



Australian Government

Department of Health and Ageing

National Vaccine Storage Guidelines

Strive for 5

2nd Edition



i M M U N I S A T I O N

i M M U N I S E
AUSTRALIA PROGRAM

A joint Australian, State and
Territory Government initiative

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The *National Vaccine Storage Guidelines 2013 – Strive for 5*, 2nd Edition will be updated when the national standards for vaccine storage devices are introduced by Standards Australia.

GLOSSARY

The list below gives the meanings of words as used in this document. Some of these words have different meanings elsewhere.

Accuracy check	A method used to ascertain the accuracy of a thermometer. See Section 6.4: How to check the accuracy of a thermometer.
Adverse vaccine storage event	Exposure of vaccines to temperatures outside the recommended range of +2°C to +8°C (excludes fluctuations up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking). An adverse vaccine storage event may be referred to as a 'cold chain breach'.
Ambient temperature	Temperature of the surrounding environment in which the vaccine refrigerator is operating.
Cold chain	The system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C.
Cold chain breach	Exposure of vaccines to temperatures outside the recommended range of +2°C to +8°C (excludes fluctuations up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking). A cold chain breach may be referred to as an 'adverse vaccine storage event'.
Cold life	The maximum time that a vaccine can be stored between +2°C and +8°C in a cooler or specialised cold box.

Cold mass	A non-technical term for materials (e.g. cooled water bottles) stored in a refrigerator to help maintain cold temperatures if, for example, the power fails or the door has been opened.
Conditioning of ice packs/gel packs	Leaving the ice packs/gel packs at room temperature to allow the ice or gel at the core to rise to about 0°C. This minimises the risk of freezing the vaccines. See Section 9.2 Freezing and conditioning ice packs and gel packs.
Cooler	This is a generic term used to describe portable solid-walled insulated containers such as Esky™/Willow™/Coleman™.
Cooling plate	The cooling plate is also known as the plate evaporator, load heat exchanger, cooling plate and cold plate. It is usually located on the back wall, inside the refrigerator.
Data logger	A small electronic device that continuously measures temperatures and keeps a record of the results.
Dual time-temperature indicator	A device that shows the accumulated time-temperature history of vaccine stock and signals when the vaccines have been exposed to temperatures outside the recommended range.
Freezing	A situation where vaccines experience temperatures at or below 0°C. Vaccines may not appear frozen but may have been damaged at these temperatures.
Gel packs	Commercial coolant products, commercial gel-packs and other non-ice coolants.
Immunisation service providers	These include medical practices, outreach providers, baby health centres, aged care facilities, large hospitals and clinics.

Mobile service

A service that spans a number of days and involves travelling long distances and providing immunisation sessions in a number of different sites. A mobile service should not be confused with an 'outreach clinic'.

Outreach clinic

An immunisation session that is conducted away from the main or 'home' immunisation venue. This service normally lasts a number of hours and staff then return to the 'home' venue before the end of the day. An outreach clinic should not be confused with a 'mobile service'.

Purpose-built vaccine refrigerators

Refrigerators designed and constructed specifically for vaccine storage.

Refrigeration

Withdrawal of heat from a chamber to achieve a temperature below ambient temperature.

Thermostat

A device that adjusts the amount of heating and cooling produced and/or distributed by automatically responding to the temperature in the environment.

1. USING THESE GUIDELINES

The *Vaccine Storage Guidelines 2013, Strive for 5*, 2nd Edition, provides information and advice for vaccine storage management. It has been written to assist all Australian immunisation service providers, from medical practices to large hospitals, clinics and outreach providers.

The publication's title refers to **Strive for 5 degrees Celsius (°C)** – that is, the point midway between +2°C and +8°C which is the temperature range recommended for vaccine storage. Many vaccines are damaged or destroyed at temperatures outside this range.

These guidelines:

- describe the best approach to ensure that clients receive effective and potent vaccines
- describe the 'cold chain' and provide advice on what should be done in the event of a cold chain breach
- include resources such as checklists, charts, posters and stickers
- apply to both purpose-built vaccine refrigerators and domestic refrigerators. If using a domestic refrigerator, refer to Appendix 4.

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2. SAFE VACCINE STORAGE

2.1 WHAT IS THE COLD CHAIN?

The 'cold chain' is the system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C.

The cold chain begins from the time the vaccine is manufactured, continues through to the state or territory vaccine distribution centres and ends when the vaccine is administered.

2.2 WHAT IS A COLD CHAIN BREACH?

A 'cold chain breach' has occurred if vaccine storage temperatures have been outside the recommended range of +2°C to +8°C. It excludes fluctuations up to +12°C, lasting no longer than 15 minutes, as may occur when stock taking or restocking refrigerators.

In the event of a cold chain breach, follow the cold chain breach protocol described in Appendix 3.

2.3 HOW SENSITIVE ARE VACCINES TO HEAT AND COLD?

Vaccines are delicate biological substances that can become less effective or destroyed if they are either:

- frozen
- allowed to get too warm, or
- exposed to direct sunlight or UV light, including fluorescent light.

When vaccines are repeatedly exposed to temperatures outside the +2°C to +8°C range, the loss of potency is cumulative and cannot be reversed.

If we don't protect our vaccines they won't protect our community!

The technology for vaccine storage is evolving. When purchasing vaccine storage equipment, it is recommended that you thoroughly investigate the item first. The information in this document will help with such investigations. For further information contact your state or territory health department. See contact details on the last page.

2.4 PRINCIPLES OF SAFE VACCINE STORAGE MANAGEMENT

Immunisation service providers must:

Store vaccines in a purpose-built vaccine refrigerator (see Section 5).

Nominate a staff member to be responsible for vaccine management, and a back-up staff member to take responsibility in their absence.

Ensure policies, procedures and protocols are in place for vaccine management in each facility (see Appendix 1).

Ensure all people involved in vaccine transport, storage and administration are trained in vaccine management to ensure the vaccines remain effective and potent.

Perform vaccine storage self-audits at least 12 monthly (see Appendix 2).

Perform temperature monitoring of vaccine refrigerators twice daily (see Section 6).

Ensure plans are in place for responses to cold chain breaches and power failures in each facility (see Section 8).

Report temperatures outside the +2°C to +8°C range to your state or territory health department. Do not use or discard vaccine until advice is given (see Appendix 3).

Follow the guidelines for using ice packs/gel packs and monitoring vaccines in coolers and cold boxes (see Section 9).

2.5 WHY IS VACCINE STORAGE MANAGEMENT IMPORTANT?

- Health professionals have a responsibility to ensure that clients receive effective health products (i.e. vaccines that have not been adversely affected by heat or cold).
- Vaccines are expensive and can be in short supply. The total financial value of the vaccines contained within one vaccine refrigerator can be significant.
- Good vaccine management precludes the need to revaccinate clients who may, under circumstances of poor vaccine management, receive an ineffective vaccine.
- Cold chain breaches can occur due to technical malfunctions, even in well-designed and well-managed systems. If there are effective procedures in place, problems will be detected and managed *before* an ineffective vaccine is used.
- Efficient vaccine storage management is a good quality-assurance measure of an immunisation service provider.
- Exposure to heat or freezing temperatures has a cumulative effect on vaccine viability.

2.6 WHY 'STRIVE FOR 5'?

Vaccines must be stored and transported within the recommended temperature range of +2°C to +8°C at all times – that is, within a maximum of five degrees Celsius range in temperature variation. Most vaccines are destroyed by freezing and some vaccines are also particularly heat sensitive.

All people responsible for handling vaccines must be educated to understand the importance of effective vaccine management.

3. TYPES OF REFRIGERATORS FOR VACCINE STORAGE

Purpose-built vaccine refrigerators are easier to manage than domestic refrigerators.

Note: Do not use bar refrigerators or cyclic defrost domestic refrigerators as they are not suitable for vaccines.

3.1 PURPOSE-BUILT VACCINE REFRIGERATORS

Purpose-built vaccine refrigerators are specifically designed to store vaccines and are the best-practice storage option. See Section 5: Considerations when choosing a vaccine refrigerator.

Purpose-built vaccine refrigerators have the following advantages:

- A stable, uniform, and controlled cabinet temperature between +2°C and +8°C.
- Standard alarm and safety features which alert to and/or prevent irregular temperature fluctuations in the cabinet.
- Inbuilt monitoring and/or data logging in some models (**Note:** a computer is required to download the data).
- Easier to manage than domestic refrigerators.
- Good temperature recovery after the refrigerator has been opened.
- Nearly all of the internal space can be used for vaccine storage; ask the manufacturer how to pack the refrigerator to accommodate the maximum quantity of vaccine.

Note: If using a purpose-built vaccine refrigerator, an additional refrigerator with a freezer section will be required for storing ice packs/gel packs.

3.2 DOMESTIC REFRIGERATORS

Domestic refrigerators are not recommended for vaccine storage. If a domestic refrigerator is the only vaccine storage option, see Appendix 4 for further information.

3.3 PORTABLE VACCINE REFRIGERATORS

A portable purpose-built vaccine refrigerator is now available on the market. Online searches will provide details.

Non purpose-built portable refrigerators have a propensity to freeze vaccines and should not be used for vaccine storage unless they have been rigorously appraised. For example, ensure:

- controls cannot be inadvertently changed
- a correct temperature can be set and maintained throughout the vaccine storage areas.

3.4 BLOOD REFRIGERATORS

A cold chain also applies to blood products, which are stored between +2°C and +6°C. This means that, if necessary, it is acceptable to store vaccines and blood products in the same refrigerator.

4. KEY RECOMMENDATIONS FOR EFFECTIVE VACCINE STORAGE MANAGEMENT

Purpose-built vaccine refrigerators are best practice and are the recommended vaccine storage option. Domestic refrigerators are not recommended for vaccine storage. If a domestic refrigerator is the only vaccine storage option, see Appendix 4 for further information.

4.1 VACCINE MANAGEMENT PROTOCOL

Ensure the following are in place:

- A trained, designated person is responsible for vaccine storage and implementation of protocols.
- A trained backup person is available to relieve the designated person when required.
- Orientation and education on safe and effective vaccine management for all staff members who may be involved in vaccine storage at any stage.
- Contact names and numbers for reporting:
 - cold chain breaches
 - refrigerator and/or logger maintenance issues
 - power failures.
- Back up vaccine storage options.

Each vaccination service must have **written policies, procedures and protocols** in place. See Appendix 1 for help with writing a vaccine management protocol. A vaccine management protocol should include written instructions for the following.

Equipment:

- Monitoring and recording the vaccine refrigerator temperature twice daily and after power outages.
- Monitoring and adjusting of equipment e.g. data logger, thermometer (see Section 6: Monitors).
- Equipment maintenance including
 - servicing the refrigerator and data logger
 - changing the logger and thermometer batteries
 - checking the accuracy of the thermometer
 - cleaning the refrigerator (see Appendix 1: Vaccine management protocol).
- Freezer storage for ice pack/gel packs (in case of power failure or outreach immunisation sessions).

Vaccines:

- Ordering and receiving vaccines. For ordering procedures, contact your state or territory health department (see contact details on the last page).
- Rotating stock so that vaccines with the shortest expiry date are used first.
- Calculating vaccine requirements (see Section 4.5: Storage).
- Storage of vaccines and diluents.

Vaccine transport:

- Managing a power failure (see Section 8).
- Packing a cooler (e.g. Esky™, Willow™, Coleman™).
- Conditioning the ice packs/gel packs (see Section 9.2).

Action and communication:

- Reporting a cold chain breach (see Appendix 3: Cold chain breach protocol).
- Action to take if the refrigerator temperature goes outside the recommended range (including what to do and how to prevent it happening again).
- Communication channels with other staff who handle vaccines (if there are any interventions taken to maintain the cold chain).
- Ongoing vaccine management education for staff, including orientation of new staff.

Rationale

Assigning the responsibility for cold chain management to one person in each facility will ensure consistency. However, other relevant staff should be trained to ensure that continuous monitoring occurs. All clinics/practices that store and administer vaccines should have documented policies, procedures and protocols in place and regular orientation, education or training sessions for staff.

Prompt identification and management of cold chain breaches will minimise the risk of an ineffective vaccine being administered and will prevent the need for recall for revaccination.

An alternative means of vaccine storage will allow providers to store vaccines between the recommended temperatures of +2°C to +8°C in the event of a power failure and this will help reduce vaccine losses.

Vaccine refrigerators should be self-audited by service providers as part of a routine quality assurance and risk management process. This will enable staff to have confidence that they are administering safe and effective vaccines (see Appendix 2: Vaccine storage self-audit).

4.2 PLACEMENT OF THE VACCINE REFRIGERATOR

- Ensure the refrigerator is placed out of direct sunlight.
- Follow the manufacturer's instructions for air circulation around the back and sides of the unit.
- Be aware of seasonal changes in the room temperature that may affect the refrigerator temperature.
- Ensure the refrigerator is in a secure area and is accessible to authorised staff only.
- Avoid placing the refrigerator against an outside wall, which may be subject to hot and cold temperatures.
- The room should be insulated if there is the potential for wide fluctuations in room temperature.
- If there are wide fluctuations in climatic conditions, an air conditioning system is required. Monitor what happens to the room temperature when the air conditioning is turned off overnight and on weekends and holidays.

Rationale

Some refrigerators need to have clearance at the sides and back to prevent heat build-up. Manufacturers usually provide recommendations regarding clearance. Placing the refrigerator in direct sunlight or near a heat source (e.g. a hot water service or warm external wall) forces the refrigerator to work harder.

The vaccine refrigerator should be placed in a secure area to:

- minimise unnecessary door openings
- reduce the risk of the power being switched off
- reduce the risk of interference with the vaccine stock by untrained staff.

4.3 POWER SOURCE RELIABILITY

- Consider using a back-up generator if there are regular power cuts or interruptions to the power supply.
- Consider alarming the refrigerator.
- Place a warning sticker on the electricity box: *'Do not turn off power before consulting the person responsible for vaccine management.'*
- Mark the power source clearly, so the refrigerator is not unplugged or turned off accidentally.
- Consider installing a power-point locking device or having the refrigerator 'wired in' so it cannot be accidentally unplugged.

Rationale

Accidental disconnection of a vaccine refrigerator from its power source can cause vaccine damage, particularly if the disconnection is not noticed immediately. The power source can be protected by placing a sticker (such as the sticker below) above the power plug and switch. The refrigerator can also be 'wired in' so that there is no switch, or there is a lockable switch. Devices to prevent refrigerators from being unplugged or turned off at the power point can be purchased from hardware stores.

A sticker should also be placed in the meter box to warn electricians that the power is sourcing a vaccine refrigerator – *'Do not turn off before consulting the person responsible for vaccine management.'*

DO NOT
TURN OFF POWER OR
DISCONNECT THIS
REFRIGERATOR

DO NOT
TURN OFF POWER BEFORE
CONSULTING THE PERSON
RESPONSIBLE FOR VACCINE
MANAGEMENT

4.4 STABILISE THE VACCINE REFRIGERATOR TEMPERATURE

- Ensure the temperature of the vaccine refrigerator is stable before stocking it with vaccine. To do this, monitor the refrigerator for a minimum of 48 hours prior to storing vaccines to ensure temperatures are maintained between +2°C and +8°C.
- If storing only a few vaccines, the temperature of the refrigerator can be stabilised by placing cooled bottles of water (cold mass) on unused shelves.

Staff should familiarise themselves with the vaccine refrigerator by recording temperatures in various sections of the refrigerator. The key areas to monitor are on each shelf from top to bottom, front to back and side to side. Leave the data logger in each position for a minimum of 24 hours.

Rationale

Stabilising the refrigerator temperature before stocking will minimise the likelihood of the vaccines being exposed to temperature variations.

In some refrigerators, the coldest area is the top shelf; in others it's the front of the bottom shelf. All models differ – even those from the same manufacturer.

It is important that the 'cold spots' in the refrigerator are identified by detailed monitoring. This can be done by placing data loggers (see Section 6.2) or thermometers in all areas of the refrigerator and noting the different temperatures before using the refrigerator for vaccine storage. Monitor each area for at least 24 hours: this will capture all of the fluctuations that occur.

Depending on the type and number of monitors you have, comprehensive temperature monitoring may take some time to complete. While assessing the 'cold spots', use a 'cold mass' (e.g. cooled bottles of water) to imitate a batch of vaccine, as refrigerators behave differently when empty. Your state or territory health department may be able to assist with logging your refrigerator. See contact details on the last page.

A recording chart is required to document minimum and maximum temperatures. This written record enables staff to monitor and take action if temperatures go outside the recommended range. See Appendix 6 for a monitoring chart.

Note: Thermometers for use with vaccines must be accurate – staff should check the accuracy of the thermometer and change its battery at least every 12 months or as specified by the manufacturer (see Section 6.4: How to check the accuracy of a thermometer).

4.5 STORAGE

- Have a reliable refrigerator, preferably purpose-built to store vaccine, which has the capacity to accommodate the facility's vaccine storage needs (including during influenza season).
- Depending on the quality and design of your purpose-built vaccine refrigerator, it may warm quickly during a power failure.
- If the refrigerator has an exposed coil, insert a guard or buffer to prevent vaccines being pushed onto the coil.
- The refrigerator should have the following sticker clearly displayed: *'Stop. Do not open door until you know which vaccines you need and where they are located.'*



- **Store the vaccines in their original packaging from the manufacturer as this helps to protect them from temperature fluctuations and ultraviolet (UV) light.**
- **Label containers clearly with names of vaccines.**
- Do not crowd the vaccines by overfilling the shelves. If not using open-weave baskets, allow space between containers for air circulation.

- Keep refrigerator door openings to a minimum.
- When storing influenza vaccine, separate and clearly label vaccines for adults and children under 5 years of age and store them in separate areas of the refrigerator. It is recommended that pictures or a map are used.
- Ensure privately purchased vaccines are clearly marked and separated from the National Immunisation Program vaccines.
- For a solid door refrigerator, place a guide on the outside of the refrigerator indicating where each type of vaccine is stored. Place a picture or map of the packed refrigerator on the door (see Figure 1).
- **Do not store food and other goods in the refrigerator.**
This would increase the likelihood of a cold chain breach by:
 - overcrowding the vaccines
 - increasing the number of door openings.

Rationale

Storing vaccines in labelled containers allows for easy identification of vaccines and minimises the time the refrigerator door remains open. The time spent searching for vaccines can also be reduced by placing a basic map or picture of vaccine locations on the refrigerator door so staff can go straight to the vaccine they require.

Purpose-built refrigerators with glass doors may not have UV filtering; storing vaccines in their original packaging protects them from light.

Overstocking the refrigerator places all vaccines at risk. It impedes cold air circulation and reduces the likelihood of achieving consistent, stable temperatures throughout the refrigerator.

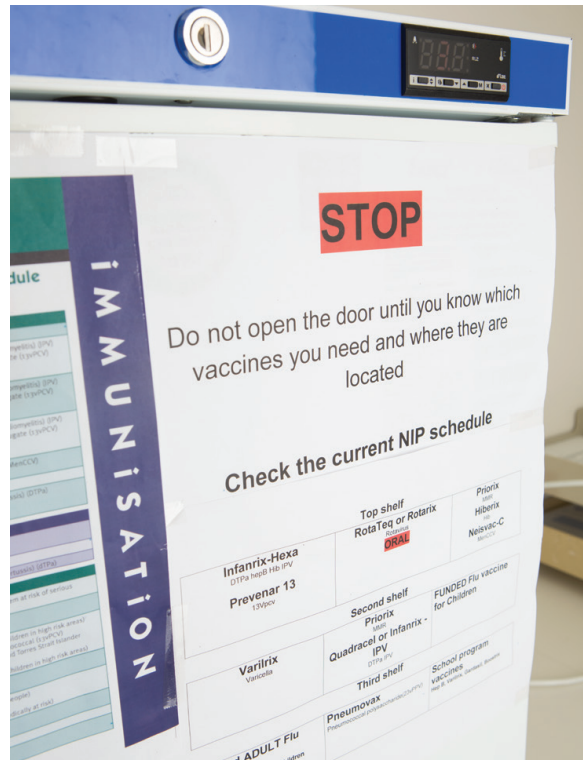


Figure 1: If using a solid door refrigerator, place a map on the outside of the door indicating where each type of vaccine is stored.

4.6 MONITOR AND RECORD REFRIGERATOR TEMPERATURES

Ensure procedures are in place to provide written records of these activities every day the facility is open, in a chart/log-book specific to each refrigerator:

- **Check and record the vaccine refrigerator temperature (minimum and maximum) twice daily: before the refrigerator is used for the first time and at the end of each day.** See Appendix 6 for a monitoring chart.
- Reset the data logger or thermometer after each reading.

The refrigerator temperature also needs to be read and recorded:

- on receipt of vaccines
- following a power failure
- hourly during outreach clinics.

This written record enables staff to monitor the temperature fluctuations of the refrigerator and take action if temperatures go outside the recommended range. Retain documentation of vaccine temperature recordings according to your state or territory health department policy or your medico-legal and statutory requirements.

Note:

The data logger or thermometer must measure temperatures in Celsius not Fahrenheit.

Each vaccine refrigerator requires its own temperature monitoring chart/log book.

Data loggers provide an accurate indication of the vaccine refrigerator's temperature at pre-set time intervals and are useful for mapping 'cold spots' in the refrigerator or investigating problems (see Section 6.2: Data loggers).

If the temperature readings are outside the +2°C to +8°C range, contact your state or territory health department for advice. See contact details on the last page.

Rationale

Checking and recording the temperatures before retrieving a vaccine enables the identification of problems before the vaccine (which may be damaged) is administered. Twice daily temperature checks give an indication of any problems in the refrigerator's function and temperature fluctuations over the course of the day. However, the temperature needs to be viewed and considered every time the refrigerator is opened.

4.7 MAINTENANCE OF THE VACCINE REFRIGERATOR

- Report breakdowns immediately and arrange for alternative monitored storage for vaccines while the refrigerator is repaired.
- Have the refrigerator serviced every 12 months and ensure it is in good working order.

- Check that the refrigerator is free of water or coolant leaks, that the compressor operates quietly, the seals are in good condition and sealing tightly and the door closes properly. Comply with the manufacturer's directions about keeping the refrigerator level.
- If there are exposed coils on the back of the refrigerator, keep them clean and dust free to improve operating efficiency.
- When cleaning the refrigerator, move the vaccines to a second refrigerator (which must be monitored during this time). Alternatively, store and monitor the vaccines in a prepared cooler (see Section 9.3: How to pack a cooler).

4.8 MAINTENANCE OF EQUIPMENT

- Recalibrate the data logger annually.
- Change the data logger battery at least every 12 months or as indicated by the manufacturer.
- Check the accuracy of the thermometer at least annually (see Section 6.4: How to check the accuracy of a thermometer).
- Change the thermometer battery at least every 12 months or as indicated by the manufacturer.

4.9 SELF-AUDIT

A vaccine storage self-audit should be undertaken by each clinic/practice at least every 12 months. Self-audits should be carried out more frequently at facilities that experience cold chain problems (see Appendix 2: Vaccine storage self-audit).

5. CONSIDERATIONS WHEN CHOOSING A VACCINE REFRIGERATOR

As always when shopping, think: Is this value for money? Will this purchase deliver what you expect? Ask questions! The quality and design of a purpose-built vaccine refrigerator may determine how quickly it warms during a power failure.

5.1 FEATURES TO CONSIDER

When choosing a vaccine refrigerator, consider the following points:

- The size of the refrigerator. Ensure the refrigerator is large enough to meet the facility's vaccine storage requirements, particularly during periods where additional vaccines may be stored, such as the seasonal influenza program.
- The size of the space in the facility. Ensure there is enough room for air circulation around the back and sides of the refrigerator as per the manufacturer's instructions.
- Be aware that an alternative freezer will be required to store ice packs and gel packs for use during outreach clinics or in the event of a power failure.

Consider choosing a refrigerator with the following features:

- An in-built temperature monitor/logger.
- An alarm system. Alarm systems have various options e.g. the capacity to notify someone remotely, either by automatic telephone dialling, or a central area that is staffed 24 hours a day. Choose the alarm system which best suits your needs.
- A 'door left open' alarm.

- An inbuilt temperature recording system. Ensure the temperature (minimum and maximum) can be easily read. Some chart recording system may be placed at the bottom of the refrigerator.

5.2 QUESTIONS TO ASK

Questions to ask the sales representative might include:

- What is the difference between solid and glass doors with respect to temperature maintenance?
- What is the energy efficiency?
- Will the refrigerator require enhancements (e.g. alarms, temperature monitoring features) and what are the associated costs?
- What are the conditions and durations of the warranty? Pay attention to the backup support and servicing, including the costs of delivery, maintenance and repairs, particularly in rural and remote areas. What are the supplier/manufacturer quality assurance processes?
- How long will the refrigerator remain within the recommended temperature range in the event of a power failure?
- Is 'cold mass' support required e.g. cooled bottles of water?

Australian Standards for medical refrigeration equipment for the storage of vaccines are under development. Check the Immunise Australia website for further details.

6. MONITORS

Even when monitors are used, minimum/maximum temperatures must still be recorded manually as a timely alert to any breach in the cold chain.

6.1 TEMPERATURE CHART RECORDING SYSTEMS

Temperature chart recording systems can record temperatures over long periods and provide visual and audio alarms. They can be set to record air and/or product temperature. These systems can be installed in refrigerator units, but check with the manufacturer as doing so may void the warranty.

6.2 DATA LOGGERS

What is a data logger?

Temperature data loggers are small electronic devices that measure temperatures at pre-set time intervals and record the results over a period of time. Data loggers should be set to record temperatures at 10–15 minute intervals.

Each logger is a self-contained miniature computer. Data loggers come in a range of shapes and sizes. Once programmed via a computer, loggers are disconnected from the computer and placed in the vaccine refrigerator near the temperature probe or vaccines. The logger then operates independently on its own battery until the recording is downloaded to the computer.

Some purpose-built vaccine refrigerators have an inbuilt data logger, which should be downloaded as recommended by the manufacturer.

Advances in technology are producing more features in data loggers; the information in this section refers to basic models.

What information do data loggers provide?

Data loggers provide an accurate indication of vaccine refrigerator temperatures and can be used to map 'cold spots' or investigate problems. Loggers use a similar measuring principle to chart recorders; however they record the data electronically. The data can be stored by the monitoring system and can also be downloaded to a computer.

The objective of data logging is to build up a 'temperature map' (see Section 4.4: Stabilise the vaccine refrigerator temperature) for the refrigerator, to identify which areas are safe for vaccine storage. In particular, it is important to identify areas where vaccine could freeze.

Twice daily minimum/maximum temperatures must still be manually recorded as a timely alert to any breach in the cold chain. If a data logger is used for routine temperature monitoring (i.e. instead of a minimum/maximum thermometer) it must have a visual display of minimum/maximum temperatures to allow twice daily real time recordings to be read and recorded.

Many data loggers can be programmed to alarm when the temperature is recorded outside the +2°C to +8°C range. The replaceable battery has a typical life of 1 to 2 years (check manufacturer's guidelines).

Using a data logger

If using a minimum/maximum thermometer, the data logger and the thermometer should be co-located in the refrigerator, otherwise different recordings can occur.

The results can be printed out in graph and numerical format, including information on the times the temperature was recorded outside +2°C to +8°C and the minimum and maximum temperatures.

All staff should be trained on how to operate/manage the data logger and interpret its readings. Data logging will help vaccination providers to get to know their refrigerator (see Section 4.4: Stabilise the vaccine refrigerator temperature). Any actions taken in response to data logging should be documented and retained according to state or territory health department policy or medico-legal requirements.

Periodic logging

Periodic logging is usually undertaken by practices that do not have a permanent data logger. The refrigerator temperature is logged for a defined period, e.g. one week, to verify cold chain efficacy and to provide documentation for accreditation purposes. The data logger is supplied to the practice by an external body e.g. the practice's local state or territory health department.

Permanent logging

Where a practice has its own data logger and permanently logs the refrigerator temperature, it is recommended that the data is downloaded weekly (under normal circumstances) as a permanent record.

Checklist for data loggers

- **Place the data logger where it is easily seen.**
- **Measure the minimum/maximum temperatures twice daily and record them.**
- **The alarm systems should be activated to alarm outside +2°C to +8°C. Check the alarm is working.**
- **Train all staff to recognise the alarm.**
- **Download and record information as soon as possible after an alarm is activated.**
- **If recordings are outside the +2°C to +8°C range, notify the relevant state or territory health department. See contact details on the last page.**
- **Regularly check and record the accuracy of the data logger and change the battery according to the manufacturer's recommendation.**

Benefits of data logging

- Provides information on the duration of a cold chain breach and supplements a cold chain audit.
- Confirms the cold chain has been maintained and provides accurate knowledge of the vaccine refrigerator temperature.
- Identifies times when risk of vaccines being frozen (0°C or below) occurs e.g. overnight, long weekends and when refrigerator is not in use.
- Assists staff to understand the functioning of the refrigerator.
- Identifies the temperature fluctuations within the shelves and the location of any 'cold spots' on each shelf.
- Confirms the efficacy of modifications made to domestic refrigerators.
- Supports accreditation documentation and audits.
- Helps to assess the refrigerator thermometer's accuracy

Points to consider when purchasing a data logger

Find out:

- Whether the logger will allow for pre-set 10–15 minute temperature recordings.
- Whether the logger is easy to use, particularly with regard to recording and downloading data.
- The accuracy of the data logger. (Is it $\pm 1^{\circ}\text{C}$ or, more usually, $\pm 0.1^{\circ}\text{C}$?)
- Whether the accuracy of the data logger can be checked by the user or requires a technician
- The battery life of the data logger
- If the logger will be used as a permanent method of monitoring temperatures
 - Does it have a visual minimum/maximum temperature display?
 - Is the current temperature visible?

6.3 THERMOMETERS

A minimum/maximum digital thermometer is essential for temperature monitoring in a domestic refrigerator and during outreach immunisation sessions and power failures. Some purpose-built vaccine refrigerators do not have a battery back-up for their temperature monitoring system and hence a minimum/maximum thermometer can assist in monitoring refrigerator temperatures. The thermometer must be reset every time the temperature is recorded on a graph or in a log book.

Choose a thermometer that reads Celsius (not Fahrenheit). Different models of minimum/maximum thermometers vary in accuracy.

Thermometers require annual checks to ensure accurate measurement; flat batteries or a damaged probe or cable can affect readings. Change the battery at least every 12 months. It is useful to have a back-up thermometer and to note its storage location on the vaccine management protocol.

The accuracy of a minimum/maximum thermometer can be checked by performing the following steps.

6.4 HOW TO CHECK THE ACCURACY OF A THERMOMETER

1. Fill a polystyrene or plastic cup with cold water.
2. Place the cup in the refrigerator freezer until a fine layer of ice forms on the top and small sections of ice form within the fluid (this may take up to 2½ hours). The presence of ice is an indication that the temperature of the water has reached 0°C.
3. Place the temperature probe into the middle of the container (be careful not to let the probe touch the container).
4. Observe the temperature on the display screen after two minutes.

Rationale

The temperature will drop quickly at first and then more slowly. The temperature should drop to 0°C within two minutes.

An 'acceptable' degree of accuracy of a thermometer can vary e.g. to within $\pm 1^{\circ}\text{C}$; check with the organisation that supplied the thermometer for the expected accuracy. Even if the thermometer is considered accurate to within $\pm 1^{\circ}\text{C}$, this check could result in the display screen showing three possible readings: $+1^{\circ}\text{C}$, 0°C , -1°C . Record the results of the accuracy check on your temperature chart. This information becomes important, particularly if the vaccine refrigerator temperature goes outside the recommended range of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$.

The thermometer must be accurate to $\pm 1^{\circ}\text{C}$ or better. If the temperature reading is more than one degree above or below 0°C at two minutes, replace the battery and test again. If still not within range, replace the thermometer.

A check of the accuracy of your thermometer is recommended:

- after the battery is changed
- at least every 12 months, for auditing purposes
- in the event of there are cold chain problems.

The supplier of the thermometer may be able to offer a validation or accuracy check for their product.

6.5 COLD CHAIN MONITORS

Cold chain monitors (CCMs), to detect heat and freeze breaches, must accompany all vaccines during transport. CCMs should be checked when the vaccine order arrives at its destination.

Breaches in the cold chain should be reported immediately to the relevant state or territory health department. See contact details on the last page. Affected vaccines should be isolated in the refrigerator and not used while awaiting advice.

Check with the relevant state or territory health department for information on:

- the type of CCMs that are in use
- whether the CCM can be used during vaccine storage in refrigerators and/or only used during transport of vaccines.

7. CARING FOR VACCINES DURING IMMUNISATION SESSIONS

7.1 KEY ISSUES

- Do not use diluents warmer than the vaccine as they can affect the potency of live vaccines
- Be aware of sensitive vaccines. Most vaccines are sensitive to any form of ultraviolet (UV) light, including fluorescent light, and must be stored in their original packaging to provide protection from UV light.
- Keep refrigerator door or cooler openings to a minimum.

Vaccines are particularly vulnerable at the time of use because:

- vials and ampoules have to be opened
- freeze-dried vaccines have to be re-constituted
- staff must handle many types of vaccines with different requirements.

7.2 OUTREACH IMMUNISATION SESSIONS

- At least 24 hours before each outreach session, check the number of ice packs/gel packs in the freezer and replenish as needed.
- Plan the outreach session carefully. Take a sufficient stock of vaccine, diluent, adrenaline (epinephrine) and icepacks.
- When using a cooler, store vaccines in their original packaging.
- If providing immunisations outdoors, choose a cool shaded site.
- For a mobile service where there is no electric power supply or refrigerator, take an extra cold box containing additional ice packs/gel packs to replace the melted ice packs / gel packs.

- Take vaccines and diluents from the cooler only as required. Reconstitute vaccines immediately prior to administering.
- When the vaccines are outside the vaccine carrier, keep them out of direct sunlight and away from other sources of heat and ultraviolet light (e.g. fluorescent light).
- Avoid handling vaccines any more than absolutely necessary.
- During outreach clinics the minimum/maximum temperature of the cooler or cold box should be monitored hourly.
- When the outreach session is over, vaccines which have been continuously stored between +2°C and +8°C should be returned to the vaccine refrigerator as soon as possible.

When preparing for long-term storage or an outreach immunisation in an extreme climate, use a specialised vaccine cold box (See Section 9.4: Specialised vaccine cold box).

Using reconstituted vaccines with diluent during an outreach

immunisation session: Reconstituted vaccines lose potency over time, even when stored between 2°C and 8°C. Storage rules vary depending on the vaccine being used. Please refer to the *Australian Immunisation Handbook* and to the current version of the relevant vaccine Product Information (PI) statement for vaccine specific information. PIs are supplied with all vaccines and are also freely available on the Therapeutic Goods Administration (TGA) website at: www.tga.gov.au

7.3 PHARMACY ACQUIRED VACCINE

Clients should be advised to purchase vaccines from the pharmacy immediately before attending their GP appointment and to notify reception on arrival that they have a vaccine to put in the vaccine refrigerator.

8. MANAGEMENT OF POWER FAILURE

Power failures occur for many reasons. How a power failure is managed in your organisation may depend upon the cause of the power outage, whether prior notice was given and the time of day the outage occurs.

Some power networks provide SMS text message alerts for power outages. Check with your local power networks if this service is available in your state/territory.

8.1 BACK-UP PLANS

Have a back-up plan and alternative storage if a power failure occurs.

This will allow providers to continue to store vaccines between the recommended temperatures of +2°C and +8°C, thereby minimising vaccine loss and disruption to businesses.

Alternative vaccine storage in the event of a power failure may include any of the following:

- a back-up power supply e.g. generator or battery/solar back-up
- a monitored refrigerator off-site. Ensure an agreement has been put in place with the relevant organisation prior to the event. Also consider that this organisation may also be affected by a power failure
- a cooler e.g. Esky®, Willow® or Coleman®. Each facility should ensure they have enough coolers for an emergency.

If using a cooler, ensure it will be large enough to accommodate:

- all vaccines
- ice packs or gel packs
- insulating material e.g. polystyrene chips or bubble wrap
- minimum/maximum thermometer or data logger.

Each immunisation facility should practise implementing its back-up plan, including practising packing vaccines into alternative storage, to ensure the plan will work in a real power failure situation. Keep in mind there may only be 20–30 minutes before the vaccine refrigerator temperature rises above 8°C – suitable alternative storage must be ready quickly. Ensure that the back-up plan is clearly documented in the vaccine management protocol. The information provided here is a general guide only and may not be applicable to each facility – careful planning and practice will ensure that your back-up plan will work for *your* facility.

8.2 WHEN POWER GOES OFF

1. Immediately isolate the vaccines, keep refrigerated between +2°C to +8°C and put a sign on the refrigerator stating '*Power out. Do not use vaccines. Keep refrigerator door closed.*'
2. Closely monitor the refrigerator temperature.
3. If the temperature rises to +8°C, move vaccines to a prepared cool box or portable vaccine refrigerator. Ensure all vaccines are packed and monitored with a digital thermometer. See Section 9.3: How to pack a cooler.
4. Ensure you have a strategy in place for long-term storage. Your state or territory health department may be able to assist you.

8.3 PURPOSE-BUILT VACCINE REFRIGERATORS

Depending on the quality and design of your purpose-built vaccine refrigerator, and the ambient temperature of the facility, the refrigerator may warm quickly during a power failure. Providers should contact the refrigerator manufacturer to establish this time period and document as part of their power outage plan.

Note: not all purpose-built vaccine refrigerators continue to display the current temperature during a power failure. To overcome this issue, use a separate battery-operated minimum/maximum thermometer to continually monitoring refrigerator temperatures during power outages.

If vaccines are at risk, use alternative monitored storage arrangements. Alternatively cover the glass door with insulating material (cardboard, bubble wrap or a blanket) and place ice bricks in empty spaces, taking care not to place them alongside the vaccine, and keep the door closed.

For domestic refrigerators, see Appendix 4.

8.4 WHEN POWER IS RETURNED

- Record the refrigerator temperature.
- Reset the temperature.
- Ensure the refrigerator temperature has returned to between +2°C and +8°C before returning vaccines.
- If a cold chain breach has occurred, report it to the relevant state or territory health department as soon as possible. See contact details on the last page. Do not use or discard vaccines until advice is given.
- Monitor the refrigerator closely e.g. hourly, then as recommended twice daily.

If necessary, follow the cold chain breach protocol described in Appendix 3. This appendix details important information to have on hand when reporting a cold chain breach to your state or territory health department.

9. COOLERS

A cooler, also known by names such as Esky™, Willow™ or Coolman, is a solid-walled insulated container with a tightly fitting lid. The temperature inside can be maintained using ice packs or gel packs. Coolers are usually portable.

High quality coolers are available from large boating, fishing or camping suppliers. They have thick refrigerator-grade insulation and fibreglass or plastic walls. Some may have small 'feet' which ensure the cooler does not contact warm surfaces such as the floor of the boot of the car. Check with the manufacturer about the technical specifications and performance of the cooler.

Coolers have a limited cold life and are therefore not adequate for vaccine storage over prolonged periods (more than 8 hours) or in extreme conditions. In these circumstances, a specialised cold box should be used for storing and transporting vaccines (see Section 9.4: Specialised vaccine cold box).

9.1 TIPS FOR USING COOLERS

- Vaccine service providers should choose coolers that will meet their facility's needs.
- Freezing episodes can occur in all coolers, usually in the first 2 hours after packing. The minimum size cooler recommended for storing vaccines is 10 litres.
- Polystyrene coolers provide limited insulation and are suitable only for storing vaccines for short periods of time (up to 4 hours).
- If using a polystyrene cooler, change to a plastic cooler if the polystyrene cooler is not maintaining a stable temperature.
- If using a plastic cooler which is not maintaining a stable temperature, consider upgrading to a higher quality cooler with refrigeration-type insulation or a specialised cold box.

The number of ice packs/gel packs (see Section 9.2) required will depend on:

- ambient temperature
- type and size of cooler
- number of vaccines
- cooler capacity
- size and type of ice packs/gel packs.

When using coolers:

- Condition the ice packs/gel packs. (See Section 9.2: Freezing and conditioning ice packs and gel packs.)
- Pre-chill the cooler before use.
- Note that correctly packing a cooler reduces the risk of freezing.
- Insulate the vaccines with the appropriate material e.g. bubble wrap, so they do not come into contact with the ice packs/gel packs which are at 0°C.
- Monitor the temperature hourly.
- Ensure the contents of the cooler are packed securely so they cannot move around during transport.
- Keep the cooler out of the direct sun.
- Remove vaccines from the cooler only as they are required.
- Check the temperature has remained within +2°C to +8°C prior to administering the vaccine.

9.2 FREEZING AND CONDITIONING ICE PACKS AND GEL PACKS

Ice packs

Ice packs are water-filled and can come out of the freezer at a temperature as low as -18°C , which is significantly lower than the freezing point of the ice pack. Achieving the lower temperature will provide a longer 'cold life' for the ice pack.

Gel packs

Some types of gel packs contain chemicals that depress the freezing point of the pack and ensure the gel remains colder than 0°C for longer than water-filled ice packs. Before purchasing gel packs, request documentation from the manufacturer that:

- validates their claims about the product's cold life
- provides clear instructions on how to freeze and condition the product before use, and how to safely pack a cooler with the gel pack and vaccine.

How to condition ice packs

Condition the ice packs as follows:

- Remove ice packs from the freezer.
- Lay out ice packs in a single row on their sides (where possible) leaving a 5 cm space around each ice pack to allow maximum air exposure. This reduces the conditioning time.
- Wait until ice packs begin to sweat. This will take up to one hour at $+20^{\circ}\text{C}$.
- The ice pack is conditioned as soon as water begins to 'slosh' about slightly inside the ice pack.

How to condition gel packs

Usually gel packs will take longer than ice packs to condition.

Follow the manufacturer's instructions on conditioning the gel pack. Although there is no 'one rule fits all' approach, there are some industry standards that can be used to guide conditioning if gel packs have been stored in the freezer at -20°C for a minimum of 36 hours.

Conditioning frozen gel packs for the times prescribed below enables the initial chill factor to be removed from the packs.

Guide to time needed to condition small and large gel packs

Gel packs weighing less than 750g

- If ambient (room) temperature is **over** +15°C, condition for 45 minutes before use.
- If ambient temperature is **under** +15°C, condition for 1 hour before use.

Gel packs weighing more than 750g

- If ambient (room) temperature is **over** +15°C, condition for 1 hour before use.
- If ambient temperature is **under** +15°C, condition for 1½ hours before use.

9.3 HOW TO PACK A COOLER

One of the greatest risks to vaccines due to freezing is transportation in a cooler or cold box. The risk of freezing increases if the ice packs/gel packs are not correctly conditioned.

Freezing episodes occur easily in all coolers, usually in the first 2 hours after packing.

OPTION ONE

Packing vaccines directly into a cooler

This option can be used for storing vaccines for up to 8 hours.

- Chill the inside of the cooler prior to use by placing ice packs/gel packs in it for a few hours and then remove these icepacks (Figure 2)
- Place polystyrene chips, or other suitable insulating material at the bottom of the container. This eliminates 'hot and cold spots'. Packaging such as polystyrene chips is preferable to bubble-wrap as it promotes air circulation. However, if using bubble-wrap avoid wrapping the vaccines tightly (Figure 3).

- Place a minimum/maximum thermometer (or a dual time-temperature indicator if they are used in your state or territory) in the centre of the vaccine stock (Figure 4).
- Surround the vaccines with packing material which allows cold air to circulate.
- Place the conditioned ice pack/gel pack(s) on top, close and seal the lid of the cooler (Figure 5). If using a larger cooler, place conditioned ice packs/gel packs around the sides of the cooler as well as on top. Experiment to find the best combination.
- Ensure vaccine stock is not in direct contact with the ice packs/gel packs to minimise risk of freezing.
- Monitor the temperature before leaving for the session, upon arrival, prior to administering vaccine and at least hourly throughout the immunisation session.



Figure 2: Chill the inside of the cooler by placing ice packs/gel packs inside for a few hours.



Figure 3: Place insulating material in the bottom of the cooler.



Figure 4: Place minimum/maximum thermometer in the centre of the vaccine stock.



Figure 5: Surround the vaccines with packing material and place conditioned ice packs/gel packs on top before closing the cooler.

OPTION TWO

Packing vaccines into a polystyrene container which is then placed into a larger cooler.

- Choose a suitably sized polystyrene container and chill the inside by placing ice packs/gel packs inside for a few hours.
- Place vaccines, a minimum/maximum thermometer and a freeze indicator (or a dual time-temperature indicator, if used in your state or territory) inside the polystyrene container and secure the lid.
- Ensure the minimum/maximum thermometer probe and freeze indicator are placed in the centre of the vaccine stock.
- Pack the polystyrene container inside a large cooler and surround it with ice packs/gel packs. Secure the lid.
- Monitor the temperature before leaving for the session, upon arrival, prior to administering vaccine and at least hourly throughout the immunisation session.

9.4 SPECIALISED VACCINE COLD BOX

A vaccine cold box is a purpose-built product. It has thick walls and is significantly more expensive than a cooler.

The cold box insulation should be at least 30 mm thick and, if possible, 80 mm thick in the walls and lid. Fibreglass cold boxes with 50 mm refrigeration grade insulation are available.

For long-term storage (more than 8 hours) or extreme conditions (where storage environment is $<0^{\circ}\text{C}$ or $>40^{\circ}\text{C}$) a specialised cold box is needed. Specialised cold boxes are available that meet World Health Organization (WHO) recommendations.

A large cold box should have a minimum cold life of 120 hours when exposed to temperature up to 43°C without any openings.

The WHO has a list of specifications at: www.who.int/immunization_standards/vaccine_quality/pqs_e04_insulated_containers/en/index.html

APPENDIX 1: VACCINE MANAGEMENT PROTOCOL

Vaccine storage procedures which comply with the *National Vaccine Storage Guidelines 2013*, *Strive for 5* are available on the Immunisation Australia website.

It is suggested that vaccine service providers download this document from the Immunise Australia website and fill in the clinic's details.

VACCINE ORDERING

- The aim when ordering vaccine is the **right** amount at the **right** time.
- Stocktake must be carried out before ordering new vaccine.
- Add details about how to order vaccines i.e.
 - where order forms are kept
 - who they are sent to
 - how to follow up on orders.

VACCINE DELIVERY

- The nominated person should accept vaccines from the courier.
- Check cold chain monitors.
- Transfer vaccines to a dedicated vaccine refrigerator in original packaging.
- Check expiry dates. Bring vaccines with the shortest dates to the front of the refrigerator.
- Record date, numbers of vaccines received, vaccine types and batch numbers.

- **Add details of who to contact if cold chain monitors show breach, noting difference between government-funded and privately purchased vaccines.**

TEMPERATURE MONITORING AND RECORDING

- When a data logger is used (purpose-built vaccine refrigerator), instructions on use and downloading data to be placed in manual.
 - **Add details of where to store data on computer.**
- When using a minimum/maximum thermometer (domestic refrigerator)
 - the thermometer must be in place to constantly check the temperature in each vaccine refrigerator.
 - the thermometer probe should be placed in a vaccine box (not in fluid) on the middle shelf of the refrigerator.
 - the thermometer is to be checked and recorded twice every working day.
 - Record the maximum and minimum temperatures of the refrigerator and reset the thermometer.
 - **Insert where to find new charts/log books.**
 - **Provide instructions on how to reset thermometer.**
- Details on who to contact during a breach for advice.

POWER FAILURE PROCEDURE

- What to do in opening hours.
- What to do out of hours.

COLD CHAIN BREACH

1. Immediately isolate the vaccines and label '**Do not use**'.
2. Keep vaccines refrigerated between +2°C and +8°C.

3. Contact your relevant state or territory health department as soon as possible in business hours.
4. Do not discard any vaccine until advised to do so by your state or territory health department.
5. For privately purchased vaccines, contact the manufacturer for advice.

DOCUMENTATION

Written procedures, instructions and log books need to be readily accessible to explain and record equipment maintenance, vaccine transport and staff education. See below.

EQUIPMENT MAINTENANCE

- How and when to change batteries. For example, the batteries in minimum-maximum thermometers require changing at least annually.
- Service details – who, when and contact details for refrigerator.
- When annual refrigerator audit to be performed.
- Cleaning procedure for the refrigerator.
- For a domestic refrigerator:
 - how and when thermometer accuracy is tested
 - if domestic refrigerator with freezer, the procedure for defrosting refrigerator and how often.

TRANSPORTING VACCINES OFF SITE

- How to condition icepacks.
- Procedure for packing cooler.
- How often to monitor cooler.

STAFF EDUCATION – VACCINE MANAGEMENT

- Procedure for orientating new staff and staff with new roles.
- Staff records of ongoing education.

APPENDIX 2:

VACCINE STORAGE SELF-AUDIT

Vaccination service providers should use this checklist to carry out a self-audit at least once every 12 months, and more frequently where there have been problems with equipment or cold chain breaches

Print off this *Strive for 5* checklist and use as required.

Self-auditing is important because:

It is part of routine quality assurance and risk management processes.

It enables staff to have confidence that they are providing a safe and effective vaccine.

You can photocopy this page and keep as a record of an audit.

Nominated person responsible for vaccine management:

Nominated back-up person for vaccine management:

Make and model of refrigerator:

Date of self-audit:

Person conducting audit:

PROCEDURES

Checklist for safe vaccine handling and storage

• Have all staff received orientation and/or annual update on vaccine management?	☐ Yes ☐ No
• Are the vaccine management policies and procedures up to date?	☐ Yes ☐ No
Last revision date was:	/ /
• Is graph/log book/chart for temperature recording readily available?	☐ Yes ☐ No
• Is the temperature of the vaccine refrigerator recorded twice a day when the facility is open?	☐ Yes ☐ No
• Are the contact numbers to report a cold chain breach easily accessible?	☐ Yes ☐ No
• Were all deviations outside +2°C and +8°C reported to the appropriate state or territory health department?	☐ Yes ☐ No
• Have the responses to all deviations outside +2°C and +8°C been documented and recommended actions taken?	☐ Yes ☐ No

EQUIPMENT

Vaccine refrigerator

• Has the refrigerator shown evidence of malfunction (e.g. poor seals so that the door opens too easily)?	☐ Yes ☐ No
• Is there an appropriate gap between the vaccines and the walls of the refrigerator?	☐ Yes ☐ No

Can the refrigerator continue to store the volume of vaccines safely according to these guidelines? (This includes times of increased demand e.g. influenza program.) If 'No', what action is being taken?	☐ Yes ☐ No
Date of last service of refrigerator:	/ /
If the refrigerator has a solid door, is there a map/guide to where vaccines are stored, located on the door?	☐ Yes ☐ No
Does the power outlet have a sign 'Do not disconnect'?	☐ Yes ☐ No

Monitoring equipment	
Date the battery for the minimum/maximum thermometer(s) was last changed:	/ /
Date the data logger(s) battery was last changed:	/ /
Date and results of checking thermometer accuracy check at 0°C (see Section 6.4: 'How to check the accuracy of a thermometer'):	/ / Result:
Is the minimum/maximum thermometer temperature probe(s) placed correctly?	/ /
Date of last service of data logger(s):	/ /

If using a domestic refrigerator	
Are the vaccines stored in enclosed labelled plastic containers prepared according to these guidelines?	☐ Yes ☐ No

• Is there an appropriate gap between the vaccines and the walls, element, air outlets and a buffer (if necessary) in place?	☐ Yes ☐ No
• Can the refrigerator continue to store the volume of vaccines safely according to these guidelines? (This includes times of increased demand e.g. influenza program). If 'No', what action is being taken?	☐ Yes ☐ No
• If the refrigerator has a freezer, is there a written procedure for regular defrosting?	☐ Yes ☐ No
• Date refrigerator last defrosted:	/ /
• Date refrigerator last logged if no permanent data logger:	/ /
• Are there water bottles and/or ice packs/gel packs in the shelves of the door, drawer and empty shelves?	☐ Yes ☐ No

Alternative vaccine storage

• Is there a readily accessible written procedure for power failure?	☐ Yes ☐ No
• Is there alternative storage (e.g. cooler, other monitored refrigerator) available for vaccine storage, if necessary (e.g. vaccine refrigerator breakdown)?	☐ Yes ☐ No
• Are ice packs/gel packs at the correct temperature available?	☐ Yes ☐ No
• Is there one minimum/maximum thermometer for each cooler?	☐ Yes ☐ No
• Is there enough insulating material for each cooler?	☐ Yes ☐ No

APPENDIX 3:

COLD CHAIN BREACH PROTOCOL

A 'cold chain breach' has occurred if vaccine storage temperatures have been outside the recommended range of +2°C to +8°C. It excludes fluctuations up to +12°C, lasting no longer than 15 minutes, as may occur when stock taking or restocking refrigerators. This poster outlines the cold chain breach protocol and important information to have on hand when reporting a cold chain breach.

Copies of this poster can be ordered from the Immunise Australia website:
www.immunise.health.gov.au

COLD CHAIN BREACH PROTOCOL

1. Immediately isolate the vaccines and label '***Do not use***'.
2. Keep vaccines refrigerated between +2°C and +8°C.
3. Contact your relevant state or territory health department as soon as possible in business hours.
4. Do not discard any vaccine until advised to do so by your state or territory health department.
5. For privately purchased vaccines, contact the manufacturer for advice.

INFORMATION NEEDED WHEN REPORTING A COLD CHAIN BREACH

- Date and time of the breach.
- The type of refrigerator in which the vaccines are stored, i.e. whether a **purpose-built vaccine refrigerator** or **domestic**.
- If using a purpose-built refrigerator, download your data logger to indicate the temperature range during the breach period.
- If using a domestic refrigerator:

- are the vaccines in enclosed plastic containers?
 - are there water bottles in the doors, unused shelves and drawers of the refrigerator?
- Minimum and maximum temperature reading.
- Are cold chain monitors (CCMs) stored with the vaccines? If 'yes', be ready to report the reading when the breach was noticed.
- Has the vaccine refrigerator had any maintenance issues recently?
- Date and time of the last thermometer reset, battery change and accuracy check (domestic refrigerator).
- Length of time the refrigerator temperature was outside +2°C to +8°C.
- Length of time that these problems have been occurring.
- Position of the temperature probe and vaccines in the refrigerator.
- Type and number of vaccines in the current stock.
- Expiry date of the vaccines.
- Have any vaccines been pushed up against the cooling plate or a cold air outlet?
- Are all vaccines in their original packaging?
- What was the cause of the cold chain breach and has it been rectified?
- Has anybody been vaccinated with potentially affected vaccines?
- Have the vaccines previously been exposed to temperatures outside of the +2°C to +8°C range?

APPENDIX 4:

DOMESTIC REFRIGERATORS

DRAWBACKS OF DOMESTIC REFRIGERATORS FOR VACCINE STORAGE

Domestic refrigerators are designed and built for food and drink storage – not for the special temperature needs of vaccines.

For vaccine storage, domestic refrigerators suffer from the following drawbacks:

- The temperature within the different compartments can vary significantly. Every time the door is opened, the temperature fluctuates and temperature recovery is slow.
- The temperature rises during the automatic defrosting cycle in frost-free refrigerators.
- The cabinet temperature is affected by ambient temperature.
- The temperature is set using a dial; this is crude and inaccurate (as there is no digital indication on the refrigerator of set temperature).
- The internal space has several areas that are inappropriate for vaccine storage, including the door, the crisper and areas within 40 mm of the back and sides of the compartment.

For these reasons, domestic refrigerators are not recommended for vaccine storage. If a domestic refrigerator is the only vaccine storage option, it is possible to take steps to reduce the risk of vaccines.

FEATURES TO CONSIDER FOR VACCINE STORAGE

If the only option is to use a domestic refrigerator for vaccine storage, the immunisation service provider needs to ensure the viability of vaccines by diligently adhering to the principles of vaccine storage management.

Domestic refrigerators need to be modified to reduce the risk of adverse vaccine storage events.

There are various types of domestic refrigerators on the market, each with positive and negative features to consider when purchasing a refrigerator to store vaccines.

Do not use bar refrigerators or cyclic defrost domestic refrigerators. Their internal temperatures fluctuate widely due to regular internal heating. Bar refrigerators are susceptible to freezing.

Domestic refrigerators generally have two compartments:

- a main compartment ('the refrigerator') for storing vaccines and diluents, in which the temperature should be kept between +2°C and +8°C. The thermostat is used to adjust the temperature.
- a second compartment ('the freezer') for freezing ice packs/gel packs. If the refrigerator is working properly, this section will be approximately -18°C.

HOLDING CAPACITY OF DOMESTIC REFRIGERATORS

A refrigerator in a health facility should be able to hold:

- A fortnight's/month's (depending on your state or territory's delivery schedule) supply of vaccines and diluents in the refrigerator compartment.
- A reserve stock of vaccines and diluents (an additional 25–50% of a fortnight's/month's supply). This will depend on whether the facility is in a remote location and your state or territory policy. Contact your state or territory health department for details. See contact details on the last page.
- Frozen ice packs/gel packs in the freezer compartment. These will assist in stabilising the temperature in your refrigerator compartment and can also be used in coolers for transporting of vaccines and at time of power failure.
- Bottles of water or unfrozen ice packs/gel packs in the refrigerator to act as a temperature stabiliser buffer to freezing and warming e.g. if there is a power failure (see Figure 6).

It is possible (although complex) to manage domestic refrigerators to reduce the risk to vaccines.



Figure 6: Modification of a domestic refrigerator



Do not store vaccines near fan unit.

Figure 7: Frost-free refrigerator with fan unit for circulation of cold air



Do not store vaccines near cold air outlet.

Figure 8: Frost-free refrigerator with cold air outlets for circulation of cold air

Frost-free refrigerators have low-level warming cycles. They usually have several temperature zones to meet the requirements of different foods. In these refrigerators, the top shelf is not necessarily the coldest part of the unit.

Cold air from the freezer is blown into the refrigerator compartment via either cold air outlets or a fan unit (see figures 7 and 8).

VACCINE STORAGE

If using a domestic refrigerator:

- It is best practice to store the vaccines in their original packaging in enclosed plastic containers (e.g. Tupperware, Décor, Willow or enclosed drawer). Open-weave plastic baskets are an acceptable alternative to enclosed plastic containers (see figure 6).
- Clearly label the containers with name(s) of vaccine(s).
- Do not store vaccines in the door of the refrigerator.
- Store vaccine with the temperature probe in enclosed plastic drawers where there is no pressure on the cord.
- Do not store food, drinks or other goods in the vaccine refrigerator.

Rationale

Enclosed plastic containers will help to stabilise temperatures and provide some protection against blasts of cold air from outlets. A buffer can be used to minimise temperature fluctuations when the container is opened. There are two approaches that can be used:

- a polystyrene strip (e.g. 12–20mm thick) can be glued to the inside or outside of each container, facing the cooling plate/condenser/cold air outlet
- an unfrozen ice pack/gel pack can be placed on edge to be a barrier inside the container.

Storing vaccines against the walls of the refrigerator or near cold air inlets will increase the risk of freezing. Ensure there is space between enclosed plastic containers and the cooling plate.

POINTS TO CONSIDER IF USING A DOMESTIC REFRIGERATOR

KNOWING THE REFRIGERATOR

Refrigerators vary, therefore it is crucial for effective vaccine management that staff '**know the refrigerator**'.

- Where are the cold and warm areas in the refrigerator?
 - What are the temperature variations from top to bottom, front to back and side to side?
 - What happens to the refrigerator temperature in hot and cold weather, or if the air conditioning fails?
 - What happens if there is a lot of use or no use such as holidays and weekends?
- Vaccines need to be protected from cold air blasts in refrigerators that have cold air outlets such as frost-free refrigerators.
 - If planning to modify a refrigerator to ensure safety for vaccine storage, check this will not affect the warranty.
 - Some domestic refrigerators become warmer in hotter weather and colder in cooler weather. Conversely, some domestic refrigerators become colder in hotter weather and warmer in cooler weather.

MONITORING

- Ensure that each vaccine refrigerator has a Celsius minimum/maximum thermometer and a temperature recording chart/log book.
- The minimum/maximum thermometer probe should be placed inside a vaccine package (box and leaflet) once a vial has been used. Label the box as 'empty' so the probe won't be inadvertently moved. The thermometer should be placed inside and near the back of an enclosed plastic container storing vaccines (ensure this is not placed in the coldest part of your refrigerator). The back row of containers should be at least 40 mm from the rear wall.

Rationale

Placing the thermometer probe inside vaccine packaging allows the probe to measure the air temperature closest to a vaccine vial and approximates the temperature of a vaccine. The box and product information provides some further protection from short-term fluctuations e.g. after the door is opened and closed.

THERMAL MASS AND UNUSED SPACE

- Place water bottles or ice packs/gel packs in your freezer.
- Fill the drawers and door with plastic bottles/containers filled with water/salt water. Leave a small space between the bottles/containers.

Rationale

Using cooled water bottles will help stabilise the temperature by increasing the 'cold mass' – that is, it keeps the temperature inside the refrigerator more stable and reduces warming periods when the refrigerator is opened. It is particularly useful if there is a power cut or other refrigerator failure.

The ice packs will also be used for vaccine transport.

Salt water may be used to make the water undrinkable (add about 1–2 tablespoons per litre). This prevents people drinking the water and leaving the bottles empty, affecting the 'cold mass.' Label the bottles 'Contains salt water.' It is important not to judge whether freezing of vaccines has occurred by observing the physical appearance of the vaccines or the water bottles. Even if the water bottles are unfrozen this is not necessarily an indication that the refrigerator temperature has not reached 0°C.

MANAGEMENT OF POWER FAILURE

See Section 8: Management of power failure.

- During a power failure of 4 hours or less the refrigerator door should be kept closed and the refrigerator temperature closely monitored.
- For power failure of more than 4 hours, an alternative means of vaccine storage will need to be used.

APPENDIX 5: FREQUENTLY ASKED QUESTIONS

Q. Why is it important to protect vaccines from hot and cold temperatures?

- A. Most vaccines are destroyed at temperatures of 0°C or below. Some vaccines are also sensitive to high temperatures. Generally, lower temperatures affect vaccine potency more than slightly elevated temperatures.

Q. Who is responsible for cold chain management?

- A. All people who handle vaccines are responsible for maintaining the cold chain. It is recommended that a key person in each facility is nominated to oversee vaccine management, with a back-up person to act in the key person's absence.

Q. How much do vaccines cost?

- A. Individual vaccines can cost up to about \$165 (e.g. privately purchased human papillomavirus (HPV) vaccine). Even a small general practice may store thousands of dollars' worth of vaccines at any one time.

Q. Will I be able to tell if a vaccine has been frozen by looking at it?

- A. No, most vaccines appear normal and can be easily drawn up even after exposure to temperatures below 0°C.

Q. Is the temperature uniform throughout the refrigerator?

- A. No, temperatures vary throughout the refrigerator, even on the one shelf. Some areas of domestic refrigerators can drop below 0°C, particularly near the cooling plate or cold air outlets.

Q. If I have a purpose-built vaccine refrigerator do I still need a minimum/maximum thermometer?

- A. Yes, you need a minimum/maximum thermometer in case you need to place the vaccines into a cool box or check the refrigerator temperature during a power cut or mechanical failure.

Q. If I'm using a domestic refrigerator why do I need to keep vaccines in their original packaging in closed plastic containers?

- A. Closed plastic containers protect the vaccines from temperature fluctuations, e.g. cold air from within the refrigerator and warm air coming in from outside when the door is open. The original packaging protects from damage caused by ultraviolet light.

Q. Why is it preferable to check the minimum/maximum temperatures twice daily rather than just daily?

- A. Recording the refrigerator temperature at the close of business helps to identify the cause if the temperature is outside the recommended range at the start of business the next day.

Q. If I have a data logger why do I need to record the temperatures twice a day on a graph or log book?

- A. Most facilities only download the data from the data logger on a weekly basis. If you are prepared to download and check the data twice daily and keep this data, then you do not need a separate recording chart.

Q. The receptionist is the only person here five days a week. Can he/she read the refrigerator temperature?

- A. Anyone with training on managing the cold chain and vaccine storage can read and record the refrigerator temperature. As long as there are clear policies and procedures for them to follow in the case of a cold chain breach, any staff member may be nominated to read and record the temperatures.

Q. What should I do if my refrigerator temperature recording shows that it was outside the +2°C to +8°C range?

A. See Appendix 3: Cold chain breach protocol, for details of what to do.

Q. The minimum/maximum thermometer says the temperature has been below 0°C but the bottles of water are not frozen. Is the minimum/maximum thermometer accurate?

A. Large bottles of water will take longer to freeze than 0.5mL of a vaccine. (Also see answer above). If you are concerned, check the accuracy of the thermometer (see Section 6.4: How to check the accuracy of a thermometer).

See Appendix 3: Cold chain breach protocol, for details of what to do next.

Q. What do I do if the maximum temperature rises to 11°C degrees for a few minutes when I'm doing a stocktake or restocking?

A. Note the event on the temperature chart and include the reason for the rise in temperature. This is not a cold chain breach and does not need to be reported. Temperature fluctuations of up to 12°C for ≤ 15 minutes require no further action.

Q. What should I do if I am having trouble maintaining my refrigerator temperature?

A. Contact your vaccine refrigerator manufacturer for advice on how to stabilise the temperature. If you are using a domestic refrigerator, see Appendix 4.

Q. Why do I need to check the accuracy of the minimum/maximum thermometer if it reads 1°C?

A. 1°C is very close to 0°C, which is the temperature at which vaccines are damaged. When a thermometer reads 1°C, it is important to check its accuracy in case the actual temperature has dropped to 0°C or below.

Q. The refrigerator temperature keeps going up or is difficult to cool down. What could be the cause of this?

A. Possible causes include:

- power failure or blackout
- refrigerator door left open
- thermometer probe placed in the wrong position (domestic refrigerator)
- refrigerator accidentally turned off or unplugged
- over-filled refrigerator
- refrigerator malfunctioning
- faulty thermostat (domestic refrigerator)
- more than one person adjusting the refrigerator thermostat (domestic refrigerator).

Q. If I have a frost-free refrigerator with cold air outlets, what should I do to protect the vaccines?

A. Store your vaccines in their original packaging in an enclosed plastic container. Glue a strip of polystyrene (12–20 mm) to the area of the container closest to the cooling plate or cold air outlet. Do not use glass or metal containers as they provide less protection against temperature deviations.

Q. Should I cover the front of my glass door vaccine refrigerator on hot days?

A. No, air must be able to circulate around the sides and back of the refrigerator. Never place the refrigerator in direct sunlight or in a hot room. Contact your vaccine refrigerator manufacturer for specific advice for maintaining your vaccine refrigerator temperature on hot days if the room temperature rises significantly.

Q. If temperature monitoring equipment is in place, including thermostat override devices, is there still a need for staff intervention and monitoring of the cold chain?

- A. Yes. Temperature monitoring equipment and thermostat override devices do not guarantee the safety of vaccines and are not a substitute for good vaccine storage management.

Q. I have a purpose-built vaccine refrigerator. What should I do if there is a power cut during business hours?

- A. If your purpose-built vaccine refrigerator has glass doors, the temperature of vaccines stored within it could rise above 8°C within 20–30 minutes of a power failure. If the power is likely to remain off for that period, move the vaccines to alternative storage immediately. See Section 8: Management of power failure.

Q. I have a purpose-built vaccine refrigerator. How do I know what the maximum temperature is when there is no power?

- A. The purpose-built vaccine refrigerator will display the maximum temperature when the power comes back on. Take note of this temperature to report any cold chain breach to your state or territory health department.

Refer to Appendix 3: Cold chain breach protocol, for further details of what to do.

Q. What should I do to stabilise refrigerator temperatures if there is a small volume of vaccines stored in the refrigerator or there is a power failure?

- A. All refrigerators must contain sufficient ‘cold mass’ to maintain a stable temperature. If using a domestic refrigerator, store cooled water bottles in the empty areas (e.g. refrigerator door, any empty shelves and the drawers) to stabilise the temperature. Store your vaccines in their original packaging in an enclosed plastic container and place the thermometer probe inside a vaccine package, inside the container.

When placing more water bottles in the refrigerator, ensure they are filled with cool water to avoid destabilising the vaccine refrigerator environment.

Q. My medical practice has moved to a new location – do I need to do anything?

- A. Yes, you should contact your state or territory health department to inform them of your move and provide your contact details. They will be able to assist you with future cold chain/immunisation queries.

Q. Clients in my practice have been vaccinated with vaccines that have not been stored between +2°C to +8°C. What should I do?

- A. Each state or territory health department has access to the *National Compromised Vaccine Guidelines* and will be able to provide advice to you regarding clients who may require re-vaccination. You should prepare a list of clients who were vaccinated, their date of birth and the vaccines they were administered during this time. Provide this list to your state or territory health department as soon as possible.

APPENDIX 6: TWICE DAILY TEMPERATURE MONITORING CHART FOR REFRIGERATORS STORING VACCINES

Copies of this poster can be ordered from the Immunise Australia website.

VACCINE FRIDGE TEMPERATURE CHART

Year	
Month	

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
record max temp														
+14														
+13														
+12														
+11														
+10														
+9														
+8														
+7														
+6														
+5														
+4														
+3														
+2														
+1														
0														
-1														
-2														
record min temp														
Current temp														
✓ when checked														
Initials														
comments														

APPENDIX 7: QUICK REFERENCE POSTER

Copies of this poster can be ordered from the Immunise Australia website.

STOP

**DO NOT OPEN DOOR UNTIL YOU
KNOW WHICH VACCINES YOU NEED
AND WHERE THEY ARE LOCATED.**

**Vaccines must be stored between +2°C and +8°C
to guarantee their potency.**

Read and record the refrigerator temperature twice daily.

**Report to nominated vaccine manager if refrigerator
temperature has been outside the +2°C to +8°C range.**

**DO NOT USE OR DISCARD VACCINES unless advised to
do so by your state/territory health department.**

Person responsible for vaccine management is: _____

Backup person for vaccine management is: _____

Useful contacts:

_____ is the number for _____ (state/territory health department)

Updated on ____/____/____

ADDITIONAL READING

Australian Immunisation Handbook. 10th Edition.

Provides clinical guidelines for health professionals on the safest and most effective use of vaccines in their practice.

Available on the Immunise Australia website at: www.immunise.health.gov.au

World Health Organization

WHO has a list of specifications at:

www.technet21.org/index.php/documents/77-cold-chain-equipment-and-cold-chain-equipment-management/view-category/Page-2.html

USEFUL CONTACTS

Australian General Practice Accreditation Limited: 1300 362 111

Australian General Practice Accreditation Limited (AGPAL) is a leading provider of accreditation and related quality improvement services to general practices.

www.agpal.com.au

Australian Medicare Local Alliance: (02) 6228 0800

Australian Medicare Local Alliance (AML Alliance) is a new national, government funded not-for-profit company. It has been established to spearhead an organised system for primary health care across the country through a network of 61 primary health care organisations called Medicare Locals (MLs).

www.amlalliance.com.au

Therapeutics Goods Administration: 1800 020 653

The Therapeutics Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods. Product information for all vaccines is freely available on the TGA website.

www.tga.gov.au

Immunise Australia Program: 1800 671 811

The Immunise Australia Program aims to increase national immunisation rates by funding free vaccination programs, administering the Australian Childhood Immunisation register and communicating information about immunisation to the general public and health professionals.

www.immunise.health.gov.au

STATE AND TERRITORY HEALTH DEPARTMENT CONTACT DETAILS

Australian Capital Territory	(02) 6205 2300
New South Wales	1300 066 055 (to connect to the relevant Public Health Unit)
Northern Territory	(08) 8922 8044
Queensland	13 4325 84
South Australia	1300 232 272
Tasmania	1800 671 738
Victoria	1300 882 008
Western Australia	(08) 9388 4868

If an immunisation service provider changes address or contact details, they should contact the relevant state or territory health department to inform them of the move and provide new contact details.



www.immunise.health.gov.au

All information in this publication is correct as at July 2013

10023 July 2013