VACCINE STORAGE AND HANDLING

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Cold Chain

“Cold chain” refers to the process used to maintain optimal temperature 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 recommended temperature for vaccine storage and handling is, at all times, at +2°C to +8°C.
- Maintaining a temperature of +5°C provides a safety margin for temperature fluctuations.

Cold Chain Break

Vaccines may be inactivated by exposure to excess light, heat or freezing, depending on the nature of the product, the temperature reached and the duration of exposure.

- Damage from successive exposures to temperatures outside of +2°C to +8°C is CUMULATIVE.
- Any loss of vaccine potency is PERMANENT and irreversible which would result in lower levels of protection against disease!

You are important!

By maintaining optimal temperatures while transporting, storing and handling vaccines you:

- Ensure the best quality vaccine for your clients
- Assist in preventing vaccine wastage
Acceptable Refrigerators for Vaccine Storage

• **Purpose-built refrigerator**
  Also called a pharmacy, vaccine, biologicals, laboratory or industrial grade refrigerator.

• **Domestic frost free refrigerator**
  Temperatures may fluctuate in different compartments within this type of refrigerator, and vaccines should only be stored in certain areas.

NOT-Acceptable Refrigerator for Vaccine Storage

Standard “bar” refrigerators (small volume combination refrigerator/freezer with one exterior door) are not adequate because they do not maintain cold chain temperatures.

Signs

• A “DO NOT UNPLUG” sign should be placed next to the refrigerator’s power outlet.

• A “VACCINE REFRIGERATOR-DO NOT DISCONNECT/DO NOT SWITCH OFF” sign should be placed on the vaccine refrigerator’s power breaker switch in the electrical panel box.
Do’s and Don’ts of Vaccine Storage in Refrigerators

- Refrigerators should be vaccine only: No food or beverages allowed.
- “First to expire, first out”. Rotate vaccine stock according to expiry date.
- Clearly label biological products that have had a cold chain incident, but are subsequently deemed to be usable. Use these vaccines as soon as possible.
- Refrigerator should be in a well-ventilated area - away from walls or other structures.
- Ensure area around the refrigerator is clean and free of dust.
- Keep refrigerator out of direct sunlight.
- Connect the refrigerator to a dedicated electrical circuit.
- DO NOT store vaccine on the door shelves.
**Vaccine Inventory**

- Establish a base order for all vaccines and minimum quantity to be kept on hand at all times (e.g., one month).
- Avoid over-ordering or early ordering. Do not stockpile vaccines.
- Check vaccine inventory regularly. Remove expired products to prevent the administration of expired products to a client.
- Multidose vials must be dated upon first entry and used within the time specified by the vaccine product monograph.

**Thermometer**

- Use a constant temperature-recording device or digital minimum/maximum thermometer (with probe) to monitor both the current refrigerator temperature and the minimum and maximum temperatures reached.
- Place the thermometer probe centrally (in the middle of the middle shelf) in the refrigerator, not at the back, the front or in the door. Placing the thermometer in the centre of the refrigerator decreases the chance of inaccurate measurement.
**Daily Monitoring of Vaccines – Data Logger (recommended)**

- Temperature data loggers are small, electronic devices that measure temperatures and keep a record of the results over a period of time.
- To obtain temperature readings the data logger is taken out of the refrigerator and connected to a computer that will download the information.
- The data logger does NOT replace daily monitoring and recording of refrigerator temperatures.

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**Daily Monitoring of Vaccines – Temperature (required)**

At the start and end of each work day, record on the temperature form:

- Current refrigerator temperature and maximum and minimum refrigerator temperatures
- Dial setting on the refrigerator
- Current room temperature
- Time the reading was taken

Record the temperatures on the form even when there is a continuous temperature recording device in use or when the refrigerator is connected to an alarmed temperature system.

Reset the min/max thermometer once you have recorded the temperatures.

Retain completed forms for a minimum of three years or as determined by the local Health Authority.
Insulated Containers

Insulated containers (coolers) are used to transport small quantities of vaccine off site during one working day, or to store quantities of vaccine needed for immunization on site during a working day, thus avoiding frequent opening of the refrigerator.

- The cooler must be able to maintain vaccine temperature at +2°C to +8°C during transport and throughout clinics.
- The temperature inside the cooler is maintained with ice packs, and insulating materials.
- The cooler should meet the following criteria:
  - large enough to store vaccines, ice packs, and insulating material;
  - strong and durable external surface material with a tight fitting lid.
Insulating Materials

- Insulating materials are used as a barrier to prevent direct contact between vaccines and ice packs.
- Insulating materials include flexible insulating blankets and gel packs at refrigerator temperature (+2°C to +8°C), bubble wrap, crumpled packing paper or styrofoam peanuts.
- A layer of paper toweling is not sufficient as a barrier to protect vaccines from contact with frozen material.

Ice Packs

- Keep enough ice packs frozen ready to meet the vaccine transport needs of your clinic or health unit.
- In the freezer, set ice packs on their edge and allow space between them for air circulation. Stacking ice packs on top of each other in the freezer may result in uneven or partial freezing, and decrease the efficacy of the ice packs.
- Ensure that ice packs are completely frozen before use.
How to Pack an Insulated Container to Transport Vaccines

- Keep vaccines in original packaging.
- Place a min/max thermometer with the vaccine in the cooler.
- Provide a protective barrier of insulating material, such as a flexible insulating blanket, between the vaccines and the ice packs.
- Place ice packs at the top of the cooler.
- Packing configuration should be tested to ensure +2°C to +8°C temperature can be maintained.

Receiving/Transporting Vaccines

- Unpack vaccines as soon as possible. All staff need to be aware of the urgency of this process.
- Transfer vaccines to the refrigerator immediately, minimizing the time that the refrigerator door is open.
- When transporting vaccines, use an insulated container (cooler) of appropriate size for vaccine order. Cooler should contain ice packs and insulating materials.
- Keep cooler out of direct sunlight.
- Keep trips as short and direct as possible from the public health unit to your office.
What is a Cold Chain Incident?

Any temperature outside of the +2°C to +8°C range requires immediate action.

Exposure of vaccines to 0°C to +2°C does not constitute a cold chain incident, taking into account the accuracy of the thermometer.

Is your equipment working properly?

• Check to see if the refrigerator door is closed.
• Check that the thermometer is working correctly.
• Check that the refrigerator has not been unplugged.
• If refrigerator temperature requires adjustment, turn dial by a small amount and monitor temperature closely.
• Have the refrigerator serviced.
What do you do with the vaccine?

- Do not return vaccines until usability has been determined.
- Place exposed vaccines in a container and label “DO NOT USE” and mark with the date and time.
- Place this container into a functioning refrigerator, ensuring that the exposed vaccines are separate from any non-exposed vaccines. Exposed vaccines must be returned to +2°C to +8°C as soon as possible.
- If a functioning refrigerator isn’t available, place vaccines in a cooler with ice packs and monitor temperature.

What do you record?

On the temperature form record date and time and the following 4 temperatures:

- Current refrigerator temperature
- Minimum temperature reached since last check
- Maximum temperature reached since last check
- Current room temperature

What do you do with the vaccine?

- Clearly label useable vaccines that have been exposed to a cold chain incident.

Who do you inform?

- Complete “Cold Chain Incident” form.
- Send the completed form to your local health unit. Health unit staff will send the form to the Biological Product Consultant (BPC).
- A BPC will:
  - assess whether the vaccine can be used using available guidelines;
  - contact BCCDC pharmacy as needed;
  - inform you whether the vaccine(s) can be used or should be returned for disposal.
- Clearly label useable vaccines that have been exposed to a cold chain incident.
Power Outages

Establish an office-specific emergency plan for power failures or equipment malfunction.

- Identify a back-up refrigerator that is accessible, monitored and functional at all times.
- On the temperature form, record the refrigerator temperature (minimum, maximum and current), room temperature, and time, as soon as possible after the start of the power failure. Reset the thermometer.
- Place a “DO NOT USE” sign on the refrigerator. Do NOT open the refrigerator except to remove vaccines for alternate storage.
- If power is expected to be restored within four hours or less, keep the vaccines in the refrigerator and keep the refrigerator doors closed.
- If a longer power outage is expected, or if the refrigerator temperature is going out of range quickly, move vaccines to a cooler with ice packs and insulating material. Take the vaccines to a facility that has a functioning monitored refrigerator (i.e., that has power or a back up generator) as per the local emergency plan.
- Continue to monitor and record refrigerator temperatures for the duration of the outage. If power failures are a common occurrence, centralize vaccine storage to a more power-stable facility.
- Record the time and refrigerator temperatures (current, minimum and maximum) when the power is restored.
Vaccine Storage and Handling Resources

To access the following resources:

- Cold chain management
- Quick references including the online version of this booklet
- Checklists & forms
- Mass immunization clinic management

Refer to the BCCDC Vaccine Management webpage: https://bit.ly/2OMI5O7

For more information:

- Cold Chain Incident Form: https://bit.ly/2YebNyl

Online education:

- Vaccine Storage and Handling Course: https://bit.ly/2r9ClVm
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