

Chapter 6 – Requirements on vaccine storage and handling under VSS

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6.1 Vaccine cold chain

1. Cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport, storage and handling of vaccines from the time they are manufactured until they are administered. The optimal cold chain temperature range for the majority of vaccines is between +2°C and +8°C. Product inserts should be referred for detailed handling on the specific vaccines
2. Vaccines are sensitive to temperature and light. When vaccines are exposed to temperatures outside the recommended ranges, or direct sunlight or ultraviolet light, they can lose their potency and effectiveness. For example, freezing vaccine can increase the risk of adverse effect by irreversibly denaturing the proteins in the vaccines and producing cracks in the vial/prefilled syringe, thereby potentially contaminating the contents. Vaccines must be stored properly to maintain the vaccine potency and effectiveness.
3. The vaccines exposed to temperatures outside the recommended range should not be used until all queries are clarified with the manufacturer(s) or supplier(s).

6.2 Responsibilities of doctors

All doctors under VSS, i.e. new enrollees and doctors already enrolled, are required to:-

1. Follow the requirements and recommendations set out in this Chapter and Section 3.3 of the **Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings - Module on Immunisation**. (https://www.healthbureau.gov.hk/pho/rfs/english/pdf_viewer.html?rfs=PreventiveCareForChildren&file=ModuleOnImmunisation_Chapter3).
2. Select and use the proper vaccine storage fridge to store vaccines. Do not use a domestic fridge for vaccine storage.
3. Ensure all vaccines are stored and handled strictly following the recommendations from respective manufacturers
4. Monitor vaccine temperature continuously using a temperature data logger or a digital maximum-minimum thermometer until the vaccines are administered.
5. Provide temperature records, photo(s) of each vaccine-storing refrigerator and the temperature monitoring device / system to CHP upon request, during VSS enrolment or

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if there is any update on the practice or the fridge.

Note: Regarding the term of "refrigerator", it should only provide cold storage/ cooling for proper storage of vaccine

6. Establish, implement and updated written protocols for:-
 - (a) Vaccine storage, ordering and handling,
 - (b) Management of Cold chain breach, and
 - (c) Vaccine disposal.
7. Designate a trained person, with at least one backup person, for proper storage and handling of vaccines.
8. Provide training to staff and ensure that they comply with the guidelines and implement the written protocols
9. When irregularities are identified, take appropriate actions promptly and inform CHP as appropriate if VSS clients are involved.

6.3 Vaccine storage in refrigerators

6.3.1 Choice of refrigerators

- (a) Doctors enrolled in VSS have to use **Purpose-built vaccine refrigerators (PBVR)** (also referred to as pharmacy or laboratory refrigerators) for vaccine storage. PBVRs are specifically designed to store vaccines (see Figure 1). **PBVRs are the only suitable option for vaccine storage on and after 1 Sep 2023.** There are range of sizes of PBVR to fit clinic's needs. The PBVR should meet the local statutory safety requirements for use in Hong Kong.

Note: Purpose-built units, sometimes referred to as “pharmaceutical-grade”, are designed specifically for storage of biologics, including vaccines.

- (i) The PBVR should have the following features:
 - Microprocessor-based temperature control system to achieve narrow tolerances within internal temperatures
 - Have a feedback system, which has narrow tolerances with internal temperatures, providing appropriate temperature regulation

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- Suitable for the storage vaccine between +2°C and +8°C (thermostat should be set at optimal midrange of +5°C)
- Forced air circulation system to main promoting stable and uniform temperature and rapid temperature recovery after door opening
- Have a digital temperature monitoring system with an alarm set at appropriate setting level. High /Low Temperature audible alarms when the inner temperature is below +2°C or above +8°C, or power failure
- Digital Temperature Display
- A lockable door
- Fully automatic defrosting

(ii) Other features

- A display with current, maximum and minimum temperature providing a convenient means to monitor the vaccine storage temperature and to facilitate manual recording of the temperature readings
- Open door sensor which alerts the user that the fridge door is not properly closed



Figure 1. PBVR are available in different sizes

(iii) Place the PBVR in a room:

- Well-ventilated, temperature-controlled, away from direct sunlight, and without seasonal variations in room temperature which may affect the refrigerator temperatures;

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- That allows a space between the unit, ceiling and any wall for air circulation around the back and sides of the unit, as recommended by the fridge manufacturer; and
- That allows the refrigerator unit to be leveled, and the doors to be opened and closed smoothly which fit squarely against the refrigerator unit;

(iv) Precautions:

- Connect vaccine refrigerators to a dedicated electric circuit so that enough power is available for safe operation without overloading the system, and as recommended by the manufacturer;

(v) Routine maintenance

- The fridge should be maintained in a clean condition

(vi) Incident reporting

- In case of fridge failure,
 - Quarantine all affected vaccines from other vaccines (but maintain in the cold chain)
 - Record all details of the incident
 - Report the incident to PMVD using the incident form

- (b) **Domestic frost-free refrigerators (should not be used),** starting from 2023/2024 season, the use of domestic refrigerators for vaccine storage will not be allowed. Domestic fridges are designed and built for food and drink storage. It is not for the special temperature requirements of vaccines.



Figure 2. Domestic Fridge should not be used in 2023/24 season

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(c) Manual defrost and bar refrigerators (Should not be used):

- (i) an ice-maker compartment within the fridge with one exterior door (see Figure 3 and 4), should not be used because they produce wide fluctuations in the internal temperatures and pose a significant risk of freezing.



Figure 3. Frost may form inside the freezer compartment



Figure 4. Bar refrigerators should not be used

(d) Commercial display refrigerators (should not be used):

- (i) Commercial display refrigerators (Figure 5) are often missing fans or advanced control mechanisms necessary to maintain temperature uniformity. They intended to store food, beverages or flowers in commercial setting. The temperature range of keeping those items are different from the pharmaceutical products, especially temperature-sensitive products such as vaccines.



Figure 5: Commercial display refrigerators should not be used

6.3.2 Stabilizing temperatures in new or repaired refrigerators

- (a) Before using a PBVR for storing vaccine, check and record the maximum and minimum temperatures for two to seven days.
- (b) Check the current, maximum and minimum temperatures at least three times daily. Adjust the temperature setting as needed.

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Note: It is important that the cold spots in the refrigerator are identified by detailed monitoring before using the refrigerator for vaccine storage.

- (c) Manually record the readings on a temperature log sheet, unless temperature logs can be generated/downloaded by your temperature monitoring device.

Samples of temperature log sheet are available on CHP website. For English, please visit <https://www.chp.gov.hk/files/pdf/temprecordeng.pdf>; for Chinese, please visit <https://www.chp.gov.hk/files/pdf/temprecordchi.pdf>.

- (d) Once the temperatures recorded are within the recommended range for two consecutive days, the refrigerator is stable and ready for use.

6.3.3 Placing the refrigerator and its maintenance

- (a) PBVR should be placed in a secure area accessible to staff only.
- (b) Ensure the refrigerator is placed out of direct sunlight. Be aware of seasonal changes in room temperature that may affect the refrigerator temperature.
- (c) Label the power source to prevent the refrigerator from being accidentally unplugged or turned off.
- (d) It is a good practice to have an annual check and maintenance of the PBVR.

6.3.4 Organizing and storing vaccines inside refrigerators

- (a) Keep vaccines in their original packaging, inside designated storage trays or open-weave baskets with clear labeling for the type of vaccine.

Note: Vaccines are stored in their original packaging to protect them from temperature fluctuations and UV light.

- (b) Place vaccines in the center of the refrigerator space, and position away from refrigerator walls and doors. Allow space between stocks for air circulation to promote proper airflow (see Figure 6).
- (c) Keep vaccines with earliest expiration dates in the front of the shelf/basket. Remove any expired vaccines.
- (d) **Do not** store food or beverage or clinical specimens alongside vaccines in the vaccine storage refrigerator.
- (e) Minimise refrigerator door opening. Tightly close the door after each opening.

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*Figure 6. Vaccine Storage and Handling Toolkit.
Centers for Disease Control and Prevention. January 2023.*

6.3.5 Temperature monitoring of refrigerators

- (a) Temperature of each vaccine-storing refrigerator must be continuously monitored by a temperature data logger, an automated temperature monitoring system or a digital maximum-minimum thermometer. An additional data logger or digital maximum-minimum thermometer (see Figure 7 and 8), is required if the in-built data logger or in-built max-min thermometer is not available. A digital display of monitoring device makes it easy to check the temperature and record it manually. Please note the type of temperature-monitoring device may change as new technology becomes available.
- (i) **Digital maximum-minimum thermometers** measure the current, minimum and maximum temperatures that have been reached since it was last reset. If not available
- Place the sensor/probe of the temperature monitoring device in the center of the vaccine-storing refrigerator away from the coils, walls, door, floor, and fan.
 - It is a good practice to calibrate the temperature data logger or digital maximum-minimum thermometer regularly.
 - Check the current, maximum and minimum temperatures of each vaccine-storing refrigerator **at least three times daily**¹ in a full working day. Regular checks provide an opportunity to identify fluctuations in

¹ According to COVID-19 Vaccination training for health workers from WHO, Module 2: Storage, handling, delivery, waste management for COVID-19 vaccines, it is recommended in the storage part to install reliable continuous monitoring system and monitor temperature more frequently (more than 2 times a day).

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temperature that might require necessary action.

- Record the temperature at the same time every day during the working day and sign the sheet.
- **Reset** the maximum-minimum thermometer after each recording.
- Post the “Temperature Chart” at visible location such as the refrigerator door.

Note: Care should be taken that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the range

(ii) Data logger

- Track the continuous temperatures which offer a historical record of fridge temperatures
- Set data loggers to record temperatures at least every 30 minutes.
- Data logger should have a digital display screen for visually checking the temperature of the refrigerator.
- The data logger temperature reading should be reviewed three times daily (if the clinic operates full day).
- Information should be downloaded at least weekly (or more often if required). Once a temperature breach is noticed; the maximum and minimum temperatures reached and the duration of the excursion should be checked and recorded. Refer to Section 6.5 for management of cold chain breach.
- Designated staff should be trained to manage the data logger.

(iii) **Remote or wireless temperature monitoring systems** are recently launched in the market and can be used to continuously monitor refrigerator(s) temperatures in real time.

(iv) **Regular thermometers** (alcohol or mercury thermometers) should not be used because they only show the temperature **at the exact time** they are checked

(b) **Manually record** the readings on a temperature log sheet, unless temperature logs can be generated/retrieved from your temperature monitoring device/system.

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- (c) Temperature records should be kept for at least **one year**²
- (d) Samples of temperature log sheet are available on CHP website. For English, please visit <https://www.chp.gov.hk/files/pdf/temprecordeng.pdf>; for Chinese, please visit <https://www.chp.gov.hk/files/pdf/temprecordchi.pdf>



Figure 7. Temperature data loggers



Figure 8. Maximum-minimum thermometers

6.4 Vaccine storage and handling under non-clinic settings (outreach or transfer vaccines)

6.4.1 Vaccine transport and temporary storage

- (a) A standard procedure for vaccine transport should be in place.
- (b) Tested cold box(es) equipped with ice packs, temperature data loggers/ digital maximum-minimum thermometers, and insulating materials (e.g. bubble wrap or Styrofoam) should be used for transporting vaccines (to and from venue) and storing them temporarily at the venue.
- (c) Transport only the required quantity for the event.
- (d) Alternatively, vaccines can be delivered directly to the venue by the vaccine supplier. In such case, doctors should:-
 - (i) Allow sufficient time for the vaccine to be delivered before the outreach vaccination activities start.
 - (ii) Monitor the temperature of each cold box by a digital maximum-minimum

² The 1-year-record can provide a whole vaccine storage temperature record that could facilitate the assessment from the manufacturers on the stability and effectiveness of the multiple excursion vaccines.

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thermometer or a data logger and ensure the temperature maintained at the recommended temperature throughout the activities.

(iii) Follow the requirements set out in **Section 6.6.1** Vaccine delivery and receipt.

6.4.2 Cold box packing

- (a) A standard procedure for cold box packing should be in place.
- (b) Use appropriate insulated cold box, with tight fitting lid, ice packs and insulating materials to hold the vaccines to ensure the cold chain is maintained between +2°C and +8°C during transport and temporary storage at the venue.
- (c) Pre-cool cold box (by placing ice packs inside the container) to desirable temperature before packing vaccine. The principles of packing a cold box should be followed as shown in Figure 9 below.
- (d) Vaccines should only be taken out from the refrigerator just before packing. Record the time and the fridge temperature when the vaccines are taken out from the refrigerator.
- (e) Unless otherwise instructed by the manufacturer, it is a good practice to use conditioned ice packs to prevent freezing of vaccines.
 - (i) Frozen ice packs may be conditioned by exposing them to room temperature, soaking in several inches of cool or lukewarm water, or putting them under running water.
 - (ii) An ice pack is properly conditioned if movement of water is heard when it is shaken.
 - (iii) The preparation time depends on the room and/or water temperature.
- (f) The whole setup of the cold boxes, should be tested for insulation time and temperature stability in cold chain before it is used for transporting vaccines (to and from venue) and storing them temporarily at the venue.
- (g) For demonstration, please refer to the video **How to Pack a Cold Box** on CHP website. (Available in Cantonese only at <https://www.chp.gov.hk/tc/features/102010.html>)

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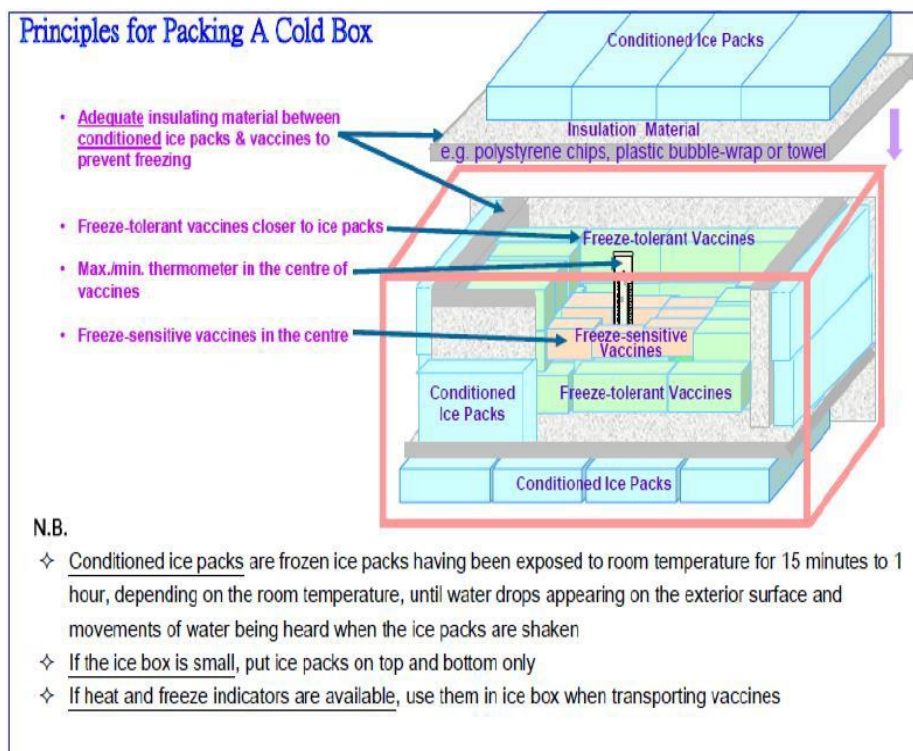


Figure 9. Principles for Packing Cold Box. (Photo source: Public Health Nursing Division, 2008.)
(Source: Nursing procedure Guidelines on Immunisation: Quality Assurance Committee, Public Health Nursing Division, Department of Health, HK (December 2014 revised))

6.4.3 Precautions on handling vaccines and cold chain equipment

(a) Vaccines

Keep vaccines in their original packaging prior to vaccination and away from direct sunlight.

(b) Cold box(es)

Keep the cold boxes properly closed and avoid frequent opening and away from direct sunlight.

(c) Ice packs

(i) Do not put ice packs in direct contact with the vaccines, sensor or probe of the temperature data logger or maximum-minimum thermometer.

(ii) Keep sufficient stock of ice packs to meet the needs of vaccine transport.

(d) Insulating materials, e.g. bubble wrap or Styrofoam

Place adequate insulating materials between conditioned ice packs and vaccines to prevent freezing.

(e) Temperature data logger/ maximum-minimum thermometer

Place the sensor/probe at the center of the cold box.

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6.4.4 Temperature monitoring under non-clinic settings

- (a) Use a temperature data logger/ digital maximum-minimum thermometer to monitor the vaccine temperature continuously during vaccine transport (to and from the venue) and temporary storage at the venue.
- (b) Record the time and vaccine temperature:-
 - (i) When vaccines are removed from the vaccine-storing refrigerator,
 - (ii) At the start of a vaccination activity,
 - (iii) At the end of the vaccination activity, and
 - (iv) Before returning the unused/surplus vaccines to the vaccine-storing refrigerator.
- (c) In case temperature excursion occurs, please refer to **Section 6.5** Management of cold chain breach.

6.5 Management of cold chain breach

6.5.1 Actions to manage cold chain breach

- 1. When vaccines are exposed to temperatures outside the +2°C to +8°C range, the loss of potency may not be reversed.
- 2. In case of temperature excursion (i.e. vaccines were exposed to temperatures outside recommended range), take appropriate actions including:-
 - (a) Immediately isolate the affected vaccines and label **“Do NOT Use”**.
 - (b) Keep the affected vaccines refrigerated between +2°C and +8°C as soon as possible to minimize the impact on vaccine potency.
 - (c) Contact the vaccine manufacturer(s) for advice of the affected vaccines and determine whether the vaccines stability and potency is maintained. If in doubt, do not use.
 - (d) The affected vaccines should not be administered until notice from vaccine manufacturer confirmation.
 - (e) Clinic staff should record the temperature range, date and duration of cold chain breach and other information required on the “Temperature Excursion Incident

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Report Form” at Chapter 4
(https://www.chp.gov.hk/files/pdf/vss_incident_report_temperature_excursion.pdf)
and submit the form to VSS Office not later than 1 working day after the incident.

3. Inform CHP if VSS clients are involved and the vaccine manufacturer has confirmed that the quality of the vaccines are affected.
4. Follow up with the concerned recipients immediately if affected vaccines are administered and assess the need for revaccination.

6.5.2 Take appropriate steps to correct and to prevent cold chain breach

1. Check the manufacturers' recommendations on the storage of individual vaccines.
2. Arrange a proper maintenance of the vaccine-storing refrigerator.
3. Enhance staff training and ensure that they comply with the guidelines and protocol for storage and handling vaccines.
4. Implement routine temperature monitoring to help to identify temperature excursions quickly and take appropriate action.
5. If mechanical problem of the refrigerator is suspected, clinic staff should call for the maintenance service immediately.
6. Clinic staff should keep all reports related to the incident e.g. temperature records, Temperature Excursion Incident Reports, etc., at the clinic for at least one year in case for inspection in the future.

6.6 Vaccine delivery, inventory control and disposal

6.6.1 Vaccine delivery and receipt

- (a) Vaccines must only be received by designated staff regardless of the settings.
- (b) When receiving the vaccines, the staff must:-
 - (i) Check against the order for discrepancies, leakage or damages.
 - (ii) Check whether cold chain is maintained during vaccine delivery and record the temperature, date and time of the vaccine delivered. Reject the vaccines if

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temperature excursion occurred during its delivery.

- (iii) Check against the order for vaccine type(s), brand(s), quantities, batch number(s) and expiry date(s) of the vaccine delivered

- (c) In clinics, vaccines must be refrigerated immediately upon receipt and must not be left at room temperature.

6.6.2 Stock level and inventory control

- (a) Order appropriate levels of stock. Overstocking of vaccines may:-
 - (i) Increase wastage and the cost of disposal.
 - (ii) Lead to poor air circulation and failure to achieve stable temperature in the refrigerator.
 - (iii) Lead to poor stock rotation and increase the risk of using expired vaccines.
- (b) Rotate stock so that vaccines with the earliest expiry date are used first.

6.6.3 Disposal of expired/unserviceable vaccines

- (a) Any expired/unserviceable vaccine should be labeled clearly and removed from the refrigerator immediately.
 - (i) Expired/unserviceable vaccines must **NOT** be administered to clients.
- (b) Expired/unserviceable vaccines should be disposed according to guidelines from the Environmental Protection Department (EPD) (Available at https://www.epd.gov.hk/epd/english/environmentinhk/waste/guide_ref/guide_cwc_sub2.html)

6.7 Handling of spillage

1. Spillage should be cleared up quickly; personal protective equipment should be worn.
2. Cover the spill with disposable absorbent materials.
 - (a) For live attenuated vaccines, mop the area with a cloth or paper towels wetted with one part of household bleach (5.25% hypochlorite solution) in 4 parts of water, leave for 10 minutes then rinse with water.
 - (b) Use 70% alcohol to disinfect metal surfaces.

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(c) Use forceps to transfer the sharps into sharps box.

3. Dispose of all contaminated waste material into appropriate plastic waste bag.
4. Spillages on skin should be washed with soap and water.
5. For mucosal contact such as spillage into the eyes, the exposed part should be washed immediately and liberally with running water. Medical advice should be sought.

6.8 Contingency plan

VSS doctors' 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 at the premises, arrangements should be prepared in advance with an alternate storage site.