747-4305
Toronto	416-338-7600	
Waterloo	519-575-4400	
Wellington-Dufferin-Guelph	519-822-2715	1-800-265-7293
Windsor-Essex County	519-258-2146	1-800-265-5822
York	905-895-4511	1-877-464-9675

Public Health Unit Contact Information

Public Health Unit: _____

Website: _____

Telephone: _____

Fax: _____

