

2

The vaccine cold chain

About this module...

The purpose of the vaccine “cold chain” is to maintain product quality from the time of manufacture until the point of administration by ensuring that vaccines are stored and transported within WHO-recommended temperature ranges.

This module provides guidance for workers at health facility level. It covers the use of cold chain and temperature monitoring equipment and the basic maintenance of cold chain equipment. The module describes the existing range of WHO prequalified equipment at the time of publication. Up-to-date information on prequalified equipment is available on the WHO Performance Quality Safety (PQS) website (http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/).

Some of the figures in this module show equipment from specific manufacturers. This is for illustrative purposes only and does not indicate WHO official endorsement of these products.

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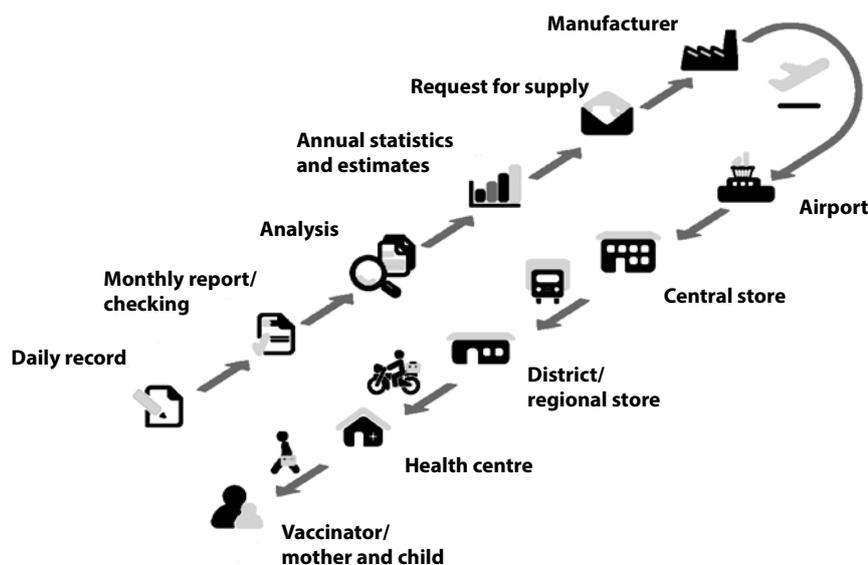
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1

The cold chain

The system used for storing vaccines in good condition is called the cold chain. It is sometimes referred to as the vaccine supply chain, or the immunization supply chain. The cold chain consists of a series of links that are designed to keep vaccines within WHO recommended temperature ranges, from the point of manufacture to the point of administration. Figure 2.1 illustrates the complete cold chain. The bottom row of arrows shows the flow of vaccines down to the health facilities; the top row of arrows shows where data are collected, recorded, checked and analysed, and how reporting information flows back up the chain. Following this sequence ensures that cold chain performance is properly monitored and that the necessary information is gathered for vaccine forecasting.

Figure 2.1 The cold chain



Source: PATH/WHO

In order to maintain a reliable vaccine cold chain at the peripheral level, the following key procedures must be observed:

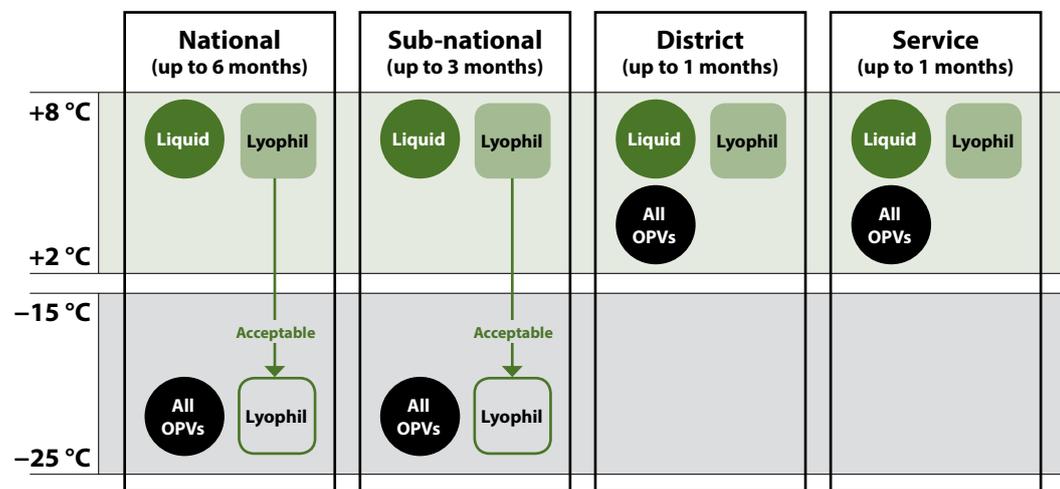
- store vaccines and diluents within the required temperature range at all sites
- pack and transport vaccines to and from outreach sites according to recommended procedures
- keep vaccines and diluents within recommended cold chain conditions during immunization sessions.

Section 5 of this module describes how to store and pack vaccines at health facility level.

1.1 Temperature requirements for vaccines

Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and others to light. Vaccine potency, meaning its ability to adequately protect the vaccinated patient, can diminish when the vaccine is exposed to inappropriate temperatures. Once lost, vaccine potency cannot be regained. To maintain quality, vaccines must be protected from temperature extremes. Vaccine quality is maintained using a cold chain that meets specific temperature requirements. Figure 2.2 shows recommended vaccine storage temperatures at each level of the cold chain. It is essential that all those who handle vaccines and diluents know the temperature sensitivities and the recommended storage temperatures for all the vaccines in the national schedule.

Figure 2.2 Recommended vaccine storage temperatures



Note:

Diluents should never be frozen.

If diluents are packaged with the vaccine, the product should be stored at +2 °C to +8 °C.

Bundled lyophilized-liquid combination vaccines should never be frozen and should be stored at +2 °C to +8 °C.

Sensitivity to heat and freezing

Figure 2.3 shows the relative heat sensitivity of vaccines. These vaccines are grouped into six categories. Within each of these six categories, the vaccines are arranged in alphabetical order, not in order of sensitivity to heat within the group. The most heat sensitive vaccines are in Group A and the least heat sensitive vaccines are in Group F.

Note that the heat stability information shown for freeze-dried vaccines applies only to unopened vials; most freeze-dried vaccines rapidly lose potency after reconstitution. In addition, it is important to keep opened multi-dose vaccine vials that do not contain preservative – whether lyophilized or liquid – cooled at temperatures between +2 °C and +8 °C during the immunization session, or within six hours after opening, whichever comes first.

Vaccines that are sensitive to freezing and should be protected from sub-zero temperatures are listed in Figure 2.4.

Figure 2.3 Vaccine heat sensitivity

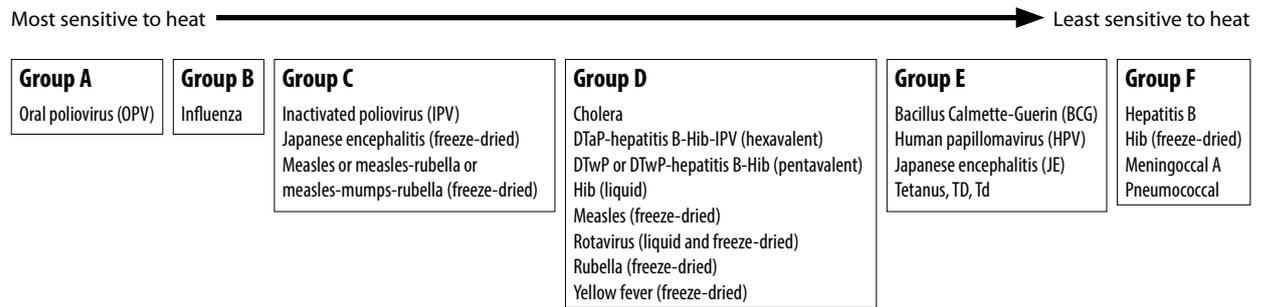


Figure 2.4 Freeze sensitive vaccines

DO NOT FREEZE THESE VACCINES!!!

- Cholera
- DTaP-hepatitis B-Hib-IPV (hexavalent)
- DTwP or DTwP-hepatitis B-Hib (pentavalent)
- Hepatitis B (Hep B)
- Hib (liquid)
- Human papillomavirus (HPV)
- Inactivated poliovirus (IPV)
- Influenza
- Pneumococcal
- Rotavirus (liquid and freeze-dried)
- Tetanus, DT, Td

Sensitivity to light

Some vaccines are very sensitive to light and lose potency when exposed to it. Such vaccines should always be protected against sunlight or any strong artificial light, and exposure should be minimized. Vaccines that are as sensitive to light as they are to heat include BCG, measles, measles-rubella, measles-mumps-rubella and rubella. These vaccines are often supplied in dark glass vials that give them some protection from light damage; but they should be kept in their secondary packaging for as long as possible to protect them during storage and transportation.

Controlled Temperature Chain (CTC)

An increasing number of vaccines are being examined to determine their compatibility with a Controlled Temperature Chain (CTC), which would allow their use at ambient temperatures. WHO defines a CTC as the on-label use of a WHO-prequalified vaccine out of the traditional +2 °C to +8 °C cold chain for a limited period of time, at temperatures of up to 40 °C, just before administration. Vaccines licensed accordingly can be used in a CTC. The CTC approach can be adopted by countries for carefully chosen circumstances, such as for special strategies or mass vaccination campaigns.

1.2 The cold chain at health centre or peripheral health facility level

At the health facility level (usually health centres and health posts), health workers can adequately protect vaccines by doing the following:

- Keep vaccines in appropriate vaccine refrigeration equipment.
- Use a temperature monitoring device to ensure temperatures remain between +2 °C and +8 °C.
- Transport vaccines to immunization sessions in a vaccine carrier, correctly packed, using coolant packs that have been properly prepared, as described in Section 2.4 of this module.
- During immunization sessions, fit a foam pad (if available) at the top of the vaccine carrier, as described in Section 2.5 of this module.

At the health facility, one person must have overall responsibility for managing the vaccine cold chain. A second person can fill in when the primary person is absent. Their responsibilities should include:

- checking and recording vaccine temperatures twice daily; typically in the morning and at the end of the session or day
- properly storing vaccines, diluents and water packs
- handling preventative maintenance of the cold chain equipment.

All health workers in a facility should know how to monitor the cold chain and what to do if temperatures are out of range, as described in Section 4.2 of this module.

2

Health facility cold chain equipment

Different levels within the national cold chain system require different types of equipment for transporting and storing vaccines and diluents within the required temperature range.

- **Primary level (national):** Depending on the capacity required, the primary level generally uses cold or freezer rooms, freezers, refrigerators, cold boxes and, in some cases, refrigerated trucks for transportation.
- **Intermediate level (province or district):** Depending on the capacity required, intermediate level generally uses cold and freezer rooms and/or freezers, refrigerators and cold boxes and, in some cases, refrigerated trucks for transportation.
- **Peripheral level (health centre/facility or health post):** Depending on the capacity required, health facilities generally need refrigerators (in certain instances with water pack freezing/cooling compartments), cold boxes and vaccine carriers. In some countries, cold boxes alone may be used for monthly or weekly immunization sessions.

To ensure optimal performance, cold chain equipment used for immunization programmes at any level must comply with relevant technical specifications, as defined under WHO prequalification standards or as determined by national regulatory authorities. This module focuses on cold chain equipment needed at peripheral-level health facilities.

2.1 Refrigerators

Health facility refrigerators may be powered by electricity, solar energy or gas (or kerosene). A health facility refrigerator should be chosen based on the most reliable power supply available and the combined capacity needed for vaccine and water pack storage. Table 2.1 briefly describes the different refrigerator categories.

Domestic refrigerators do not have good temperature control and they cannot keep vaccines cool during electricity cuts of more than one or two hours. These units are not specifically built or designed to store vaccines. For this reason, domestic refrigerators are not recommended by WHO for vaccine storage.

Table 2.1 Types of vaccine refrigerators

Categories of vaccine refrigerators	Description
Electric <i>(also referred to as compression units)</i>	Ice-lined refrigerators are the preferred option where there is reliable mains electricity for at least eight hours per day. Even with periodic breaks in electricity, the inner lining of the unit can preserve the +2°C to +8°C holdover time. A few models are available that can operate effectively on as little as four hours of electricity per day (see Figure 2.19). Ice-lined refrigerators can expose vaccines to freezing temperatures if vaccines are not loaded properly.
Solar energy <i>(also referred to as photovoltaic units)</i>	Solar refrigerators are more expensive to buy and install than electric refrigerators, but they have no running costs, apart from cleaning and preventative maintenance. The two types are: a) solar-battery units connected to a battery bank, which is charged by the solar panels and b) solar direct-drive units that are powered directly by the solar panels.
Bottled gas (or kerosene) <i>(also referred to as absorption units)</i>	Bottled gas (or kerosene) refrigerators may be necessary in places where there is insufficient sunshine for a solar-powered unit. Gas-powered units are better than kerosene models because they need less maintenance and have better temperature control. Bottled gas and kerosene refrigerators can expose vaccines to freezing temperatures. Keeping vaccines in the +2°C to +8°C range is particularly difficult with kerosene refrigerators.

Since 2009, all WHO prequalified ice-lined, solar battery and solar direct-drive refrigerators have been fitted with thermostats that cannot be adjusted by the user. Provided power cuts are not excessive, the temperature in these refrigerators should always remain between +2 °C and +8 °C. If there is a recurring problem with the temperature control in these models, you must notify your supervisor and call the refrigerator technician. These newer refrigerators all carry a round red and blue sticker: the top red semi-circle shows the maximum allowable operating temperature and the bottom blue semi-circle shows the minimum operating temperature.

For older ice-lined and solar equipment, domestic refrigerators, and all gas and kerosene refrigerators, proceed as follows:

- When the refrigerator is first installed, set the thermostat so that the refrigerator compartment stays between +2 °C and +5 °C during the coldest part of the day (typically the morning). It is essential to avoid freezing temperatures and the freezing risk is greatest when the ambient room temperature is low.
- Once you can see that the daily temperature range remains consistently between +2 °C and +8 °C, the thermostat is correctly adjusted and the **setting should not be changed**, even if electrical power is lost.
- Do **not** adjust the thermostat if the temperature occasionally rises a degree or so above +8 °C after a power cut, or in very hot weather.

A health facility refrigerator must never be packed solid – always leave plenty of space around the vaccines and diluents to allow air to circulate freely, and to make vaccine handling easier. Typically, a health facility refrigerator should be chosen so that it is able to hold:

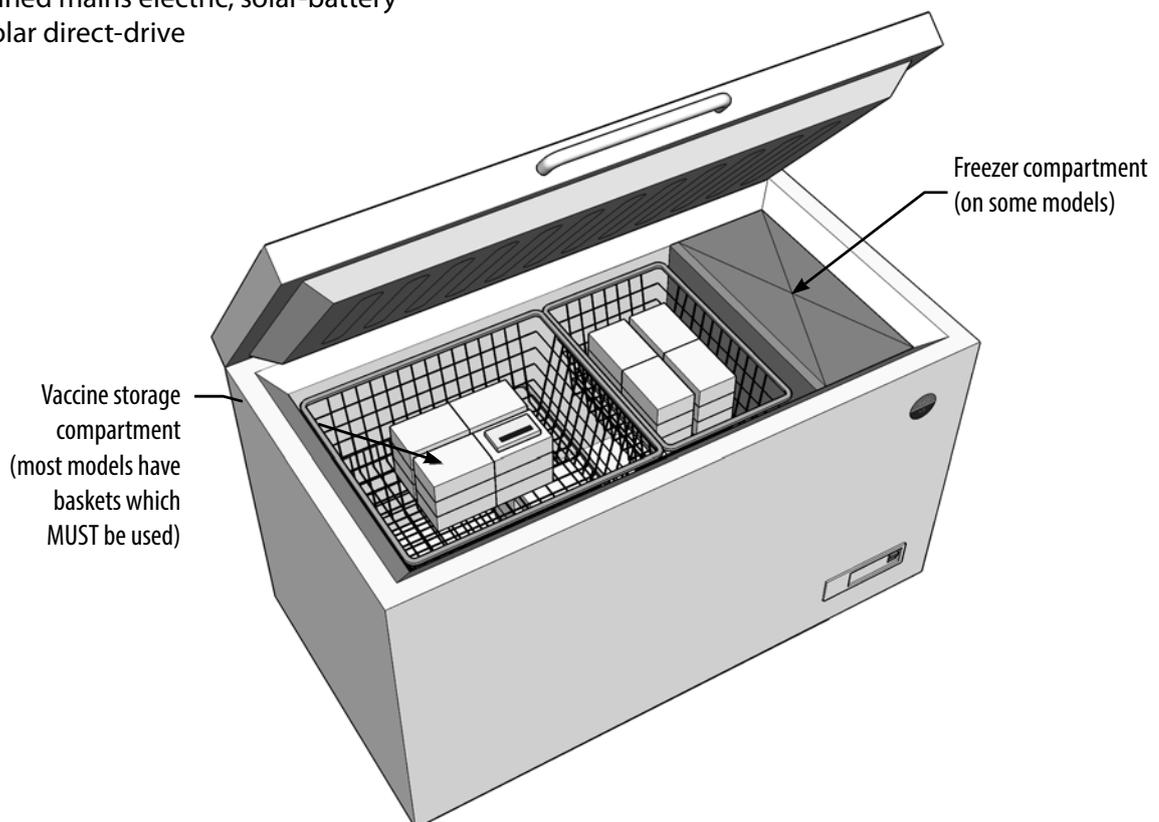
- at least one month's supply of vaccines and diluents in the refrigerator compartment
- a one- or two-week reserve stock of vaccines and diluents (usually an additional 25–50% of the one-month supply)
- a minimum of four water packs in the freezer/cooling compartment.
(Note: For technical reasons, some solar direct-drive refrigerators cannot freeze ice packs.)

Figure 2.5 shows three commonly used types of refrigerators.

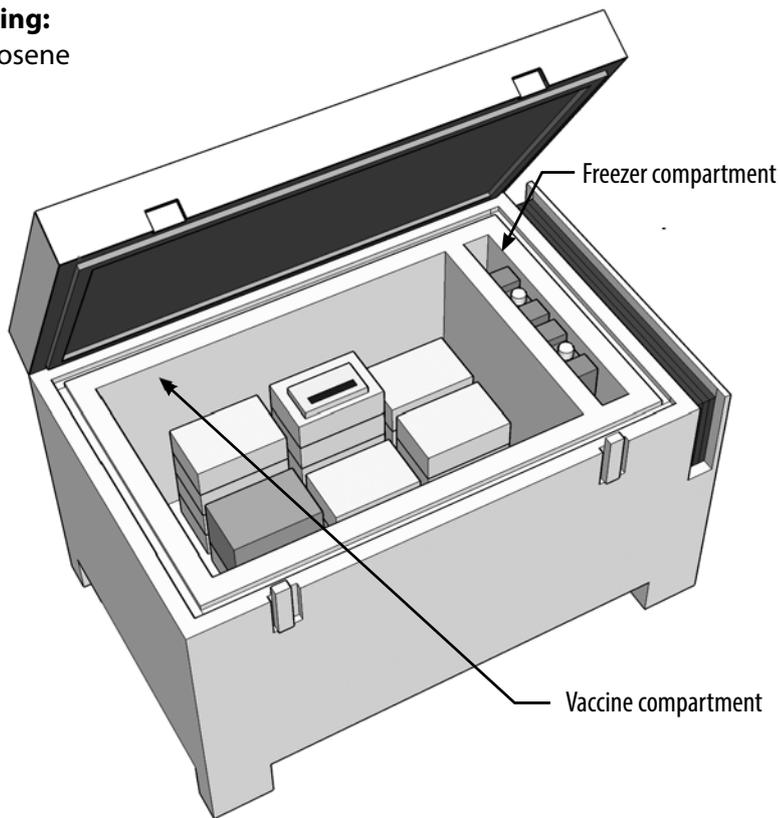
Figure 2.5 Three commonly used refrigerator types

Top opening:

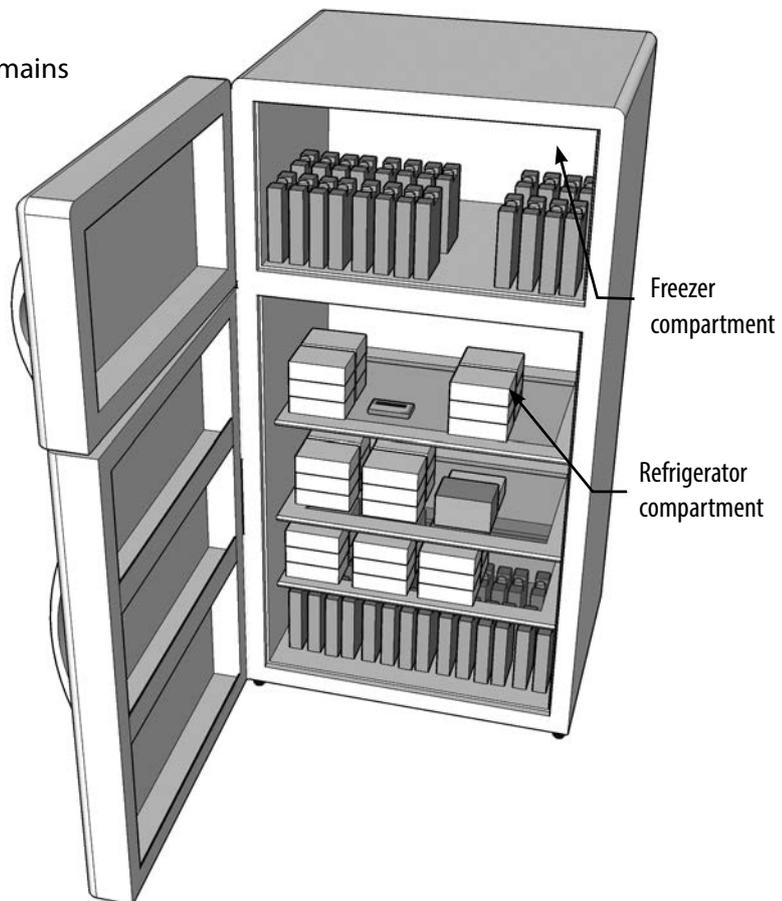
ice-lined mains electric, solar-battery or solar direct-drive



Top opening:
gas or kerosene



Front opening:
gas, kerosene or domestic mains
electric model



2.2 Cold boxes

A cold box is an insulated container that can be lined with water packs to keep vaccines and diluents in the required temperature range during transport or short-term storage – see Figure 2.6. Depending on the model, cold boxes can be used to store vaccines for periods of up to two days or more when there is no electricity available, when the health facility refrigerator is out of order, or when a passive container is needed while the refrigerator is being defrosted. Once packed, cold boxes should not be opened until the vaccine is needed.

The “cold life” of a cold box is the maximum length of time that a closed cold box can maintain temperatures below +10 °C when it is lined with frozen ice packs. Current prequalified cold box models have a maximum cold life of two to seven days when tested at a constant +43 °C.

The “cool life” of a cold box is the maximum length of time the closed cold box can maintain temperatures below +20 °C if lined with cool water packs that have been stored in a refrigerator. Current prequalified cold box models have a maximum cool life of 12 hours to two days when tested at a constant +43 °C.

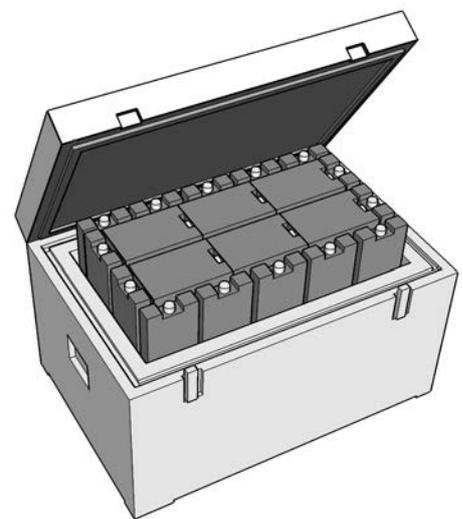
A cold box to be used at health facility level should be chosen based on the following factors:

- The vaccine and diluent storage capacity needed for the supply period.
- The cold or cool life required, which depends on the maximum time vaccines will be stored in the box (including transport time).
- The type and number of water packs designed to be compatible with the size of the cold box.

Different models of cold boxes have different vaccine storage capacities and need different numbers and sizes of water packs. It is important to use the correct number and size of water packs, exactly as specified by the container manufacturer, otherwise cold life or cool life will be affected.

Cold boxes can be used to carry monthly vaccine supplies from district stores to the health facility and also from the health facility to outreach sessions if a vaccine carrier is too small (see Section 2.3). In general, a cold box in a health facility should be large enough to transport at least a one-month supply of vaccines.

Figure 2.6 Vaccine cold box

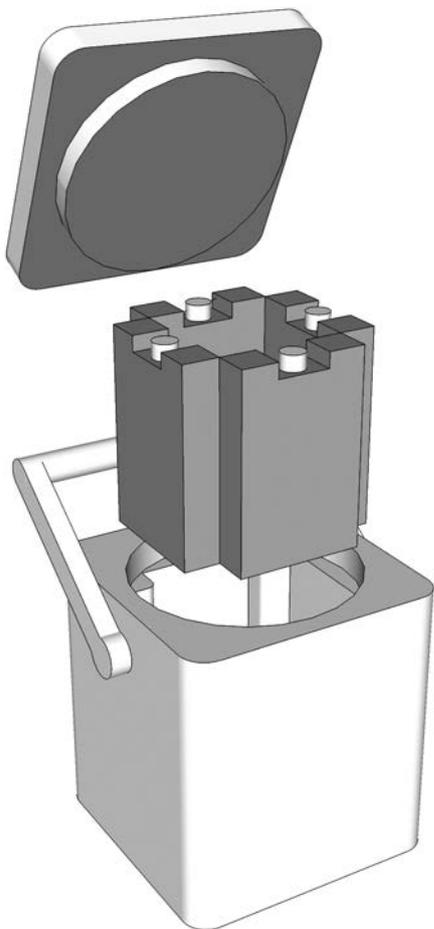


2.3 Vaccine carriers

Vaccine carriers are smaller than cold boxes and easier to carry (see Figure 2.7). Current prequalified vaccine carriers have a cold life with frozen ice packs of between 18 and 50 hours at +43 °C and a cool life with cool water packs of between three and 18 hours.

Vaccine carriers are generally used for the following purposes:

Figure 2.7 Vaccine carrier



- To transport vaccines and diluents to outreach sites and store them during health facility immunization sessions.
- To store vaccines temporarily when the health facility refrigerator is out of order or is being defrosted.
- To transport monthly vaccine supplies from the district store to small health facilities.

Vaccine carriers used at the health facility should be chosen based on the following factors:

- The type and quantity of vaccines and diluents to be transported.
- The cold or cool life needed for the longest planned journeys.
- The transport method used (for example, the requirements for a vaccine carrier that will be carried for short distances on foot are not the same as those for one that will be transported for long distances on the back of a motorcycle).

2.4 Water packs

Water packs are flat, leak-proof plastic containers that can be filled with tap water. They are used to line the inside of the cold box or vaccine carrier (see Figure 2.8). Water packs are used to keep vaccines at the required temperature range inside cold boxes and vaccine carriers. In order to protect the vaccines it is important to use the correct number and size of water packs and to follow the instructions printed inside the lid of the container. To ensure optimal performance, WHO recommends the use of pre-qualified water packs.

Health facilities must have a minimum of two complete sets of water packs for each of their cold boxes and vaccine carriers so that one set can be frozen or cooled in the freezer/refrigerator while the other set is being used in the cold box or vaccine carrier.

The appropriate temperature of the water pack will depend on the type(s) of vaccines being transported, the ambient temperatures to which the cold box or vaccine carrier will be exposed, and the duration of transport. Water packs can be used in any of the following ways:

- **frozen ice packs**, taken directly from a freezer at temperatures between -10°C and -25°C
- **conditioned ice packs** containing a mixture of water and ice at an initial temperature of about 0°C
- **cool water packs**, containing liquid water at an initial temperature of $+5^{\circ}\text{C}$ or less
- **warm water packs**, containing liquid water, initially at room temperature, between $+18^{\circ}\text{C}$ and $+24^{\circ}\text{C}$.

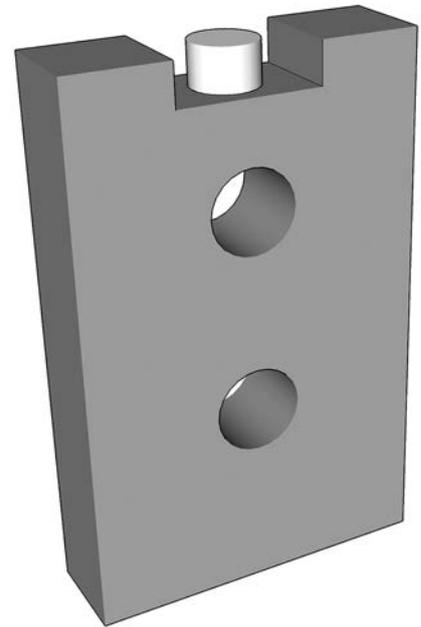
The appropriate water pack strategy to use at health facility level, for transport or outreach operations, will be guided by national policy and practice.

If cool water packs are used for outreach operations, there must be additional provision at the outreach session to keep both reconstituted lyophilized vaccines – and unpreserved multi-dose vaccines that have been opened – cool at between $+2^{\circ}\text{C}$ and $+8^{\circ}\text{C}$. Exposure of reconstituted unpreserved vaccines and liquid vaccines that do not contain preservative to temperatures above $+8^{\circ}\text{C}$ during immunization sessions can result in an increased risk of microbial growth in opened vials of vaccine. In practice, this means that one or more frozen or conditioned ice packs must also be available at the session.

Note that taking frozen, conditioned or cool water packs out of the vaccine carrier will shorten their cold/cool life. Therefore, water packs should not be removed during immunization sessions to hold opened vials. Opened vials should be placed in the foam pad that is provided with the vaccine carrier, as described in Section 2.5.

WHO strongly discourages the use of wet ice in plastic water bags as this may expose vaccines to freezing temperatures.

Figure 2.8 Water pack

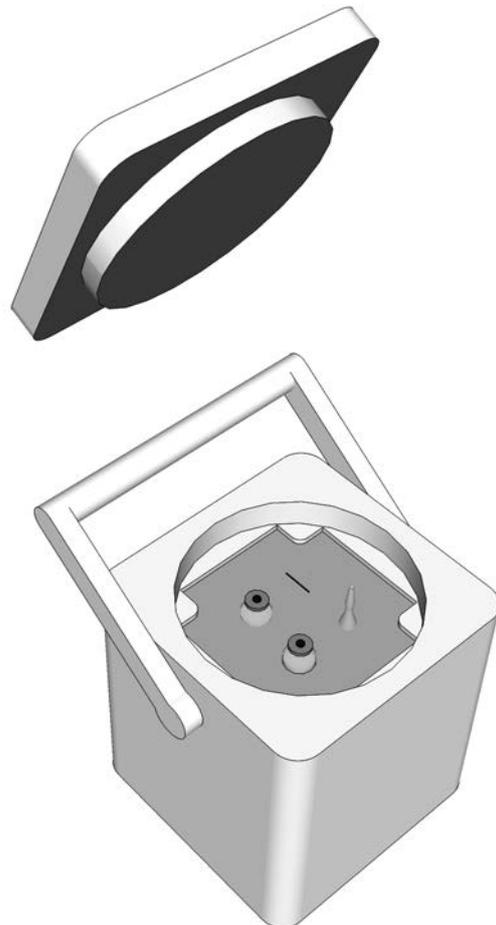


2.5 Foam pads

A foam pad is a piece of soft sponge-like material that fits precisely on top of the water packs inside a vaccine carrier (see Figure 2.9) while still permitting the lid of the vaccine carrier to fully close. The foam pad is provided by the manufacturer of the vaccine carrier. The foam pad usually has slits in which vaccine vials can be inserted snugly and protected. The foam pad should be used during an immunization session as a temporary lid to securely hold opened vials, while protecting unopened vials in the cool chamber below inside the carrier. Note that opened vials of heat-sensitive vaccines can be protected from heat damage for longer periods during immunization sessions if they are pushed into the foam pad. Even with a foam pad, however, it is important to keep the hard vaccine carrier lid closed whenever possible to conserve the inner temperature.

WHO does not recommend the use of homemade foam pads. Health workers should use the pad supplied with the carrier and try to keep it clean and free from dirt or dust.

Figure 2.9 Foam pad in use



3

Temperature monitoring devices

It is essential to monitor and record the temperature of vaccines throughout the supply chain. This is the only way to prove that vaccines have been kept at the right temperature during storage and transport. Temperature monitoring also shows up any problems with equipment and procedures. More detailed information is given in the WHO *Vaccine Management Handbook* (Module VMH-E2-01.1. How to monitor temperatures in the vaccine supply chain), which is available online (http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index1.html).

This section only describes the type of temperature monitoring equipment that is used in health facilities: these facilities are generally equipped with one or two vaccine refrigerators, cold boxes and vaccine carriers.

3.1 Monitoring heat exposure using vaccine vial monitors

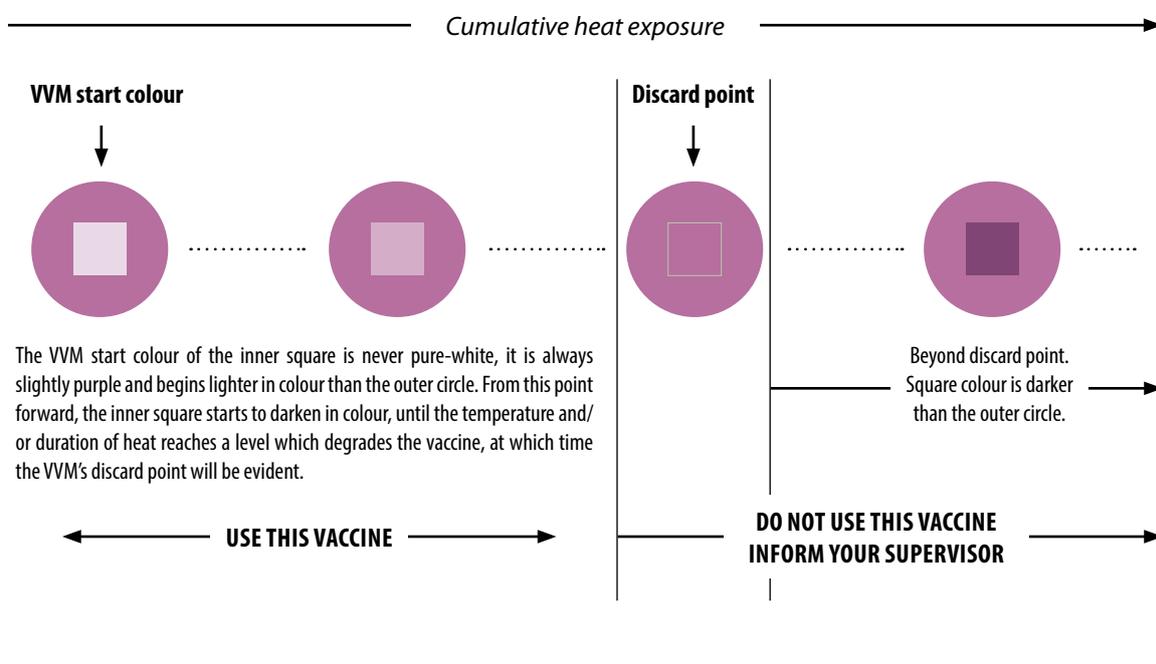
Vaccine vial monitors (VVMs) are the only temperature monitoring devices that routinely accompany vaccines throughout the entire supply chain. A VVM is a chemical indicator label attached to the vaccine container (vial, ampoule or dropper) by the vaccine manufacturer. As the container moves through the supply chain, the VVM records its cumulative heat exposure through a gradual change in colour (see Figure 2.10). If the colour of the inner square is the same colour or darker than the outer circle, the vaccine has been exposed to too much heat and should be discarded.

There are currently four types of VVM, chosen to match the heat sensitivity of the vaccine. These four types are VVM2, VVM7, VVM14 and VVM30. The VVM number is the time in days that it takes for the inner square to reach the colour indicating a discard point if the vial is exposed to a constant temperature of 37 °C.

The main purpose of VVMs is to ensure that heat-damaged vaccines are not administered. The VVM status is also used to decide which vaccines can safely be kept after a cold chain break occurs thus minimizing unnecessary vaccine wastage. In addition, VVM status helps the user decide which vaccine should be used first – a batch of vaccine showing significant heat exposure should be distributed and used before a batch that shows lower heat exposure, even if its expiry date is longer.

VVM status should always be checked and recorded manually on the arrival voucher when it first reaches the health facility. The vaccinator must also check the VVM before the vaccine is opened to see whether the vaccine has been damaged by heat. Only use the vial if the expiry date has not passed, and if the inner square of the VVM is lighter in colour than the outside circle. VVMs do not measure exposure to freezing temperatures. If the vaccine is freeze-sensitive and freezing is suspected, then the Shake Test must be conducted (see Section 7 of this module).

Figure 2.10 VVM showing colour change sequence and interpretation



Where is the VVM?

There are two different locations for VVMs (see Figure 2.11) and each is associated with specific guidance for handling opened multi-dose vials of vaccine:

1. WHO-prequalified vaccines, where the VVM, if attached, is on the label of the vaccine. The vaccine vial, once opened, can be kept for subsequent immunization sessions up to 28 days, regardless of the formulation of the product (liquid or freeze-dried).
2. WHO-prequalified vaccines where the VVM is attached in a location other than on the label (e.g., cap or neck of ampoule). In this instance, the vaccine vial, once opened, must be discarded at the end of the immunization session or within six hours of opening, whichever comes first. This is regardless of the formulation of the product (liquid or freeze-dried). This would apply, for example, to a reconstituted product of which the vaccine vial cap, which has a VVM attached, has been discarded after opening.

Figure 2.11 Location of VVMs on ampoules and vials



3.2 Temperature monitoring devices

30-day electronic temperature loggers (30 DTR)

These devices are placed with the vaccine load in a vaccine refrigerator. They record the refrigerator temperature at no more than 10-minute intervals and show the temperature history for any day in the last 30 days. They also record and display a 30-day history of any heat and freeze alarms that have occurred. Alarms are triggered if the temperature of the refrigerator drops to $-0.5\text{ }^{\circ}\text{C}$ or below for 60 minutes or if it exceeds $+10\text{ }^{\circ}\text{C}$ for a continuous period of 10 hours. As long as the temperature has remained within the recommended range, the device displays “OK” or a tick symbol. Several types of 30 DTR are prequalified by WHO and Figure 2.12 shows two examples. On newer models, data can also be downloaded via a connection to a computer. 30 DTRs should not be used in vaccine freezers. Current models have built-in batteries with a battery alarm feature; the device must be discarded and replaced when the battery expires, which is typically every two or three years.

30 DTRs should be placed in an accessible position where they can be read easily and are unlikely to be damaged. This will vary depending on the type of refrigerator. Try to observe the following rules:

- If the refrigerator is used to store vaccines that are not freeze-sensitive, place the device on top of the load, in the warmest part of the refrigerator.
- If the refrigerator is used to store any freeze-sensitive vaccines, the device should preferably be placed in the coldest part of the refrigerator that is being used to store these vaccines. This will be the bottom of a basket in chest refrigerators or nearest to the evaporator plate in front-opening models and absorption units.

Figure 2.12 30-day electronic temperature loggers



FridgeTag2™ with USB

LogTag® temperature recorder

Electronic freeze indicators

These are small digital devices that are placed with freeze-sensitive vaccines during transport or storage. The devices have a visual indicator that shows whether the vaccine has been exposed to freezing temperatures. Once the alarm indicator is triggered, the device is no longer usable and should be discarded. Otherwise the device can be used until the built-in battery expires. Figure 2.13 shows two types.

Note that electronic freeze indicators are not needed in refrigerators where a 30 DTR is used.

Figure 2.13 Electronic freeze indicators



FreezeAlert™

Q-Tag® Quad

Integrated digital thermometers

Current prequalified vaccine refrigerators and freezers are equipped with devices like the one shown in Figure 2.14. An internal temperature sensor monitors the storage compartment and an instantaneous temperature reading is displayed on the unit's control panel. Solar direct-drive refrigerators typically have a device powered by an integrated photovoltaic cell; these do not work at night or in dim light and may have to be activated by shining a torch onto the display.

Figure 2.14 Integrated digital thermometer



Source: Dulas Solar

Stem thermometers

These devices only provide an instantaneous temperature reading. For this reason, WHO no longer recommends them as the main monitoring device in vaccine refrigerators. However, they remain an essential back-up device because they do not require a battery or other power source. Figure 2.15 shows an example. WHO no longer recommends bi-metallic dial thermometers (see Figure 2.16) for any purpose because they lose their calibration over time, especially if they are dropped.

Figure 2.15 Stem thermometer

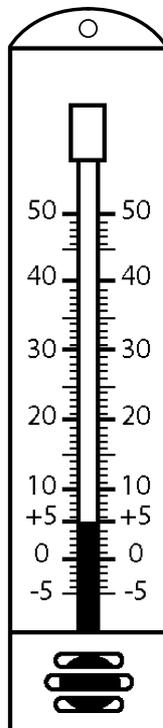
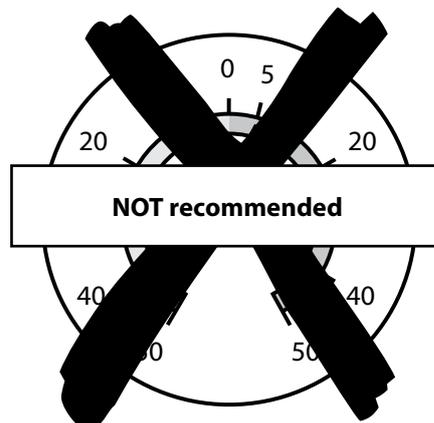


Figure 2.16 Dial thermometers – not recommended by WHO anymore



3.3 Recommended equipment

Table 2.2 sets out the temperature monitoring options for health facility storage and transport, in order of preference.

Table 2.2 Temperature monitoring options in health facilities

	Vaccine refrigerator	Cold boxes and vaccine carriers
Best practice	<ul style="list-style-type: none"> • 30-day temperature logger • Integrated digital thermometer • Stem thermometer for back-up • VVMs where supplied 	<i>Conditioned ice packs</i> <ul style="list-style-type: none"> • Freeze indicator • VVMs where supplied
		<i>Cool water packs</i> <ul style="list-style-type: none"> • Stem thermometer • VVMs where supplied
		<i>Warm water packs</i> <ul style="list-style-type: none"> • Freeze indicator • VVMs where supplied
Minimum requirement	<ul style="list-style-type: none"> • Integrated digital thermometer • Stem thermometer for back-up • Electronic freeze indicator • VVMs where supplied 	

Vaccine vial monitors

VVMs provide a key indicator during storage and transport because they show whether the individual vaccine container has been exposed to excessive heat. Remember: VVMs do not measure exposure to freezing temperatures, only to heat.

Refrigerators

Wherever possible, health facility refrigerators should be equipped with a 30-day temperature logger and facility staff should be trained in their use. These devices provide a complete history of the refrigerator temperature. Thermometers cannot do this; they only indicate the temperature at the time when a reading is taken. An electronic freeze indicator and a stem thermometer is the next best choice. The freeze indicator shows whether freeze-sensitive vaccines have been exposed to sub-zero temperatures – the most common cause of damaged vaccine. However, a freeze indicator cannot be used again once it has been triggered; it must be replaced immediately with a new one. The worst choice is a stem thermometer on its own. As noted above, a thermometer only indicates the temperature at the time a reading is taken, which is no more than 14 times per week. A 30-day temperature logger takes at least a thousand readings a week.

Cold boxes and vaccine carriers

If conditioned ice packs are being used to transport freeze-sensitive vaccines, an electronic freeze indicator should be included with the load – the indicator shows if the vaccines have been exposed to freezing temperatures. Freeze indicators are not needed if cool water packs are used because there is no freezing risk. If warm water packs are used to protect freeze-sensitive vaccines in very cold climates it is also good practice to use freeze indicators, since the temperature of the load may drop below zero on a long journey.

4

Monitoring cold chain temperatures

The data gathered from temperature monitoring devices must be recorded and analysed on a regular basis to demonstrate that vaccines are being stored and transported at the correct temperatures. This section reviews temperature monitoring of vaccine refrigerators, cold boxes and vaccine carriers at the health facility level.

4.1 Monitoring vaccine refrigerator temperature

A standard manual temperature-recording chart should be attached to the door or lid of every vaccine refrigerator. Readings should be taken twice a day at least five days per week and preferably every day, including weekends and holidays. Daily readings should be taken from the same temperature monitoring device each time. The health worker should read the 30 DTR and write the data on the chart. If there is no 30 DTR, you should check the integrated dial thermometer or, where necessary, the stem thermometer. Recording temperatures in this way provides evidence that the refrigerator is being monitored and that regular readings are being taken. This can help identify performance trends, sometimes even before automatic alarms are generated.

Manual readings should be recorded on a temperature chart attached to the refrigerator door using the following procedure:

- Check the refrigerator temperature first thing in the morning and at the end of the working day.
- Record the temperature by date and time on the temperature chart (an example specifically designed for 30 DTRs is shown in Figure 2.17). When a chart is completed, replace it with a new one. Keep completed charts together in a file for future reference. (Note: action should be taken when the temperature goes out of range; see Section 4.2 of this module.)

4.2 Taking action when a vaccine refrigerator's temperature is out of range

If the temperature of the refrigerator is below +2 °C, which is too low, a report should be made to the supervisor. The corrective action includes the following procedure:

- Turn the thermostat knob so the arrow points to a higher number. This will make the refrigerator warmer.
- Check whether the door of the freezer closes properly. The seal may be damaged. If broken, a technician should be called to make repairs.
- If the temperature has fallen below 0 °C for any length of time, check freeze-sensitive vaccines to see if they have been damaged by freezing using the Shake Test (see Section 7 of this module).



Remember: slight heat exposure is less damaging to most liquid vaccines and diluents than freezing exposure.

If the temperature is above +8 °C, which is too high, a report should be made to the supervisor. The corrective action includes the following procedure:

- Make sure that the refrigerator is working. If it is not working, check whether the power supply (electricity, gas, kerosene or solar) is adequate.
- Check whether the door of the refrigerator or the freezing compartment closes properly; if the seal is broken, the temperature will fluctuate. Call a technician to make repairs.
- Check whether frost is preventing cold air in the freezing compartment from entering the refrigerator compartment. Defrost if necessary.
- If the power supply, door seal and frost levels are all in working order, turn the thermostat knob so that the arrow points to a higher number. This will make the refrigerator cooler.
- If the temperature cannot be maintained between +2 °C and +8 °C, store vaccines in other cold chain equipment that can maintain this temperature range until the refrigerator is repaired.



Remember: to avoid freezing vaccines, do not adjust the thermostat to a cooler (higher number) setting after a power cut or when vaccines arrive.

4.3 Maintaining the correct temperature in cold boxes and vaccine carriers

To maintain the correct temperature in cold boxes and vaccine carriers, proceed as follows:

- Place the correct number and type of properly conditioned ice packs or cool water packs in the cold box or vaccine carrier.
- If you are using conditioned ice packs you should preferably put an electronic freeze indicator in each cold box or vaccine carrier containing freeze-sensitive vaccines.
- Keep the cold box or vaccine carrier in the shade.
- Keep the lid tightly closed.
- Use the foam pad to hold opened vials at the top of the vaccine carrier during an immunization session; keep the hard carrier lid closed whenever possible.
- During the immunization session, vaccines must be kept at the recommended temperatures after opening. In particular, it is important to keep opened multi-dose vaccine vials that do not contain preservative – whether lyophilized or liquid – cooled at temperatures between +2 °C and +8 °C.
- At the end of the immunization session, health workers should follow national policy in handling remaining vials. In general, this means:
 - discarding all opened vials of vaccines that do not contain preservative; this includes all reconstituted vaccines and some liquid multi-dose vaccines
 - checking the VVMs of all unopened vials and returning the unopened vials with VVMs that are not past the discard point to a working refrigerator or appropriate cold box as soon as possible
 - where multi-dose vial policy is applied, check the VVMs of all opened vials that contain preservative and return those with VVMs that are not past the discard point to a working refrigerator or appropriate cold box as soon as possible. Use these vaccines first for the next immunization session.

5

Arranging vaccines inside cold chain equipment

Vaccines must be arranged inside cold chain equipment in a manner that helps ensure that they remain in good condition with minimum risk of exposure to damaging temperatures. This section describes how to arrange vaccines inside vaccine refrigerators, cold boxes and vaccine carriers.

5.1 General rules for using vaccine refrigerators

Health facility refrigerators are used to store vaccines and diluents. Several types of refrigerator are available and the arrangement of items inside them varies according to the type.

The following general rules (Do's and Do Not's) apply to all health facility refrigerators.



DO arrange the vaccines in the health facility refrigerator like this:

- Wherever possible, store vaccines and diluents in a refrigerator that is reserved for this purpose only. If other heat-sensitive supplies, such as drugs, ointments, sera and samples, have to be stored in the refrigerator, **label them clearly and keep them completely separate** from the vaccines and diluents.
- Always arrange vaccines and diluents so that air can circulate freely; this also makes it easier to handle the vaccines.
- If vaccines or diluents are supplied in their original cartons, arrange the boxes so that there is at least a two-centimetre space between stacks. Mark the cartons clearly and make sure the markings are visible when the door or lid is opened.
- If vaccines or diluents are supplied as individual containers (vials, ampoules or tubes), use a plastic tray, plastic box or other arrangement to store the vaccines in an orderly fashion. Figure 2.18 shows a good arrangement using local-made stacking boxes.
- If diluent is packaged with the vaccine, store the complete packaged product in the refrigerator. If diluents are supplied separately from the vaccine, store them in the refrigerator if there is adequate space. If there is not adequate space, move the diluents to the refrigerator at least 24 hours before they are needed so they are cooled.

Figure 2.18 Purpose-made tray for vials and ampoules



Source: Anthony Battersby

- Place vaccines with VVMs that show the most heat exposure (darker squares) in a separate container in the refrigerator, clearly marked “Heat-exposed vials – use first”. If there are other vaccines of the same type in the refrigerator, the vaccines with the darkest squares should always be used first **even if the expiry date is later than the vaccines with the lighter squares**.
- If a multi-dose vial policy is in place, follow the instructions for handling opened multi-dose vials exactly as described in the national policy. If an opened multi-dose vial will be used for the next session, the vials must be placed in a separate container in the refrigerator, which is clearly marked “Opened vials – use first.” A summary of the WHO Multi-dose Vial Policy is outlined in the box below. The local policy may be different.



DON'T arrange the vaccines in the health facility refrigerator like this:

- Never store food or drink in a vaccine refrigerator.
- Do not open the door or lid unless it is essential to do so. Frequent opening raises the temperature inside the refrigerator.
- If there is a freezer compartment, do not use it to store vaccines and diluents.
- Do not keep expired vaccines in the refrigerator. Do not keep vaccines with VVMs that have reached, or are beyond, their discard point. Do not keep reconstituted vaccines for more than six hours, or after the end of an immunization session. Discard all these items immediately according to your national guidelines. Refer any questions to your supervisor.

Summary of WHO Multi-dose Vial Policy (MDVP), 2014

All opened WHO-prequalified multi-dose vials of vaccines should be discarded at the end of the immunization session, or within six hours of opening, whichever comes first, unless the vaccine meets all four of the criteria listed below. If the vaccine meets the four criteria, the opened vial can be kept and used for up to 28 days after opening. The criteria are as follows:

1. The vaccine is currently prequalified by WHO.
2. The vaccine is approved for use for up to 28 days after opening the vial, as determined by WHO.
3. The expiry date of the vaccine has not passed.
4. The vaccine vial has been, and will continue to be, stored at WHO- or manufacturer-recommended temperatures; furthermore, the vaccine vial monitor, if one is attached, is visible on the vaccine label and is not past its discard point, and the vaccine has not been damaged by freezing.

If ALL of the criteria cited above are present, the vaccine vial may be kept and used for up to 28 days after opening, or until all the doses are administered.

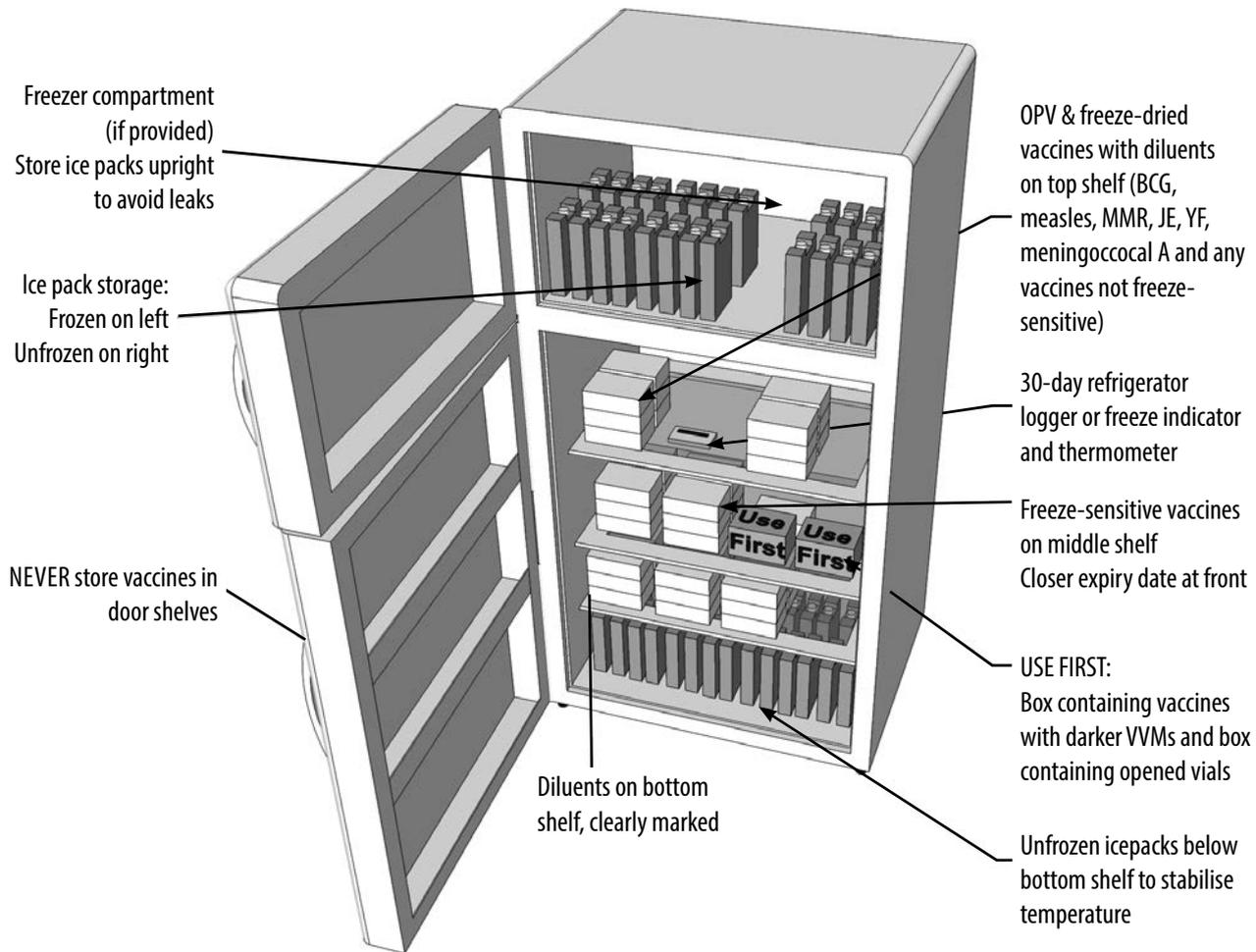
5.2 Specific rules for using front-opening refrigerators

Table 2.3 briefly describes the three types of front-opening vaccine refrigerators used for storing vaccines. Figure 2.19 shows how a gas or kerosene vaccine refrigerator or a domestic electric front-opening refrigerator should be organized.

Table 2.3 Types of front-opening vaccine refrigerators

Types of front-opening vaccine refrigerators	Description
Type 1	Gas or kerosene models, with an ice pack freezing compartment: There are no recently prequalified models of this type, but large numbers remain in use.
Type 2	Mains electric domestic models: Typically these have an ice pack freezing compartment.
Type 3	Prequalified water-lined models powered by mains or solar electricity: These models do not have an ice pack freezing compartment.

Figure 2.19 Vaccine and diluent arrangement in a front-opening domestic, gas or kerosene vaccine refrigerator



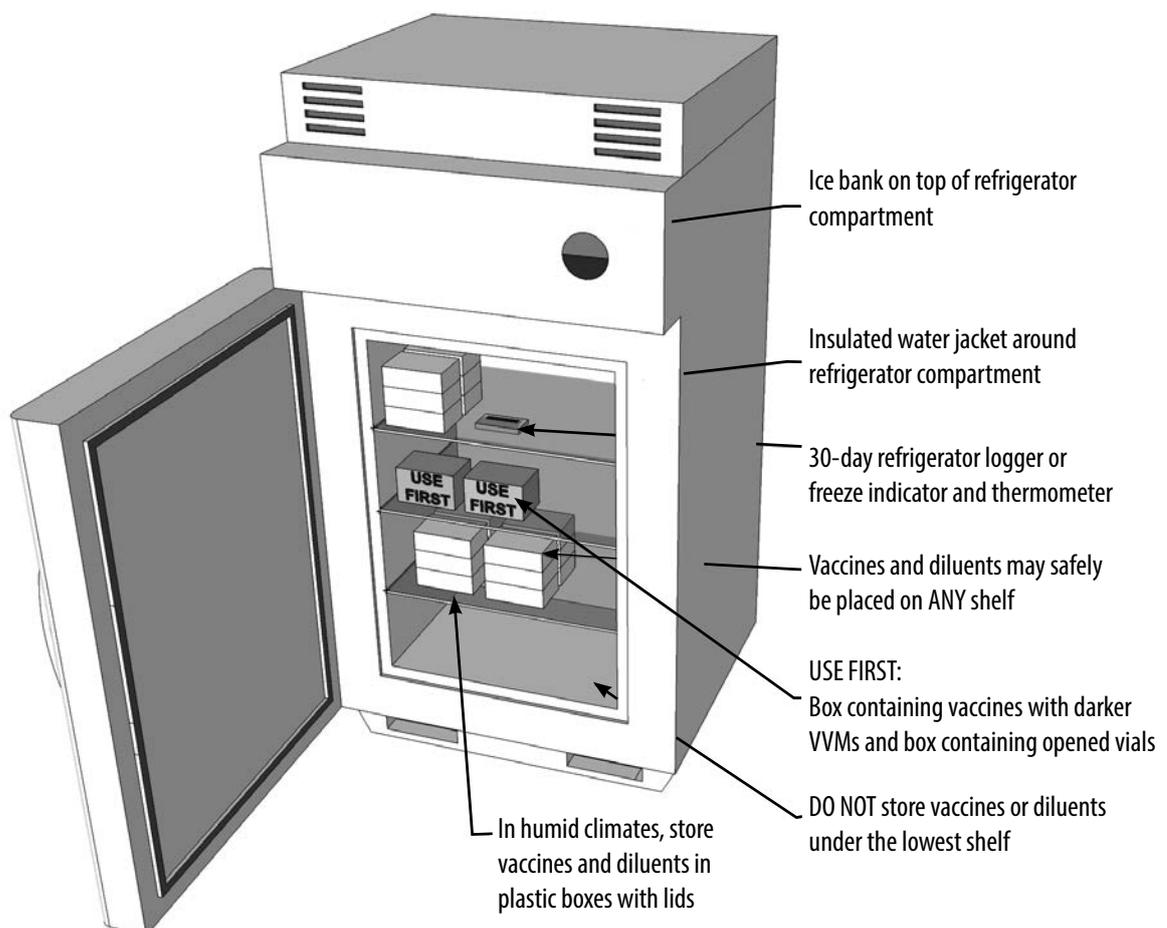
The following rules apply for front-opening refrigerators:

- Never put vaccines or diluents in the door shelves. The temperature is too warm for vaccine storage and vaccines are exposed to room temperature each time the door is opened.
- Never put freeze-sensitive vaccines in contact with, or close to, the evaporator plate in the refrigerator.
- Put water packs or plastic bottles full of coloured water in the space below the bottom shelf. This helps to stabilize the temperature if there is a power cut. Do not use the water packs in vaccine carriers. Never drink the water.

- Put measles, MR, MMR, BCG, OPV, yellow fever, Japanese encephalitis, meningococcal A conjugate and/or any other vaccines not damaged by freezing on the top shelf.
- Put DTP, DT, Td, TT, HepB, DTP+HepB, DTP+HepB+Hib, Hib, HPV, rotavirus and/or any other freeze-sensitive vaccines on the middle or lower shelves.
- Store the diluents next to the freeze-dried vaccine with which they are supplied, on the appropriate shelf. If there is not enough space on the shelf, put the diluents on the bottom shelf, clearly labelled so they can be easily identified to their matching vaccine.

Figure 2.20 shows the recommended arrangement for an upright ice-lined refrigerator. In these models there is very little variation in the temperature inside the refrigerator compartment, so vaccines and diluents can be placed safely on any of the shelves. However, in humid climates, there is a risk of condensation. Cartons and vials should be stored in plastic boxes with tightly fitting lids to reduce the risk of moisture damage. Never store vaccines below the bottom shelf – this area may be wet because it collects and drains the condensation from the roof and walls of the compartment.

Figure 2.20 Vaccine and diluent arrangement in a front-opening water-lined refrigerator



5.3 Specific rules for using top-opening refrigerators without baskets

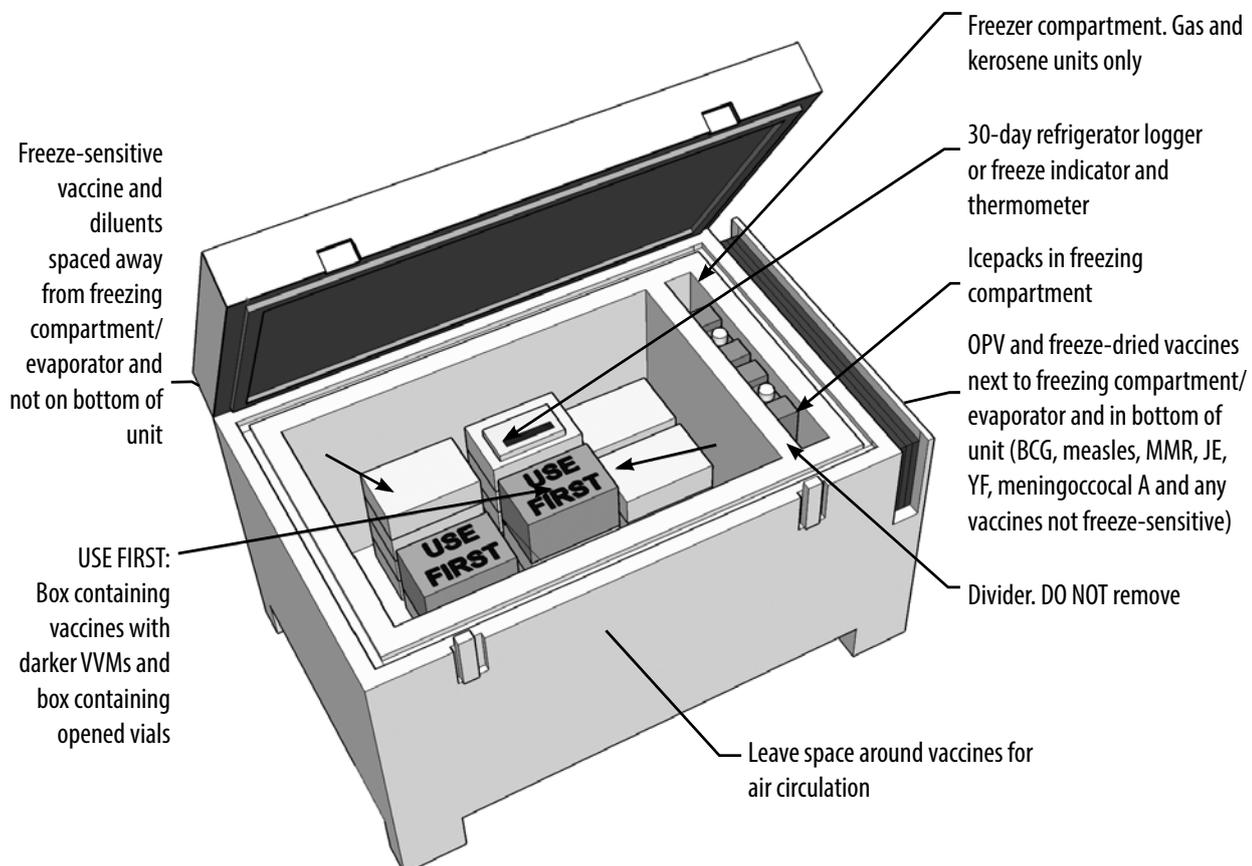
Table 2.4 briefly describes the two types of top-opening vaccine refrigerators used for storing vaccine. Some top opening refrigerators are supplied without baskets.

Figure 2.21 shows the arrangement of vaccines and diluent in a top-opening refrigerator without baskets.

Table 2.4 Types of top-opening vaccine refrigerators

Types of top-opening vaccine refrigerators	Description
Type 1	Gas or kerosene refrigerators: These have a small compartment for freezing ice packs.
Type 2	Solar direct-drive models with a lining containing a phase-change material (PCM) to protect the vaccine overnight and during cloudy periods: The PCM freezes at around +5 °C so vaccine can be in contact with the lining without risk of damage. Current models do not have a freezer compartment.

Figure 2.21 Vaccine and diluent arrangement in a top-opening refrigerator without baskets



The following rules apply to these two types of refrigerator:

- Never put freeze-sensitive vaccines in the bottom of gas and kerosene refrigerators or next to the freezer compartment. There is a risk of freezing in these areas.
- Put measles, MR, MMR, BCG, OPV, yellow fever, Japanese encephalitis and/or any other vaccines not damaged by freezing in the bottom of the compartment.
- Put diluents, DTP, DT, Td, TT, HepB, DTP+HepB, DTP+HepB+Hib, Hib, meningococcal, HPV, rotavirus and/or any other freeze-sensitive vaccines in the upper part of the compartment and well away from the freezing compartment in gas and kerosene models.
- Store the diluents close to the freeze-dried vaccine with which they were supplied. If this is not possible, make sure the diluents are clearly labelled so they can be easily identified to their matching vaccine.

5.4 Specific rules for using top-opening refrigerators with baskets

Many top-opening ice-lined refrigerators are supplied with baskets for storing vaccines. There are also a few top-opening solar-battery models; typically, these models do not have an ice lining, but they generally have baskets.

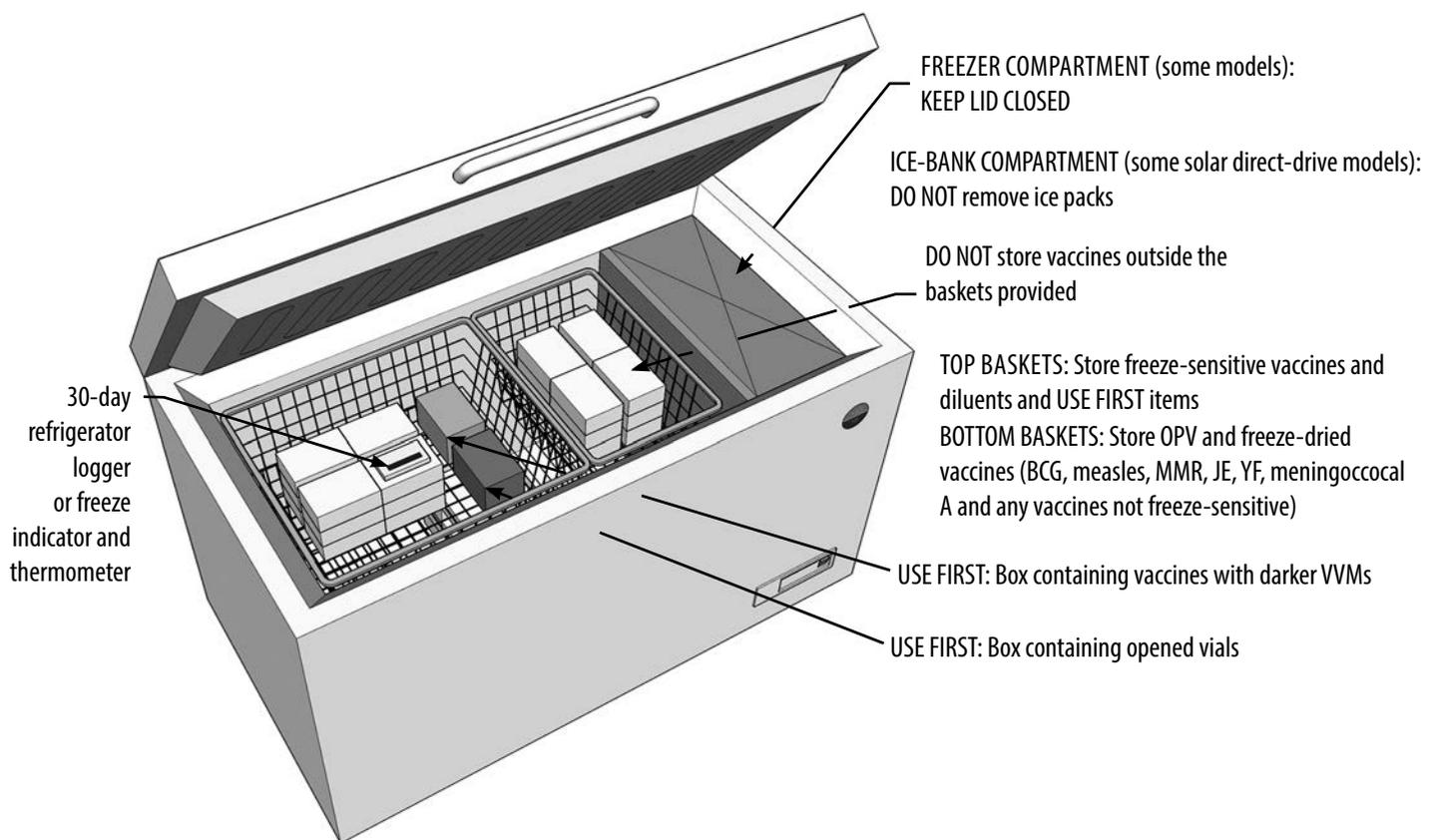
Figure 2.22 shows how these refrigerators should be organized.

The following rules apply to these refrigerators:

- Always store vaccines and diluents in the baskets provided. Never store them outside the baskets.
- If there is an internal lid on the freezer compartment and/or the refrigerator compartment, always replace it before closing the main lid.
- Some solar direct-drive refrigerators have an ice-bank at one end. Never remove ice packs from this area.
- Some solar direct-drive refrigerators have a separate ice pack freezing compartment. Make sure to follow the manufacturer's instruction on the use of this feature – instructions vary.
- Use the bottom baskets to store measles, MR, MMR, BCG, OPV, yellow fever, Japanese encephalitis and/or any other vaccines not damaged by freezing.

- Use the top baskets to store products for immediate use and to store diluents, DTP, DT, Td, TT, HepB, DTP+HepB, DTP+HepB+Hib, Hib, HPV, rotavirus and/or any other freeze-sensitive vaccines. Never put freeze-sensitive vaccines in the bottom baskets. In some models there is a risk of freezing in these areas.
- Store the diluents close to the freeze-dried vaccine with which they were supplied. If this is not possible, make sure the diluents are clearly labelled so they can be easily identified to their matching vaccine.

Figure 2.22 Vaccine and diluent arrangement in a top-opening refrigerator with baskets



5.5 Preparing ice packs and cool water packs

If the vaccine refrigerator has a freezer compartment, this can be used to freeze and store ice packs. If cool water packs are used, these must be prepared and stored in a separate refrigerator, never in a refrigerator that is used to store vaccines.

Every health facility should have at least two sets of water packs that correspond in size and number to its stock of cold boxes and vaccine carriers.

Filling and checking water packs

New water packs are supplied empty and must be filled before use. All water packs should be checked for leaks. Proceed as follows:

1. New empty water packs: Fill each pack with clean water, up to the fill line. Do not over-fill; leave a little air space at the top. Fix the cap on tightly.
2. Used water packs: It is not necessary to empty and refill water packs unless they have leaked. If there is a leak, top up the water and make sure the cap is fixed securely.
3. Before use: Hold each pack upside down and squeeze it to make sure it does not leak. If the pack has been damaged, discard it.

Freezing ice packs

Depending on a range of factors, it can take 24 hours or more to fully freeze a batch of ice packs.

Most mains electric ice-lined refrigerators, domestic refrigerators, or larger gas refrigerators have a separate freezing compartment; these models can freeze up to six large or 12 small water packs every 24 hours. Small gas or kerosene models may be able to freeze only one or two packs per day.

Some recent solar direct-drive refrigerators can also freeze ice packs. However, their freezing capacity depends on the amount of sunshine available, and in cloudy weather it may not be possible to freeze any ice packs. The ice packs will always melt slightly overnight when there is no power and there may well be some liquid water in the packs at the beginning of the day, but this is normal.

Older solar direct-drive models do not have an ice pack freezing compartment. The latest models do. Instead of an ice lining, the Vestfrost Solar Chill and Haier solar direct-drive models have a bank of standard water packs in a compartment that looks like a freezer compartment. These water packs must **never be removed** for use in vaccine carriers.

Always follow the manufacturer's instructions and never overload the freezing compartment. Put packs in the freezer, arranged upright or on their sides so that the surface is touching the evaporator plate. If there is a door or lid to the compartment, make sure it is properly closed.

The more packs placed in the freezing compartment, the longer they will take to freeze. If too many water packs are placed in the unit, they may not freeze at all. Keep extra, unfrozen water packs that do not fit into the freezer in the bottom part of the main refrigerator compartment to keep this section cold in case of a power failure. When these water packs are placed in the freezer, they will freeze relatively quickly because they are already cold. Never store frozen water packs in the refrigerator compartment; this will lower the temperature and increase the risk of freezing vaccines.

Conditioning frozen ice packs

Frozen ice packs, taken directly from the freezer, are not suitable for immediate use. If they are not correctly conditioned it is very likely that freeze-sensitive vaccines will be frozen and destroyed. Wrapping vaccines in newspaper or other materials does not protect against freezing.

Except where cool water packs are used, WHO recommends the use of “conditioned” ice packs for transporting vaccines in cold boxes and vaccine carriers. An ice pack is correctly conditioned when it has melted enough to allow the ice to move inside the pack. Use the following procedure to achieve this:

1. Remove the required number of frozen ice packs from the freezer compartment. The number and type of pack required is shown on the inside of the lid of the cold box or vaccine carrier.
2. Lay the frozen ice packs on a work surface in a single layer leaving gaps of about 5 cm between packs.
3. Wait until **all** packs are properly conditioned – there must be liquid water inside every pack and the ice-cores should move inside the packs when shaken (see Figure 2.23). This will take at least 30–45 minutes in hot weather and much longer in cooler conditions – from 90 to 120 minutes at +20 °C.

Figure 2.23 Checking that an ice pack is properly conditioned



Preparing cool water packs

Where cool water packs are used for vaccine transport, the health facility must be equipped with a separate refrigerator for preparing these packs. This refrigerator must not be used for storing vaccines and the thermostat should be set as low as possible to ensure the water packs are cooled to +5 °C or below.

! **Note:** If a cool water pack strategy has been adopted for outreach operations, one or more frozen ice packs must be brought to the session to ensure that opened multi-dose vaccine vials are kept at recommended temperatures. It is particularly important that vaccines that do not contain preservative – whether lyophilized or liquid – are kept at temperatures between +2 °C and +8 °C during the session.

5.6 Packing vaccines in cold boxes and vaccine carriers

It is very important to pack cold boxes and vaccine carriers correctly. Proceed as follows.

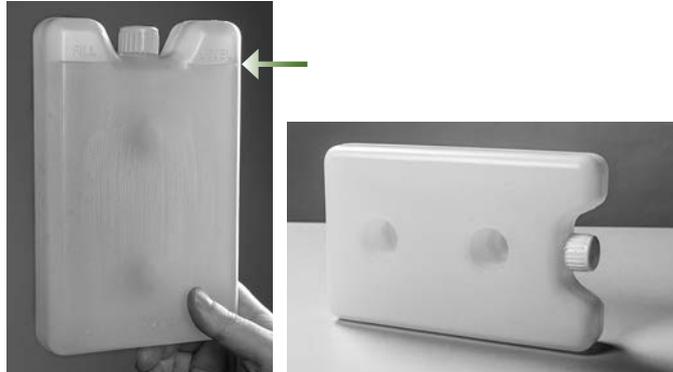
1. Arrange the conditioned ice packs or cool water packs in the cold boxes and/or vaccine carriers exactly as shown on the manufacturer's instructions on the inside of the lid.
2. Put the vaccines and diluents in a plastic bag in the middle of the cold box or carrier to protect them from damage due to condensation.
3. If conditioned ice packs are used, put an electronic freeze indicator with the vaccines.
4. For vaccine carriers, place the foam pad in the top of the container.
5. Close the cold box or vaccine carrier lid tightly.

Figure 2.24 illustrates the procedures for arranging cold boxes and vaccine carriers.

Figure 2.24 Arranging a vaccine carrier

1 Prepare ice packs for freezing

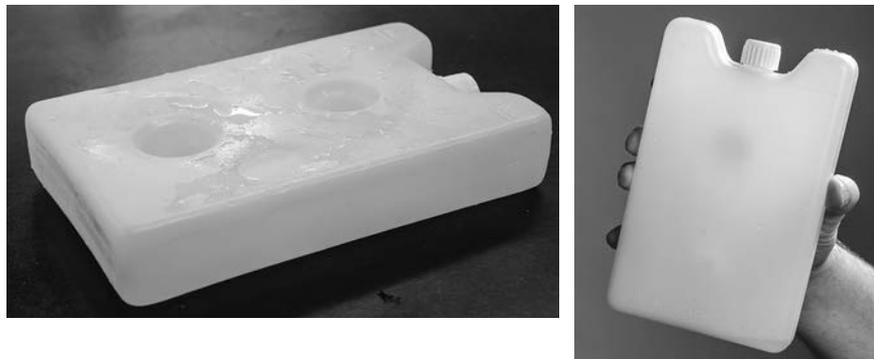
- Fill the ice pack with water to mark. Check water level before every use. Do NOT add salt to this water.
- Fit the stopper and screw on the cap tightly.
- Make sure the ice pack does not leak.
- Wipe the ice pack dry and place in the deep freezer.



2 Condition frozen ice packs

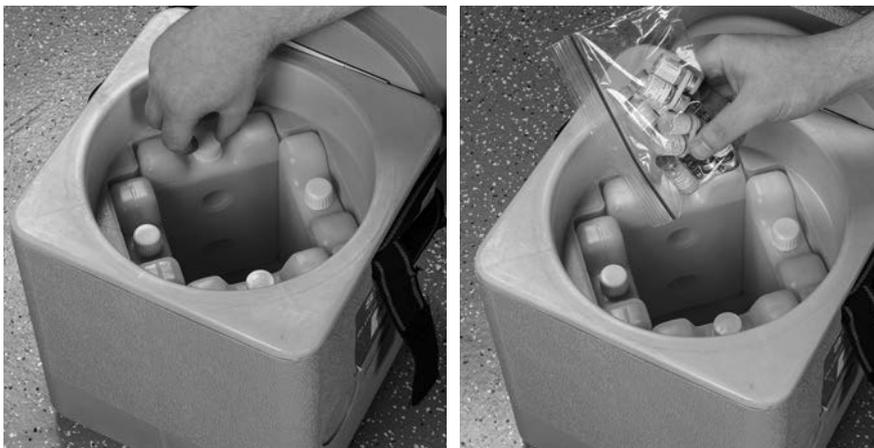
- Place frozen ice packs in the open till they “sweat” (some condensation or droplets of water).
- Check if an ice pack has been conditioned by shaking it and listening for water.

Unconditioned ice packs may damage freeze sensitive vaccines.



3 Pack the vaccine carrier

- Place four conditioned ice packs against the sides of the carrier.
- Place the plastic bag containing all vaccines and diluents in the centre of the carrier.



4 Remember

- Collect vaccines in the carrier on the session day (note that vaccine carriers may not store vaccines effectively beyond 12 hours).
- Do not drop or sit on the vaccine carrier.
- Do not leave in sunlight. Keep in shade.
- Do not leave the lid open once packed.

6

Basic maintenance of cold chain equipment

6.1 Defrosting vaccine refrigerators

A refrigerator only works well if it is properly installed and is then cleaned and defrosted regularly.

Thick ice in the freezer compartment and on the evaporator plate does not keep a refrigerator cool. Instead, it makes the refrigerator work harder and uses more electricity, gas, kerosene or solar power. Refrigerators should be defrosted regularly, or when the ice is more than 0.5 cm thick, whichever comes first.

To defrost and clean a refrigerator:

- Remove all the vaccines and transfer them to another refrigerator or to a cold box or vaccine carrier lined with conditioned ice packs.
- Switch off the electrical supply for a mains or solar-battery refrigerator. Turn off the gas supply for a gas refrigerator. Extinguish the flame for a kerosene refrigerator.
- Leave the door open and wait for the ice to melt. Never try to remove the ice with a knife or ice pick; this can permanently damage the refrigerator. A pan of boiling water can be placed inside and the door closed.
- Clean the inside of the refrigerator and door seal with a clean damp cloth.
- Re-start the refrigerator. Do not adjust the thermostat.
- When the temperature in the main section falls to +8 °C or lower (but not less than +2 °C), arrange the vaccines, diluents and water packs in their appropriate places.



If a refrigerator needs to be defrosted more than once a month, check for these common problems:

- Staff are opening the door too often (more than three times daily).
- The door is not closing properly.
- The door seal needs to be replaced.

6.2 Maintaining solar power systems

Solar panels need to be cleaned and checked and the batteries of solar battery refrigerators must be inspected and maintained. Tasks can be divided into daily, periodic and annual.

Daily

- Check the status of the control panel display. Take appropriate action as described in the instruction manual if status is not normal.
- For battery systems only: Check the indicator lights on the battery charge regulator every day. Do not freeze water packs if the low battery warning light is on. Move vaccine to a safe location if the load-disconnect warning light or alarm sounder are activated.

Periodically

Clean dust or snow off the solar array. The frequency with which this needs to be done will vary. **In very dusty areas, clean the array weekly.** Remove any snow accumulation as soon as possible.

- Do not attempt to carry out this task unless you have the correct access and safety equipment and have received training in safe working at height. Make sure you have somebody to help you and to hold the ladder.
- Never stand on corrugated roof sheets or tiles – use a properly designed roof ladder.
- Clean the array in the early morning or evening when the sun is weak.
- Use a soft cloth dampened with water. Wipe gently, starting at the top and working downwards.
- Do not lean or stand on the array panels because you may damage them. Report any damage to wiring or hardware to your supervisor.

Once a year

- Make sure the solar panels are not shaded by trees, plants, new buildings or overhead cables between 9.00 am and 3.00 pm. If there is shading from vegetation, arrange for the vegetation to be cut back. If there is shading from newly constructed buildings or new overhead cables, contact your supervisor. The solar array may have to be moved or increased in capacity.
- Check the electric cables between the solar array, the charge regulator, the batteries and the refrigerator. Inspect grounding/lightning protection. If you see any damage, contact your supervisor.

! Solar battery and solar direct-drive refrigerators should be defrosted only on a sunny day; they should never be defrosted in cloudy or rainy weather. A solar direct-drive refrigerator should generally be defrosted in the early morning. It will have partly defrosted overnight so this will speed up the process. Defrosting in the early morning will also allow the refrigerator to make best use of the day's supply of solar power.

6.3 Maintaining gas refrigerators

Daily

- Check the burner flame is blue. If it is not, clean the gas burner and gas jet as described in the equipment manual. Adjust the thermostat or flame control setting as necessary.
- Make sure there is enough gas in the bottle. If not, change the bottle. Always change the bottle before it is completely empty and always keep a spare bottle.

Periodically

- Check weekly that you have enough gas for at least another week. If not, obtain a new supply immediately.
- Carry out the following tasks at least once a year and always clean the flue if the flame has been smoking.
 - Clean the flue and baffle as described in the equipment manual.
 - Clean the gas burner and gas jet as described in the equipment manual.
 - Check the gas line connections for leaks. Brush soapy water onto the connections. If bubbles form, there is a leak. Gas leaks are dangerous. Contact your supervisor unless you have been trained to repair leaks yourself.

6.4 Maintaining kerosene refrigerators

Daily

- Fill the tank with clean kerosene. Always fill the tank before it is completely empty. Always keep enough spare kerosene to ensure you never run out. Never use any other fuel (e.g. diesel or gasoline).
- Check the flame height and colour is correct for the type of burner fitted. If the flame smokes, turn it down a bit. If it still smokes, clean or trim the wick, burner, flue and baffle as shown in the instruction manual. Always clean the flue if the flame has been smoking.

Weekly

- Clean the burner, flue and baffle as shown in the instruction manual.
- Trim the wick as shown in the instruction manual. Use a wick trimmer if possible.
- Check that there is enough kerosene for at least another week. If not, replenish the supply immediately.

Periodic tasks

- Check the fuel tank to see if there is sediment at the bottom. If there is, blow out the burner and remove the tank. Remove the burner from the tank. Empty out the dirty kerosene. Flush the tank with a little clean kerosene. Wipe the outside of the tank with a clean cloth dipped in kerosene. Replace the burner and refill the tank.
- Replace the wick when you cannot turn it up any more to trim it. Use the correct type of wick and follow the instruction manual. Always keep two spare wicks in a safe place.

6.5 Managing vaccine refrigerator breakdowns

If a vaccine refrigerator stops working, first protect the vaccines and then check the cause of the problem.

Protecting the vaccines

Move the vaccines to other cold chain equipment until the refrigerator is repaired. For a problem that can be solved quickly, a cold box or vaccine carrier lined with conditioned ice packs can be used for temporary storage. For a problem that might take longer to solve, another refrigerator is needed. Always keep a freezer indicator with the freeze-sensitive vaccines.

Restoring the refrigerator to working order

- Check the electricity, gas, kerosene or solar power supply and make arrangements to deal with any interruptions.
- If a lack of electricity, gas, kerosene or solar power is not the problem, contact your supervisor and ask for a repair service visit. Do not attempt to repair the refrigerator yourself unless the problem is a simple one that you have been trained to deal with.
- Record the breakdown on the daily temperature monitoring chart.

6.6 Maintaining cold boxes and vaccine carriers

Vaccine carriers and cold boxes must be dried well after use, with their lids propped open. If they are left wet with their lids closed, they will become mouldy. Mould and damp can affect the seal of the cold boxes and vaccine carriers and may contaminate the vaccines. If possible, store cold boxes and vaccine carriers with the lids open.

Knocks and sunlight can cause cracks in the walls and lids of cold boxes and vaccine carriers. This exposes the insulation and increases the risk of heat exposure to the vaccines inside. If a cold box or vaccine carrier wall has a small crack, use adhesive tape to cover it until an undamaged container becomes available.

7

The Shake Test

7.1 What is the Shake Test?

The Shake Test is used to check whether freeze-sensitive vaccines have been damaged by exposure to temperatures below 0 °C. After it has thawed, a vial of vaccine that has been frozen no longer has the appearance of a cloudy liquid, but tends to form flakes that settle at the bottom of the vial.

The Shake Test requires two vials of the same vaccine from the same manufacture and with the same batch number. One of these is a vial that you suspect has been frozen and the other is a vial that you have deliberately frozen solid overnight. Allow the frozen test vial to melt completely, shake the two vials in the same hand, place them side-by-side and watch the contents settle. If the suspect vial settles at the same speed as the frozen vial you know that it has been frozen. If it settles more slowly, it has not been frozen.

7.2 When is the Shake Test needed?

If a freeze indicator is activated, or temperature recordings show negative temperatures, freeze-sensitive vaccines may have been damaged. If this occurs, notify your supervisor. If they decide to proceed, carry out the Shake Test on a sample of the freeze-sensitive vaccines.

7.3 How is the Shake Test done?

The Shake Test protocol is shown below.



NOTES:

- 1) **This protocol must not be altered.** There is only one correct way to conduct a Shake Test.
- 2) The test procedure described below should be repeated with all suspect batches. In the case of international arrivals, the shake test should be conducted on a random sample of vaccine. However, if there is more than one lot in the shipment, the random sample must include a vial taken from each and every lot.

1. Take a vial of vaccine of the same type and batch number as the vaccine you want to test, and made by the same manufacturer.
2. Clearly mark the vial as “FROZEN.”
3. Freeze the vial in a freezer or the freezing compartment of a refrigerator until the contents are completely solid.
4. Let it thaw. Do **NOT** heat it!
5. Take your “TEST” vial from the batch that you suspect has been frozen.
6. Hold the “FROZEN” vial and the “TEST” vial together in one hand.
7. Shake both vials vigorously for 10–15 seconds.
8. Place both vials on a flat surface side-by-side and start continuous observation of the vials until the test is finished.

(**NOTE:** If the vials have large labels that conceal the vial contents, turn both vials upside down and observe sedimentation in the neck of the vial.)

Use an adequate source of light to compare the sedimentation rates between vials.

IF,

9. The TEST vial sediments slower than the FROZEN vial,

THEN,

10. Sedimentation is similar in both vials

OR

The TEST vial sediments faster than the FROZEN vial

THEN,

11. Use the vaccine batch.

11. Vaccine damaged:

Notify your supervisor. Set aside all affected vaccine in a container marked “DAMAGED VACCINE FOR DISPOSAL – DO NOT USE”

12. Discard all affected vaccine once you have received permission to do so.

13. Fill in the Loss/Adjustment Form.



Compare the deliberately frozen vial next to the suspect vial

