

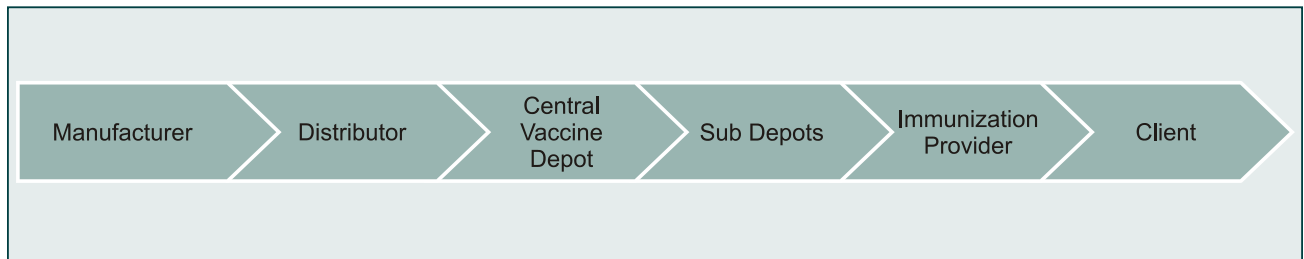
Standard 3.4 - Vaccine Storage and Handling

Preamble:

Immunization programs have had a major impact on the health status of people in all countries. A key component to successful immunization programs is the efficient storage and handling of vaccines so that vaccine potency is maintained and wastage is reduced.

The Information herein is intended for use by all those who store, handle and administer publicly funded vaccine and provides an overview of storage and handling practices. Vaccine co-ordinators should also be familiar with the [National Vaccine Storage and Handling Guidelines for Immunization Providers, 2015](#).

The term “cold chain” is used to describe a system of equipment and procedures that are in place to ensure that vaccines are maintained in optimal temperature and light conditions. Maintaining the cold chain is a shared responsibility of all individuals from the time a vaccine is manufactured until it is administered.



The cold chain – from manufacturer to client:

Any interruption of the cold chain has the potential to decrease the potency of vaccines that, if used, could result in decreased levels of protection in individuals and/or communities. Loss of vaccine is costly and may result in a supply shortage that impacts immunization programs.

Three elements are required to ensure the safe handling and storage of vaccines:

1. trained personnel;
2. appropriated storage and transport equipment; and
3. vaccine storage and handling procedures (written).

The majority of cold chain incidents can be prevented when these three elements are in place.

3.4.1 - Trained Personnel

Each office, facility or location where vaccines are stored, handled or used must have a *designated vaccine co-ordinator* to oversee storage and handling practices. This individual is required to have:

1. a knowledge and understanding of the importance of the cold chain;
2. a knowledge of specific to vaccine storage and handling practices; and
3. the knowledge of how to and the ability to respond to breaks in the cold chain.

In addition to the designated co-ordinator, an appropriate back-up person should be in place to cover routine or unexpected absences of the vaccine co-ordinator.

3.4.2 - Storage and Handling Equipment

Refrigerators:

Ideally, all vaccines should be stored in a *purpose-built vaccine refrigerator*. Household and bar refrigerators are not designed to maintain the precise temperatures required for vaccine storage and therefore should not be used. **If domestic refrigerators are being used, plans should be made to replace them with purpose-built refrigerators.**

The selection, location and organization of vaccine refrigerators (and accessories) within facilities must take into account conveniences for staff, technical features of the refrigerators and vaccine requirements. The following should be considered:

1. Select a purpose-built vaccine refrigerator that will maintain the internal temperature between 2° and 8° Celsius. Always check the vaccine product monograph for specific storage and handling information.
2. Choose a refrigerator that is large enough to store the maximum volume of vaccine required at any given time and provide space for adequate air circulation around vaccine packages.
3. Use the refrigerator only for vaccines. Food, drink or laboratory specimens *must not* be stored in vaccine refrigerators. Although it is preferable to store medications in separate fridges, in “small practice” fridges, medications and vaccines can be stored in the same refrigerators, but all other conditions for vaccine storage must be followed.
4. Place the refrigerator in a secure location, ideally in a room with a lockable door to prevent unauthorized handling or refrigerator entry after office hours. If this is not possible, the refrigerator should be located in a low-traffic area.
5. Plug the refrigerator into a protected electrical outlet where it cannot be unplugged or turned off accidentally. Signage should be clearly visible by outlets or switches controlling vaccine refrigerators.
6. Connect the refrigerator to a back-up power source.
7. Place bottles of water on any empty shelves and door spaces to maintain a more constant temperature in the event of a power failure.
8. Use temperature monitoring devices in all refrigerators containing vaccines (refer to the section on temperature monitoring devices).
9. Check and log the refrigerator temperature twice daily. Although data loggers record the temperature, they do not preclude the need to check the temperature regularly. Since alarms can fail, physical checks should still be done.
10. Install an alarm to signal when temperature parameters are exceeded.
11. Protect vaccine from sunlight and fluorescent light if the refrigerator does not have a solid door. Always check the product monograph for specific product information about light exposure.
12. Organize the products in the vaccine refrigerator:
 - place the same vaccines together;
 - always move the vaccines with shorter expiry dates to the front so that can be used first;
 - remove expired vaccines from the refrigerator and return to vaccine depot as directed;
 - clearly mark vaccines that have been quarantined or in some way have limited use;
 - store vaccine on internal shelves, not on door shelves;
 - bins or baskets used to group products must have slotted sides to allow for air circulation; and
 - store open and unopened vaccines in their original boxes until administration.
13. Place a product location map on the outside of the refrigerator so that vaccines can be easily located and the door does not need to remain open while searching for a product.
14. Minimize opening and closing the refrigerator door, and always ensure that it is closed tightly after use.

15. Ideally, stand-alone freezers should be used to store ice packs and vaccines that require freezer conditions. At the very least, the freezer must have door separate from the refrigerator section. The temperature should be maintained below -15°C.
16. Keep freezer packs in the freezer compartment or in the freezer. These can be used when transporting vaccines or in the event of refrigerator failure or power interruption.
17. Perform daily checks of the refrigerator and its accessories.
18. Perform monthly inspections of the refrigerator and its accessories.
19. Service the refrigerator and its accessories at least annually.
20. Maintain logs of monthly maintenance and service activities.
21. Have back-up storage available in case of refrigerator failure.

Vaccine Coolers, Transportation and Shipping containers:

When packing vaccines for transportation, a number of factors need to be considered: ambient temperature; distance and time in transit; mode of transportation; and amount of vaccine being packaged. It is essential that vaccines be transported in appropriate containers that are packed so that they are protected from temperature and light excursions. Consider the following when selecting and packing containers:

1. Minimize the number of times vaccine is handled and/or transported.
2. Protect the cold chain at all times, no matter how brief the period "out of refrigeration."
3. Transport vaccines in insulated containers large enough to hold vaccine, ice/gel packs, insulating material and temperature monitors.
4. Transport vaccines in temperature monitored containers.
5. Use appropriate freezer and gel packs. DO NOT use loose ice or snow.
6. Use signage on the outside of the container to indicate that it contains "*vaccine requiring controlled temperatures.*"
7. Use sturdy coolers that have a minimum insulation thickness of 30 mm to 80 mm. The cooler may be either soft or hard sided, but it must be strong and durable.
8. DO NOT place vaccines in the trunk of a vehicle.
9. Protect transport containers from direct sunlight.
10. Protect transport containers from vehicle air vents.
11. Protect vaccine from sunlight and fluorescent light.
12. Do not leave vaccines in an unattended vehicle.

Ice Packs:

Ice packs are required to maintain the cold chain during transportation of vaccine or out of refrigeration storage.

1. Ideally, ice packs should be kept in a separate freezer; at the very least, in a refrigerator that has a separate freezer section.
2. Ensure that the ice pack is completely frozen before use.

Insulating Material (including gel packs):

Insulating materials are used as a barrier between the vaccines and ice packs.

1. Gel packs should be kept refrigerated between 2° C and 8° C.
2. Crumpled packing paper, bubble wrap, shredded paper or styrofoam peanuts.

Temperature-Monitoring Devices:

Temperature-monitoring devices are necessary in all refrigerators in which vaccine is stored. Accurate and up-to-date storage logs are essential when assessing the impact of temperature excursions. The temperature should be checked and recorded twice daily. It is impossible to conclude that vaccines are being stored between 2° C and 8° C if temperature-monitoring devices are not used. Consider the following:

1. Do not use any thermometer that is not specifically recommended to monitor temperatures inside vaccine storage units.
2. Use a min-max or digital thermometer that is calibrated to +/- 1° C.
3. Ideally, a thermometer that can be read from the outside of the refrigerator or insulated cooler should be used.
4. The min-max thermometer or the temperature probe of the digital thermometer should be placed centrally in the refrigerator, not in the back, near the door or directly adjacent to cooling elements of the refrigerator.
5. Every min-max thermometer and digital thermometer is different. Read and follow each manufacturer's operating instruction carefully.
6. Inspect and service the min-max thermometer regularly. Change the batteries every six months (with the change to and from daylight savings time).
7. Always keep a supply of batteries on hand.
8. Always reset the min-max thermometer after recording the readings.

Warm and Cold Mark Indicators:

Warm and cold mark indicators are types of cold chain monitors that indicate whether vaccine containers have reached temperatures that are either too warm **or** too cold.

1. They are used to monitor temperatures during transport only and are NOT a substitute for twice daily temperature reading of vaccine refrigerators.
2. Warm and cold mark indicators should be placed on a vaccine box or card. They should not be placed directly on the shipping container or close to freezer packs.
3. Warm and cold mark indicators are to be used year-round.

Warm mark indicators used in transporting vaccine should have an activation temperature of 10° C. Once the activation temperature is reached, a dye is released that gradually moves across four windows. If the temperature drops below the activation temperature, the dye does not disappear but remains to provide an indication of the length of time the temperature has been outside of the activation temperature. Warm mark indicators must be conditioned and activated prior to use (refer to the manufacturer's directions) and are to be used year-round.

Cold mark indicators used in transporting vaccine have an activation temperature of 0° C. They do not give any indication of how long a vaccine has been exposed to temperatures of 0° C or below, just that the temperature has reached 0° C. Follow the manufacturer's directions and use cold mark indicators year-round.

Data Loggers:

Data loggers are continuous temperature recording devices that provide an account of refrigerator temperatures. They are invaluable following a temperature excursion because they can indicate when the exposure occurred and how long the vaccines were exposed to less than optimal temperatures.

1. Data loggers do not preclude the need to monitor temperatures twice daily.
2. Information from data loggers should be downloaded and/or printed out each month and retained for one year.

3.4.3 - Vaccine Storage and Handling Procedures

Written storage and handling procedures are necessary to ensure that there is a routine, systematic process for all aspects of vaccine storage and handling. **Each office, facility or location where vaccines are stored, handled or used should have written procedures or protocols that address or include:**

1. Monitoring vaccine inventory:
 - a. identification of person responsible;
 - b. twice daily temperature check;
 - c. maintenance of temperature logs (Refer to Appendix 4.10 – *Sample Temperature Log*);
 - d. determining inventory requirements;
 - e. weekly and monthly inventory levels;
 - f. placement of vaccine within refrigerators;
 - g. expiry dates – first-in, first-out; and
 - h. product storage requirements (temperature and light) information.
2. Ordering, receiving and disposal of vaccine:
 - a. identification of person responsible;
 - b. minimal inventory levels required for a one-month supply;
 - c. expiry dates of products;
 - d. ordering process (Refer to Standard 3.6 – *Vaccine Supply* and Appendix 4.1.5 and Appendix 4.1.6– *Vaccine Order Forms*)
 - i. Central Serum Depot (CSD);
 - ii. Sub depots (Refer to Appendix 4.5 – *List of Sub Depots*);
 - e. receipt of product
 - i. confirmation of maintenance of cold chain;
 - ii. product received matches what was ordered;
 - iii. addressing discrepancies; and
 - f. return of shipping containers.
3. Transportation of vaccine and temporary storage of vaccine:
 - a. identification of person responsible;
 - b. how to procure packing materials;
 - c. how to pack vaccines
 - d. temporary storage of vaccine in practice setting;
 - e. emergency storage of vaccine; and
 - f. transporting vaccine.
4. Maintenance of vaccine storage equipment:
 - a. identification of person responsible;
 - b. monthly equipment inspection;
 - c. annual vaccine refrigerator service;
 - d. maintenance of inspection and service logs;
 - e. identification of service personnel; and
 - f. contingency plans for refrigerator malfunctions or electrical disruptions.

5. Responding to vaccine storage and handling problems including temperature and light excursions:
 - a. identification of person responsible;
 - b. management of storage excursions (Refer to Standard 3.7 – *Management of Storage Excursions*);
 - c. equipment failures;
 - d. power outages;
 - e. alternate storage location; and
 - f. identification of resources including, but not limited to: biomedical technicians; product manufacturers; Centre for Disease Control unit; CSD, etc.

References:

1. *National Vaccine Storage and Handling Guidelines for Immunization Providers, 2015*. <https://www.canada.ca/en/public-health/services/publications/healthy-living/national-vaccine-storage-handling-guidelines-immunization-providers-2015.html>.
2. *CDC Manual, Immunization Section*, BCCDC, <http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm>.
3. *Vaccine Storage and Handling Guide*, Ontario Ministry of Health and Long-Term Care http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/reference/vaccine%20_storage_handling_guidelines_en.pdf.
4. *Vaccine Storage and Handling Guide, Protect your vaccines – Protect your patients*, US Center for Disease Control, October 2011 <https://www.cdc.gov/vaccines/hcp/admin/storage/index.html>.