NATIONAL VACCINE STORAGE GUIDELINES

STRIVE FOR 5

ISBN: 0 642 82750 8

Publications Approval number: 3713

Contents

Acknowledgments

The Department gratefully acknowledges the principal authors (Sandi Grant, Andrew Langley, Karen Peterson, Ann Kempe, Nan Miller, Vicki Bryant, Jennifer Morton), members of the National Immunisation Committee and the many others who provided comment as part of the development of the guidelines.

Dr Neil Hearnden kindly provided an example from his own practice in the Case Study in Appendix 3.

Glossary

Accuracy check	A method used to ascertain the accuracy of a thermometer. This becomes very important if there has been an episode when the refrigerator temperature has been outside the recommended range for storing vaccines (see p 22 for details on 'How to check the accuracy of your thermometer').
Adverse vaccine storage event	A situation when vaccine storage temperatures have gone outside the recommended range of +2°C to +8°C (excludes excursions up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking). In this document an adverse vaccine storage event is often referred to as a 'cold chain breach'.
Ambient temperature	Temperature of the surrounding environment in which the vaccine refrigerator is operating. If there is no air conditioning these temperatures may fluctuate during a day.
Cold chain breach	Vaccine storage temperatures have been outside the recommended range of +2°C to +8°C (excludes excursions up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking). In technical documents a cold chain breach may be referred to as an 'adverse vaccine storage event'.
Cold life	The cold life is the longest time that the vaccine will be able to be stored within the recommended temperature range in a cooler or specialised cold box.
Cold mass	A non-technical explanation for describing the presence of materials (e.g. cooled water bottles) in a refrigerator that will help to maintain cold temperatures, for example, if the power fails or the door has been opened.
Commercial coolant packs	Commercial coolant products, commercial gel-packs and other non-ice coolants.
Cooler	This is a generic term used by department stores to describe Esky™/Willow™ type solid-walled insulated containers.
Cooling plate	A component of a mechanical refrigeration system. The cooling plate is a vessel where high pressure liquid refrigerant vaporises to a gas. Refrigeration of an enclosed space (load) is achieved when liquid refrigerant withdraws heat energy from the load as it changes to a gas. Withdrawal of heat energy is based on the principle of the latent heat of evaporation. The cooling plate is also known as plate evaporator, load heat exchanger, cooling plate and cold plate. It is usually located on the back wall, inside the refrigerator (see Figure 3 p 42).

Data logger	Temperature data loggers are small, electronic devices that measure temperatures and keep a record of the results.
Freezing	In this document 'freezing' refers to 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.
Lagging	Lagging is the process of using specific materials (e.g. fluid or metal) and thickness of materials for the temperature probe so they don't respond to short term fluctuations (e.g. when the refrigerator door is open). This gives a better indication of the actual temperature of the vaccine and prevents the alarm going off unnecessarily.
Outreach clinic	An outreach clinic is defined as an immunisation session that is conducted in another venue away from the main or 'home' immunisation venue. This service would normally last a number of hours and staff would then return to the 'home' venue before the end of the day. An outreach clinic should not be confused with a mobile service which normally spans a number of days and includes travelling longer distances and providing immunisation sessions in a number of different sites.
Purpose-built refrigerators	Refrigerators designed and constructed for a particular purpose e.g. vaccine storage.
Refrigeration	Withdrawal of heat from a chamber to achieve temperatures lower than ambient temperatures.
Thermostat	A device that adjusts the amount of heating and cooling produced and/or distributed by automatically responding to the temperature in the environment.

For further reading see the Proceedings of the National Workshop on Vaccine Storage Management: http://immunise.health.gov.au/vaccinestorage.htm especially for 'Fundamentals of Freezing' and 'Technical Issues with Refrigerators'.

INTRODUCTION

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

This document is aimed at Australian vaccination service providers as a concise, practical, user-friendly guide to vaccine storage. Because of the Australian context and evolution in technology, knowledge and vaccines there are differences to World Health Organization documents and the *Australian Immunisation Handbook 8th Edition 2003*. This document replaces *Keep it Cool (2nd Edition 2001)*.

This document outlines the basic principles for safe vaccine management. The technology for vaccine storage is changing rapidly. If you are purchasing equipment it is recommended that you thoroughly investigate the item. The material in this document may help you with your investigations. For further information contact your state or territory health department.

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

WHAT'S NEW?

- It is recommended that vaccines are stored in a purpose-built vaccine refrigerator.
- Bar refrigerators are not recommended for vaccine storage.
- Management of storing vaccines in a domestic refrigerator has changed. Vaccines are at greater risk in domestic refrigerators. Therefore, modifications and a diligent management plan are essential.
- With rapidly changing technology in refrigeration it is not possible to give generalised statements on management that apply to all refrigerators. There are, however, general recommended guidelines on managing vaccines. It is crucial that you 'know your refrigerator'.
- Recommendation for workplace policies and procedures for vaccine management.
- Emphasis on all people involved in transporting, storing and administering vaccines to be trained in vaccine management to ensure the vaccine remains effective and potent.
- Self-audits (at least 12 monthly) of refrigerators storing vaccine are recommended.
- Increased emphasis on timely reporting of refrigerator temperatures outside of +2°C to +8°C to your state or territory health department.
- Advice about frequency of recording vaccine storage temperature has changed.
- Changes to guidelines on use of ice packs/gel packs and monitoring vaccines in coolers and cold boxes.

Why are we concerned about vaccine storage management?

1. As health professionals we need to ensure people receive an effective health product (i.e. a vaccine that has not been adversely affected by heat or cold).
2. It is important to carefully manage resources. Vaccines are expensive (privately purchased conjugate pneumococcal vaccine can cost up to $180) and can be in short supply.
3. It is professionally unacceptable as well as uncomfortable to be in a position where you have to inform people that they or their child may have received ineffective vaccine and will require revaccination. Cold chain breaches can occur even in well-designed and well-managed systems as a result of technical malfunctions but if there are good procedures in place, problems will be detected and effectively managed before ineffective vaccine is used.
4. Efficient vaccine storage management is a good quality assurance measure of a vaccine service provider.

Vaccines must be stored and transported within the recommended temperature range of +2°C to +8°C at all times.

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, moves through to the state or territory vaccine distribution centres and ends when the vaccine is administered.

Vaccines must be stored and transported at all times within the recommended temperature range of +2°C to +8°C

How sensitive are vaccines to heat and cold?

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

- Frozen;
- Allowed to get too hot; and
- Exposed to direct sunlight or fluorescent light.

Freezing of vaccine is the most common reason for vaccine damage and loss in Australia.

In this document 'freezing' refers to a situation where vaccines experience temperatures at or below 0°C. Vaccines may not appear frozen but may have been damaged at these temperatures. Most vaccines are considered to be damaged at 0°C.

Most vaccines are considered to be damaged at 0°C.

For vaccines that are cold or freeze-sensitive, the loss of potency following freezing is immediate and these vaccines must not be administered.

When vaccines are exposed to repeated episodes of heat the loss of vaccine potency is cumulative and cannot be reversed.

Basic principles of vaccine storage management

Objective

Keep all vaccines in the range +2°C to +8°C. 'Strive for 5!' as this gives a greater leeway for protection from temperature fluctuations.

'Strive for 5!' as this gives a greater leeway for protection from temperature fluctuation.

Process

- Simple, routine processes need to be established. Processes should be designed to be easily maintained.
- Establish written protocols for your vaccination service (templates may be available from your state or territory health department or local Division of General Practice). Accreditation of your practice may require a written protocol. Protocols need to include:
  - Monitoring and recording of the vaccine refrigerator according to the recommendations in these guidelines.
  - Ordering and receiving vaccines.
  - Rotating stock so that vaccines with the shortest expiry date are used first.
  - How to calculate vaccine requirements taking into account national guidelines for safe storage.
  - Storage of vaccines, diluents and ice packs/gel packs.
  - Monitoring and adjusting of equipment e.g. data logger, thermometer, thermostat.
  - Equipment maintenance: including changing of thermometer batteries, checking the accuracy of the thermometer, defrosting and cleaning of the refrigerator.

- 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 handling vaccines (if there are any interventions taken to maintain the cold chain e.g. adjustment of the thermostat).
- Ongoing education of staff on vaccine management, including orientation of new staff.
- How to manage a power failure.
- How to pack a cooler (e.g. Esky™, Willow™, Coleman™) and condition the ice packs/gel packs.

- The system and the vaccine storage records are reviewed at least annually e.g. through an audit, self-audit, peer review system or accreditation process.
- Retain documentation of vaccine temperature recordings according to your state or territory health department policy or your medico-legal and statutory requirements.

Equipment

- Have a refrigerator that has the capacity to store your maximum vaccine storage needs (including influenza season).
- Have reliable, regularly maintained/serviced equipment.
- All domestic refrigerators vary, therefore it's crucial for safe vaccine management that you 'know your refrigerator':
  - Where are the cold and warm areas in your 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?
- Ensure your thermometer measures temperatures in Celsius not Fahrenheit (confusion does occur!).
- Do a check on the accuracy of your thermometer at least every 12 months using the process outlined in 'How to check the accuracy of your thermometer' (see p 22).
- Change thermometer battery at least every 12 months or as indicated by the manufacturer.

'Know your refrigerator'

It's crucial for safe vaccine management.

- Have a temperature monitoring chart for each vaccine refrigerator. Check with your state or territory health department or your local division for details on how to obtain a supply.
- Place a sticker on the refrigerator and power point—'Vaccine Refrigerator', 'Do not turn off or disconnect'.
- To secure the power point you may consider installing a device or having your refrigerator 'wired in' so your refrigerator cannot be accidentally unplugged.
- Keep refrigerator door openings to a minimum.
- Do not store food and other goods in the refrigerator.
- A thermostat override device is no substitute for good refrigerator management and should not be used.
- Check that any alterations to a refrigerator will not void your warranty.
- Data loggers are not essential but may be useful in mapping 'cold spots' in your refrigerator or investigating problems (see Appendix 6 p 49).

Do not store food and other goods in the refrigerator.

People

- All people handling vaccines need to receive education on how to manage them so the vaccines remain safe and effective. This involves all staff members whose roles may affect safe vaccine storage at any stage.
- Have a trained, designated person responsible for vaccine storage and implementation of protocols.
- Have a trained nominated backup person(s) available to relieve the designated person when required.

It is important that people handling vaccines understand the reason behind what they are doing and why they are doing it!

Checklist for vaccine storage

1. Reliable and stable refrigerator with adequate capacity.
2. Accurate and reliable temperature monitoring equipment.
3. Written process for monitoring and recording temperatures.
4. Temperature probe is placed appropriately.
5. Education and information for everyone handling vaccines (ensure this includes new staff and reception staff).
6. Maintenance schedule for temperature monitoring equipment, checking the accuracy of the thermometer and changing the batteries.
7. Written process for dealing promptly with a cold chain breach (include identification, response procedures, documentation and recording, prevention of recurrence).
8. Written process for ordering and rotating stock.
9. Written process for receiving vaccine.
10. Written process for managing a power failure (e.g. having an alternative storage such as an Esky™ with ice packs/gel packs).

REFRIGERATORS FOR VACCINE STORAGE

Introduction

Domestic refrigerators are designed and built for food and drink storage—not for the special temperature needs of vaccines. They are designed to meet the temperature requirements of fresh and frozen foods, they generally do not have particularly accurate temperature controlling systems, and can have significant temperature variation within the one compartment.

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

- Temperature varies significantly every time the door is opened.
- Temperature rises during defrosting cycle in cyclic defrost and frost-free refrigerators.
- Cabinet temperature is easily affected by ambient temperature.
- Temperature setting using a dial is crude and inaccurate (as there is no digital indication of set temperature).

For these reasons, domestic refrigerators are not recommended for vaccine storage.

Domestic refrigerators are not recommended for vaccine storage.

However, if the only alternative is to use a domestic refrigerator for vaccine storage, the following information is provided.

Domestic refrigerators

Modification of domestic refrigerators is necessary to reduce the risk of adverse vaccine storage events.

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There are various types of domestic refrigerators on the market. All types have some positive and negative features that will need to be considered when using a refrigerator to store vaccines.

Cyclic defrost (see p 48) and **bar refrigerators are not recommended** because they produce wide fluctuations in the internal temperatures, with regular internal heating.

Frost-free refrigerators (see p 47) do not have heating cycles but 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.

Bar refrigerators are unsuitable for storing vaccines and should not be used!

Bar refrigerators, in particular, **are strongly not recommended** because of the risk of freezing, temperature instability and susceptibility to ambient temperatures.

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.

Refrigerators have different capacities for storing vaccines and for freezing and storing ice packs/gel packs. A refrigerator in a health facility should be able to hold:

- A one-month supply of vaccines and diluents in the refrigerator compartment.
- Have a reserve stock of vaccines and diluents (an additional 25% to 50% of a one-month supply). This will depend on whether you are in a remote location and your state or territory policy. Contact your state or territory health department for details.
- Frozen ice packs/gel packs in the freezer compartment (will assist in stabilising the temperature in your refrigerator compartment).
- Bottles of water or unfrozen ice packs/gel packs in the refrigerator (to act as a buffer to freezing and warming e.g. if there is a power failure) (see Figure 1 p 17).

Domestic refrigerators are unsuitable for vaccine storage if the vaccine service provider does not have appropriate vaccine storage procedures that are diligently undertaken.

Domestic refrigerators are unsuitable for vaccine storage if the vaccine service provider does not have appropriate vaccine storage procedures that are diligently undertaken to ensure that vaccines are stored safely.

Use of domestic refrigerators for vaccine storage

Storing vaccines

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

If you already have an existing vaccine refrigerator in use the following criteria should be met:

- The refrigerator is used exclusively for the storage of vaccines.
- The refrigerator maintains temperatures without fluctuating into the danger zones (<+2°C, >+8°C).
- The refrigerator is reliable and has not required repairs over the last two years.
- The refrigerator is free of any water or coolant leaks.
- The refrigerator compressor is quiet (a noisy or audible compressor may require attention).
- The seals are in good condition and are sealing tightly.
- The door of the refrigerator closes properly (ensure you comply with the manufacturer's directions about the refrigerator being level).
- The refrigerator is an adequate size for the clinic/practice storage needs.
- Staff have relevant knowledge about storing vaccines which is detailed in a written protocol.

If you cannot meet all these criteria you should consider a replacement purpose-built vaccine refrigerator.

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

Do not store food and other goods in the refrigerator.

Consider a replacement purpose-built refrigerator.

Using your domestic refrigerator for vaccine storage

Step 1:

Ensure the refrigerator is placed out of direct sunlight and the manufacturer's instructions for air circulation around the back and sides are followed. Be aware of seasonal changes in the room temperature that may affect the temperature of the refrigerator. Ensure the vaccine refrigerator is in a secure area accessible to staff only.

Step 1: *Place the refrigerator out of direct sunlight.*

Rationale:

Some refrigerators need to have clearance at the sides and back to prevent heat build up. Manufacturers usually provide recommendations regarding the clearance required. Placing the refrigerator in direct sunlight or near heat sources (e.g. a hot water service or warm external wall) increases the potential for higher temperatures and requires the refrigerator to work harder. The vaccine refrigerator should be placed in a secure area to minimise the risk of unnecessary door opening, power being switched off at the power point and tampering with stock.

Step 2:

Mark the power source clearly so the refrigerator is not unplugged or turned off accidentally.

Ensure the power source is marked clearly in a way to prevent the refrigerator from being accidentally unplugged or turned off.

Rationale:

Accidental disconnection from the power source can cause heat damage to vaccines, particularly if unnoticed for a long period. 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 a lockable switch. Check your hardware store for the availability of devices to prevent unplugging or turning off the refrigerator at the power point.

Step 3:

Place water bottles or ice packs/gel packs in your freezer.

Place water bottles or ice packs/gel packs in your freezer.

Rationale:

This will assist in stabilising the temperature in your refrigerator compartment as in most frost-free refrigerators cold air is distributed from the freezer to the fresh food compartment. This will also help to stabilise freezer temperatures and 'on-off' cycling of the refrigerator as well as being available for vaccine transport.

Step 4:

Fill the lower drawers and the door with plastic water bottles/ containers.

Fill the lower drawers and the door with plastic bottles/containers filled with water. Leave a small space between the bottles/containers. If you are not storing many vaccines you can help maintain temperature stability by placing cooled water bottles on unused shelves.

Rationale:

Domestic refrigerators often present a risk to vaccines due to the 'cold' spots.

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 cause of refrigerator failure.

- 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 an indication that temperatures have not reached 0°C.

Frozen or damaged vaccine may not appear solid or changed in appearance.

Step 5:

Know your vaccine refrigerator by recording temperatures throughout the refrigerator. The key areas to monitor are on each shelf from top to bottom, front to back and side to side. The recording device (data logger/thermometer probe) needs to be left in each position for a minimum of 24 hours. The coldest area is often near a cold air outlet or the cooling plate.

Step 5: *'Know your vaccine refrigerator' by monitoring and recording the temperatures throughout the refrigerator.*

Rationale:

In some refrigerators the coldest area is the top shelf, or the front of the bottom shelf. However this is not necessarily true of all refrigerators as all models differ—even those from the same manufacturer. The coldest area is often near a cold air outlet or the cooling plate.

It is important that 'cold spots' are identified by detailed monitoring throughout the refrigerator. This can be done by placing data loggers (see Appendix 6 p 49 for information on data loggers) or temperature probe(s) in all areas of the refrigerator noting the different temperatures before commencing vaccine storage. The minimum time for monitoring in each position is 24 hours. This will capture all the fluctuations that occur in domestic refrigerators. Depending on the type and number of monitors you have access to, comprehensive monitoring of your refrigerator may take some time to complete. While assessing the 'cold spots', it is recommended to use some type of 'cold mass' to imitate a batch of vaccine (e.g. cooled water bottles) as refrigerators behave differently when empty. Your state or territory health department or local division of general practice may be able to assist with logging your refrigerator.

You need to be aware of how to manage a refrigerator effectively i.e. where the air vents are (see p 47), and how to adjust the thermostat.

Step 6:
Modify and stabilise the temperature of the vaccine refrigerator before stocking with vaccine.

Step 7:
Store vaccines in their original packaging in labelled, enclosed plastic containers.

Vaccines must never be stored in the door of the refrigerator.

Storing vaccines in their original packaging, in enclosed plastic containers, helps to protect them from temperature fluctuations.

Step 6:

Modify and stabilise the temperature of the vaccine refrigerator before stocking with vaccine.

Rationale:

The refrigerator temperature needs to be stabilised before using for vaccine storage. This will minimise the effect of temperature variations on vaccine.

Step 7:

Store the vaccines in enclosed plastic containers, in their original packaging (e.g. Tupperware™, Decor™, Willow™ or enclosed drawer). Label containers clearly with name(s) of vaccine(s).

Do not crowd the vaccines by overfilling the shelves. Allow space between containers for air circulation. Have a protective barrier (e.g. polystyrene strip/unfrozen ice pack/gel pack) for each container (see 'Rationale'). Ensure a gap of at least 4cm from all refrigerator walls, including the back. If using tightly sealed enclosed plastic containers (e.g. Tupperware™, Decor™, Willow™) you will need to create an opening or gap to avoid damage to the temperature probe cord. Alternatively store vaccine with the temperature probe in enclosed plastic drawers where there is no pressure on the cord. **Vaccines must never be** stored in the door of the refrigerator.

Rationale:

Storage of vaccines in labelled enclosed plastic containers allows easy identification of vaccines and minimises the time spent with the door opened searching for vaccines. Time spent searching can also be reduced by having a basic map of vaccine locations on the outside of the refrigerator door so people can go 'straight' to the vaccine when the door is opened.

Enclosed plastic containers will help to stabilise temperatures a little and provide some protection in borderline freezing episodes as well as against effects from the cooling plate and blasts of cold air from outlets. A buffer such as a small unfrozen ice pack/gel pack will add 'cold mass' and therefore minimise temperature fluctuations when the container is opened to access vaccines. There are two approaches that can be used:

- A polystyrene strip (e.g. 12–20mm thick) glued to the inside or outside of each container, on the side which is facing the cooling plate/condenser/cold air outlet. This will provide further protection for vaccines.
- An unfrozen ice pack/gel pack can be placed on edge to be a barrier inside the container. This will have the further advantage of providing 'cold mass' within the container to help stabilise temperatures.

Both of these approaches can be combined if you are storing a small quantity of vaccine and/or you have unstable refrigerator temperatures.

Air circulation between enclosed plastic containers is necessary to maintain a more constant ambient temperature.

Storage of vaccine against refrigerator walls increases the risk of freezing. It is necessary to ensure a space between enclosed plastic containers and the cooling plate. The same applies in refrigerators where streams of cold air are used to lower temperatures (typically in frost-free models); vaccines near any air vent (which can often be a duct at the rear or from overhead) are at risk of freezing. Therefore a barrier may protect these vaccines also.

Overstocking of vaccine will place all vaccines at risk as cold air circulation will be impeded and consistent, stable temperatures throughout the refrigerator will be difficult to achieve.

Safe storage capacity will be reduced when using enclosed plastic containers. Is your refrigerator big enough for your needs?

Do not overstock your refrigerator with vaccines.

Step 8:

Place freeze-tolerant vaccines in the shelves identified as being the coldest and freeze-sensitive vaccines on shelves identified as having more stable temperatures (e.g. no 'cold spots'). Knowing this will depend on identification of the coldest areas in your vaccine refrigerator (see Step 5 p 11).

Step 8:
Place freeze-sensitive vaccines on shelves with stable temperatures. Place freeze-tolerant vaccines on shelves identified as being the coldest.

Rationale:

Measles, Mumps, Rubella, OPV and Tuberculosis (BCG) vaccine will not be affected by temperatures less than 0°C. Freeze-sensitive vaccines (DTPa containing vaccines; Hib, Pneumococcal, Influenza, Hepatitis, Polio (inactivated—IPV) and some Varicella vaccines) are better placed on the shelves where the temperature is more stable. The lower drawers and the door get too warm for safe vaccine storage and are best used to store cooled water bottles to provide 'cold mass' to stabilise temperatures.

Step 9:

Ensure that each domestic refrigerator storing vaccine has a Celsius digital minimum/maximum thermometer and a temperature recording chart.

Step 9:
It is essential that each domestic refrigerator storing vaccine has a Celsius digital minimum/maximum thermometer and a temperature recording chart.

Rationale:

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. Check with your state or territory health department or your local division for details on how to obtain a supply.

Note: Thermometers need to be accurate—check the accuracy and change the battery at least every 12 months or as specified by the manufacturer (see 'How to check the accuracy of your thermometer' p 22).

Thermometers need to be accurate.

Check the accuracy and change the battery at least every 12 months or as specified by the manufacturer.

Step 10: *Place the digital minimum/ maximum thermometer probe inside a vaccine box in a container storing freeze-sensitive vaccines.*

Step 11: *Check and record temperatures at least daily, before the vaccine is used.*

Step 10:

The thermometer probe should be placed:

- inside vaccine packaging (box and leaflet) once a vial has been used;
- inside and near the back of an enclosed plastic container (storing freeze-sensitive vaccines); and
- avoid putting this container in the coldest part of the refrigerator.

Rationale:

Placing the thermometer probe inside vaccine packaging (the box and leaflet) allows the probe to measure the air temperature closest to where a vaccine vial would be and simulates vaccine temperature. The box and leaflet (product information) provide some further protection from very short term fluctuations e.g. after the door is opened and closed. An empty box with the product information is used so that the probe does not get misplaced when vials are used. Label the box as 'empty' so the probe won't be inadvertently moved.

Step 11:

Check and record minimum/maximum temperatures at least daily, before the vaccine is used.

Rationale:

Daily temperature recording is a minimum requirement but it is highly desirable to check refrigerator temperatures twice daily (at the beginning and end of each day). Checking and recording the temperatures before using vaccine enables the identification of problems before vaccine (which may be damaged) is given. Twice daily temperature checks will give you a better indication of any problems in your 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. The temperature needs to be read and recorded:

- on receipt of vaccines;
- every day before vaccination commences (and, ideally at the end of the working day);
- last thing Friday afternoon and first thing Monday, if the centre closes over the weekend; and
- during outreach clinics the minimum/maximum temperature should be monitored hourly.

It is assumed that many clinics/practices don't operate seven days a week: temperature recording does not need to be done on the days the practice is closed providing the minimum/maximum temperatures are monitored and recorded before commencing vaccination.

Step 12:

Keep the **door closed** as much as possible. Vaccine refrigerators should have a sticker to remind staff to keep door opening to a minimum.

Rationale:
Reducing door opening helps to keep internal temperatures stable.

Step 12:
Keep refrigerator door openings to a minimum.

Step 13:

Ensure that one person is responsible for adjusting refrigerator controls but that all staff are appropriately trained to ensure continuous monitoring.

Rationale:
There should be one key person in each facility who is responsible for cold chain management to enable consistency. However other relevant staff should be trained to ensure that continuous monitoring is maintained. All clinics/practices should have documented protocols and procedures and regular education or training sessions to ensure staff awareness.

Step 13:
Only one person should be responsible for adjusting the refrigerator controls.

Step 14:

Establish and document protocols for response to cold chain breaches.

Rationale:
In order to ensure that effective vaccine is administered it is important to promptly identify and manage cold chain breaches. This will minimise the risk of ineffective vaccine being administered, resulting in recall for revaccination. All staff need to be aware of these protocols.

Step 14:
Establish protocols for cold chain breaches.

Step 15:

A vaccine storage self-audit should be undertaken by the clinic/practice at least every twelve months. Perform it more frequently if you are experiencing cold chain problems (see 'Vaccine Storage Self-Audit tool' Appendix 1 p 36–38).

Rationale:
It is important to self-audit your vaccine refrigerator as part of a routine quality assurance and risk management process. It also enables you to have confidence that you are administering safe and effective vaccines.

Step 15:
Complete a vaccine storage audit at least every 12 months.

Ordering vaccine

Keep vaccine stock to a minimum by regularly ordering only the quantity of vaccine required for the period until the next delivery. Rotate stock so vaccines with the shortest expiry date are used first.

Rotate stock so vaccines with the shortest expiry date are used first.

The following formula can be applied when ordering vaccines for a clinic/practice.

Quantity required (i.e. quantity used in last period) ***minus*** the amount left over from last period ***plus*** 10% of quantity used in the last period (buffer or reserve stock). Contact your relevant state or territory vaccine distribution centre about its policy for ordering vaccines before using this formula.

Example:

30 DTPa (quantity used last period) ***minus*** 5 DTPa (amount still in the refrigerator) ***plus*** 3 DTPa (10% of quantity used in the last period). Quantity required is 28 DTPa.

Ensure your refrigerator is in good working order.

Maintenance of the vaccine refrigerator

- Report breakdowns immediately and arrange for alternative monitored storage for vaccines while the refrigerator is repaired.
- Regularly check the refrigerator seals to ensure a good seal is maintained. Replace the seals if they are damaged or cold air is leaking from the refrigerator.
- Defrost refrigerator regularly, if required, to prevent build-up of ice which will result in unstable temperatures. Regular defrosting also aids in the efficient functioning of your refrigerator.
- If there are exposed coils on the back of the refrigerator keep them clean and dust free to improve operating efficiency.

Defrosting or cleaning

When defrosting or 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 cooler (see cooler section on p 28–30 for packing guidelines).

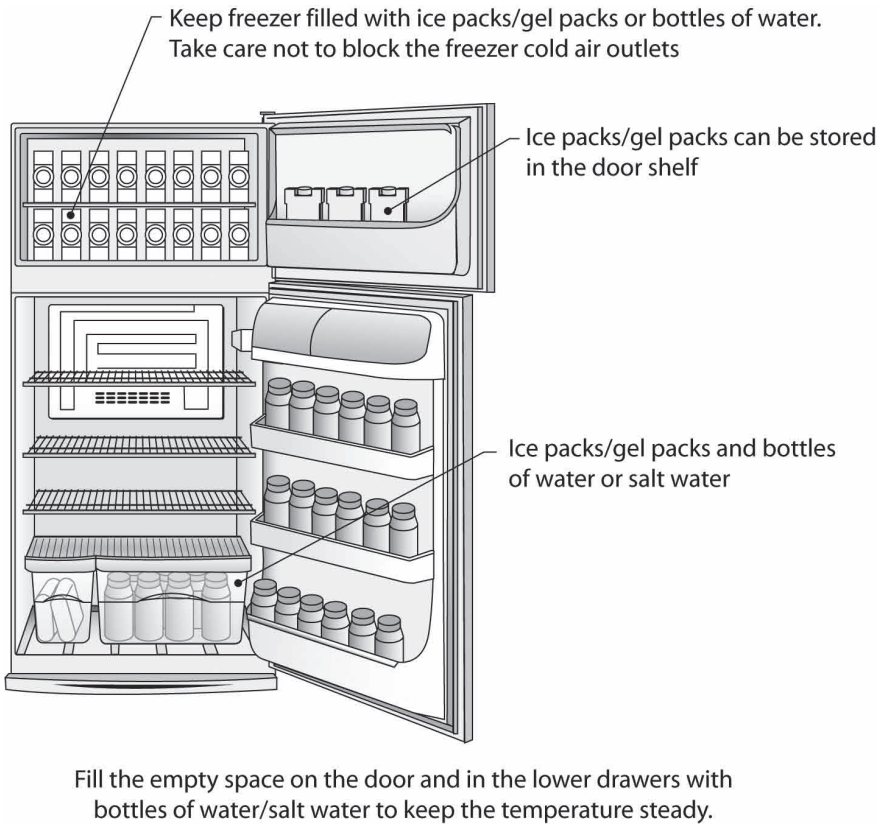

Figure 1: Modification of a domestic refrigerator

Further points to consider if using a domestic refrigerator

Purpose-built refrigerators are recommended for safe storage of vaccine. Bar refrigerators are unsuitable and should not be used to store vaccine.

Bar refrigerators are unsuitable for storing vaccines and should not be used.

1. The refrigerator (see p 47–48)

- The refrigerator needs to have a separate freezing compartment.
- Vaccines need to be protected from cold air blasts in refrigerators that have cold air outlets such as frost-free refrigerators.
- Vaccines need to be protected from the cooling plate (usually on the inside back wall) if you have a cyclic defrost refrigerator.

- The refrigerator needs to have the capacity required to store vaccines safely, including busy times such as pre-winter influenza programs. Using enclosed plastic containers will reduce the storage capacity.
- If outreach clinics are conducted the refrigerator needs to have a freezer big enough to freeze sufficient ice packs/gel packs.
- Consider back up service including costs of delivery, maintenance and repairs.
- If you plan to modify your refrigerator to ensure safety for vaccine storage, check this will not affect the warranty.
- Consider energy efficiency.

Warning
Refrigerator temperatures fluctuate seasonally and vaccines can be at increased risk of freezing, especially during cold snaps.

2. Placement of the vaccine refrigerator

- Avoid placing the refrigerator against an outside wall, which can be subject to hot and cold temperatures as the weather changes.
- The room ideally needs to be insulated if there are extremes of room temperatures.
- Many refrigerators become warmer in hotter weather and colder in cooler weather but some refrigerators become colder in hotter weather and warmer in cooler weather. If there are wide fluctuations in climatic conditions an air conditioning system is important. Be aware of what happens when the air conditioning is turned off overnight, and on weekends and holidays.
- Ensure sufficient ventilation space around the refrigerator.

3. Power source reliability

- Consider the use of a back-up generator if there are regular power blackouts or interruption to supply.
- Consider alarming the refrigerator.
- Make sure the refrigerator cannot be inadvertently unplugged (see Step 2 p 10).

4. Training

- Ensure education and training for those who monitor the refrigerator and manage the vaccines.
- Where people performing maintenance on refrigerators storing vaccines are employed in your organisation, ensure they receive education and training.

PURPOSE-BUILT VACCINE REFRIGERATORS

The main features of purpose-built vaccine refrigerators are:

- A stable, uniform, and controlled cabinet temperature unaffected by ambient temperature.
- Defrost cycle allowing defrosting without rises in cabinet temperature.
- Standard alarm and safety features alert and/or prevent irregular temperature fluctuations in cabinet.

Advantages of having a purpose-built vaccine refrigerator

- Management of a purpose-built refrigerator is less demanding than a domestic refrigerator.
- After programming, all temperatures within the refrigerator are maintained in the +2°C to +8°C range. This minimises the risk of vaccines being stored outside the recommended temperature range.
- Good temperature recovery e.g. when the refrigerator has been opened to access vaccines.
- Nearly all of the internal space can be used for storing vaccines (check with the manufacturer about how to pack the maximum amount of vaccine and suitability of storing vaccines on the floor of the refrigerator). Therefore, the size of the purpose-built vaccine refrigerator may be smaller than your previous domestic refrigerator.
- Storage of other temperature sensitive medical products e.g. pharmaceuticals stored between +2°C to +8°C is acceptable in a vaccine storage refrigerator.

Management of a purpose-built refrigerator is less demanding than a domestic refrigerator.

In a purpose-built refrigerator nearly all of the internal space can be used for storing vaccines.

The following points should be considered when purchasing a purpose-built vaccine refrigerator.

Questions to ask yourself

- How big does my refrigerator need to be? What is the maximum amount of vaccine I need to store, particularly during special programs such as the influenza program?
- Do I have the space in my clinic/practice for this size refrigerator?
- If the service does outreach clinics, do I need to consider ice pack/gel pack freezing capacity?
- If I do not buy a purpose-built vaccine refrigerator what are the risks to my clients and what is my legal risk?
- Where will the refrigerator be placed? If it is against an outside wall it may be hotter in summer and potentially affect the performance of the equipment.

How to choose a purpose-built vaccine refrigerator

Some parts of the section 'Further points to consider if using a domestic refrigerator' (see p 17) will be relevant.
Also consider:

Are you getting good value for your money?

Is it really a vaccine refrigerator?

Will it deliver what you expect? Ask questions!

1. Capacity for having an alarm system. Alarm systems have various options e.g. capacity to notify someone remotely, by automatic telephone dialing, or a central area that is staffed 24 hours a day. Choose the alarm system which best suits your needs.
2. Does it have a 'door left open' alarm?
3. The temperature recording system may be visual, or chart form. Ensure the temperature can be easily read and accessed e.g. some refrigerators have the chart recording system placed at the bottom of the refrigerator.
4. Does it have an easy to use minimum/maximum temperature display feature?
5. Does the temperature probe have appropriate temperature lagging (see glossary) device?
6. Does it need enhancements (e.g. alarms, temperature monitoring features) and what do these cost?
7. If purchasing enhancements ensure they are easy to use.
8. Warranty: What are the conditions and duration? Will modifications to the refrigerator void the warranty?
9. Back up support and servicing varies from company to company. Determine availability and cost.
10. Does the supplier/manufacturer have quality assurance processes?
11. What size space do you have for the refrigerator?
12. Can the refrigerator record how long the unit has been without power?
13. How long will it stay within the recommended temperature range if there's a power failure (do you need to add 'cold mass' e.g. cooled water bottles)?

Issues to note

- Even though there is more usable space it is important not to overstock your purpose-built vaccine refrigerator. You need to discuss the usual and maximum level of stock you can hold in your purpose-built vaccine refrigerator with the manufacturer. Your state or territory health department may be able to help you calculate your maximum storage needs.
- If you are storing very small amounts of vaccine in a purpose-built vaccine refrigerator check with the manufacturer if you need to add more 'cold mass' (i.e. cooled water bottles) to the refrigerator.
- The placement of the purpose-built vaccine refrigerator in the clinic/practice is very important, refer to the refrigerator company for advice. The space around the purpose-built vaccine refrigerator is determined by the manufacturer's recommendations and must be applied during installation.
- Vaccines can be stored in shallow plastic baskets/trays clearly labelled with the name(s) of vaccine(s). It is not necessary to use enclosed plastic containers as the purpose-built vaccine refrigerator has constant temperature control. Do not crowd the vaccines by overfilling the shelves. Allow space between baskets/trays for air circulation.
- Cool the vaccine refrigerator before stocking with vaccine.
- Even with vaccine purpose-built refrigerators, temperatures need to be monitored and recorded at least daily, before vaccine is used (see Step 11 page 14).
- If you have any concerns setting up your new purpose-built vaccine refrigerator contact the service technician.
- Depending on the quality and design of your purpose-built vaccine refrigerator, it may warm quickly during a power failure. Always have an alternative means of vaccine storage available.
- Purpose-built refrigerators with glass doors may not have ultraviolet (UV) filtering. This is another reason why vaccines must be stored in their original packaging to protect them from the light.

Your state or territory health department, Public Health Unit or Division of General Practice may have a list of current purpose-built vaccine refrigerator suppliers in your state or territory.

Depending on the quality and design of your purpose-built vaccine refrigerator, it may warm quickly during a power failure.

Be aware of light sensitive vaccines (most vaccines are sensitive to any form of UV light, including fluorescent light).

MONITORS

Thermometers

A minimum/ maximum thermometer is an essential requirement for temperature monitoring.

A minimum/maximum digital thermometer is an essential requirement for temperature monitoring. The most common types used for refrigerators are dial and digital. The minimum/maximum thermometer must be reset regularly (i.e. at least daily, on work days) for meaningful temperature recording. Ensure you choose a thermometer that reads Celsius. Different models of minimum/maximum thermometers may vary in accuracy. They also require annual checks to ensure accurate measurement, as flat batteries or a damaged probe or cable can affect readings. You can check the accuracy of a minimum/maximum thermometer by performing the following steps:

Check the accuracy of your thermometer and change the battery at least every 12 months.

'How to check the accuracy of your thermometer'

1. Two-thirds fill a polystyrene or plastic cup with cold water. Place 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). Using this method the mixture is 0°C if ice is present. Place the temperature probe into the middle of the container (be careful not to let the probe touch the container).
2. Observe the temperature on the display screen at 2 minutes.

Rationale:

The temperature will drop quickly at first and then more slowly. The temperature should drop to 0°C within 2 minutes.

An 'acceptable' degree of accuracy of a thermometer can vary e.g. to within ±1°C. Even if your thermometer is considered 'accurate' this check could result in the display screen showing three possible readings: +1°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°C to +8°C. Check with the organisation who supplies your thermometer about the expected degree of accuracy.

The thermometer needs to be accurate to ±1°C or better. If your 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 and at least every 12 months for auditing purposes, or if you are having cold chain problems.

Temperature Chart Recording Systems

Temperature chart recording systems can record temperatures over a long period of time as well as providing 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 this may void your warranty.

Data loggers

Data loggers can be used in audits and to enable you to 'know your refrigerator' by recording patterns of temperatures over time. Loggers use a similar measuring principle to chart recorders but record the data electronically. The data can be stored by the monitoring system and can be downloaded. Daily minimum/maximum temperatures still need to be manually recorded as a timely alert to any breach in the cold chain. If using a data logger for routine temperature monitoring (i.e. instead of a minimum/maximum thermometer) it must have a visual display of minimum/maximum temperatures to allow daily real time recordings to be read (see Appendix 6 for further information on data loggers).

Daily minimum/ maximum temperatures still need to be recorded manually as a timely alert to any breach in the cold chain.

Cold chain monitors

Cold chain monitors (CCMs) should accompany all vaccines during transport. If CCMs are placed with vaccine deliveries, they should be checked for colour change and the temperature recorded when the vaccine order arrives at the clinic.

Dual time-temperature indicators are a type of cold chain monitor and work by showing colour change on the indicator strip so the duration of time the temperature exceeds a set threshold can be estimated. Examples of dual time-temperature indicators are WarmMark™ and MonitorMark™.

Freeze indicators have colour bulbs that release a dye at the threshold temperature at or below 0°C. There are different models available in Australia from a variety of manufacturers: Freeze Watch™, ColdMark™. In Australia models that activate at 0°C are recommended.

Combined Indicators: Stop!Watch™: this monitor combines a dual time-temperature indicator (MonitorMark™) with a freeze indicator (Freeze Watch™ activated at 0°C).

In Australia freeze indicators that activate at 0°C are recommended.

CARING FOR YOUR VACCINES DURING IMMUNISATION SESSIONS

Key issues

Store the diluents with the vaccine.

- Do not use diluents warmer than the vaccine as they can affect the potency of live vaccines (e.g. using a diluent for reconstitution that is warmer than a freeze-dried preparation, such as MMR, can affect the potency of the vaccine).
- Be aware of light sensitive vaccines (most vaccines are sensitive to any form of UV light including fluorescent light).
- Keep refrigerator door/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 reconstituted, and staff must handle many types of vaccines with different requirements.

During immunisation of groups at the clinic or practice

Keep refrigerator door/cooler openings to a minimum.

- Take vaccine (and diluent if needed) from the cooler only as required. Reconstitute vaccines immediately prior to administering.
- Administer the vaccine and dispose of used injection equipment in the sharps container immediately.
- Always shake the vaccine in the vial or ampoule briskly to mix the contents just before administration in order to reduce risk of local reactions. Check the contents for clarity.
- 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.

Outreach immunisation sessions

- Place new, unfrozen ice packs/gel packs in the freezer so they will be ready for the next working day.
- Plan the session carefully. Ensure you take a sufficient stock of vaccine, diluent, adrenaline and ice packs.
- If doing immunisation sessions 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 extra ice packs/gel packs to replace the melted ice packs/gel packs.

If your circumstances require the use of a specialised vaccine cold box see 'Specialised Vaccine Cold Box' p 35.

Using MMR and other freeze-dried vaccines with diluent, during an immunisation session:

- Diluents may appear to be water, but usually contain a variety of chemicals and additives specifically designed for the needs of each vaccine, and therefore, are not interchangeable.
- Use only the diluent supplied by the vaccine manufacturer for use with that vaccine.
- Make sure that the diluent is as cool as the vaccine. Do not freeze the diluent. Diluents need to be the same temperature as the vaccine at the time of reconstitution.
- Use the entire volume of the cooled diluent supplied when reconstituting the vaccine.
- Reconstituted vaccine is very unstable and quickly loses potency at room temperature after reconstitution. Reconstituted vaccines should be used within one hour (30 minutes for Varicella), providing they have been kept between +2°C to +8°C and protected from sunlight and fluorescent light. However, reconstituted MMR can be stored in the plastic syringe in a dark place between +2°C to +8°C without loss of potency for up to eight hours but then must be discarded if not used.

Check storage rules for other reconstituted vaccines like varicella-zoster vaccine, some types of Hib vaccines and some travel vaccines as the guidelines differ slightly.

Source: NHMRC (2003), page 184; WHO, UNICEF, BASICS/USAID (1998) WHO/EPI/LHIS/98.02.

INVOLVING PEOPLE IN COLD CHAIN

If a person purchases a vaccine the safest cold chain procedure is to advise them to get it from the pharmacist immediately before attending the GP. If this is not possible, make them aware of the risks of freezing and warming the vaccine and advise them on safe storage procedures. An alternative is for people to leave the vaccine with the GP, clearly labelled with the person's name and when it will be used.

If a person is purchasing a vaccine the safest cold chain procedure is to advise them to collect it from the pharmacist immediately before attending the GP for vaccination.

MANAGEMENT OF COLD CHAIN PROBLEMS

Always have an alternative means of vaccine storage available.

Power failure

Domestic refrigerator

- During a power failure of 4 hours or less the refrigerator door should be kept closed.
- For power failures more than 4 hours store your vaccines in a cooler with conditioned ice packs/gel packs (see 'How to pack a cooler' p 29–30). Continue to monitor the temperature of the vaccines by placing the thermometer probe inside a vaccine box inside the cooler.

Purpose-built vaccine refrigerator

- Monitor the temperature of your refrigerator. If vaccines are at risk use alternative storage arrangements (some refrigerators may not hold the temperature very long).

Depending on the quality and design of your purpose-built vaccine refrigerator, it may warm quickly during a power failure. Do you need to add 'cold mass' (e.g. cooled water bottles) to your refrigerator?

Cold chain breach

1. Immediately isolate the vaccines until you have been in touch with the relevant state or territory health department (see p 53).
2. Keep vaccines refrigerated between + 2°C and +8°C and label **'do not use'.**
3. Do not discard any vaccine until advice has been sought from your relevant state or territory health department.
4. Contact your relevant state or territory health department as soon as possible (in business hours).
5. Take active steps to correct and prevent the problem recurring.
6. For privately purchased vaccines contact the manufacturer for advice.

The following information will assist with rapid decision making about a suspected cold chain breach when you contact your state or territory health department:

- Date of the breach.
- Do you store your vaccines in a domestic or purpose-built vaccine refrigerator?
- Minimum and maximum temperature reading?
- Are Cold Chain Monitors (CCMs) stored with the vaccines? If 'yes', be ready to report the reading when breach was noticed.
- When was the thermometer last reset?

- When was the thermometer battery last changed?
- When was the last check on the accuracy of the thermometer done?
- How long do you think the temperature was outside +2°C to +8°C?
- How long do you think these problems have been occurring?
- Where is the temperature probe situated?
- Where are your vaccines stored in the refrigerator?
- What type and number of vaccines are in your current stock?
- What is the expiry date of your vaccines?
- Have vaccines been pushed up against the cooling plate or a cold air outlet?
- Are the vaccines in their packaging?
- If a domestic refrigerator—are the vaccines in enclosed plastic containers?
- Are there water bottles in the doors, unused shelves and drawers of the refrigerator?
- What do you think was the cause of the cold chain breach?
- Has the cause of the cold chain breach been rectified?
- Has anybody been vaccinated with potentially affected vaccines?

Management of a suspected cold chain breach:

- *Isolate vaccines within the refrigerator;*
- *Do not use them or destroy them;*
- *Contact your state or territory health department ASAP (in business hours); and*
- *If a cold chain breach involves privately purchased vaccines contact the manufacturer for advice.*

COOLERS

Choose the correct cooler for your needs.

A cooler, also known by names such as Esky™ or Willow™, is a solid-walled insulated container with a tight fitting lid with the temperature inside maintained by ice packs or gel packs.

Coolers are normally not adequate for the transport of vaccines for prolonged periods (more than 8 hours or extreme conditions) as their cold life is limited. In this circumstance a specialised cold box would be recommended for storing and transporting vaccines (see section on 'Specialised Vaccine Cold Box' p 35).

Tips for using coolers

- Choose a cooler that will meet your needs.
  - Freezing episodes happen very easily in all coolers, usually in the first 2 hours after packing. The minimum size cooler recommended for storing vaccines is 10L.
  - If you are experiencing difficulty maintaining a stable temperature and are using a polystyrene cooler, change to a plastic cooler which provides better insulation. If using a plastic cooler and you are unable to maintain a stable temperature, consider upgrading to a higher quality cooler with refrigeration-type insulation or a specialised cold box.
- Experiment with your cooler to know how many ice packs/gel packs you will need. This will depend on:
  - ambient temperature
  - type and size of cooler
  - number of vaccines
  - cooler capacity
  - size and type of ice packs/gel packs
- Condition the ice packs/gel packs (see 'How to condition ice packs and gel packs' p 32–33).
- Insulate the vaccines so they do not come into contact with the ice packs/gel packs which are at 0°C temperature.
- Monitor the temperature of the vaccines.
- Ensure the contents of the cooler are packed securely so they cannot move around during transport.

Always condition the ice packs/gel packs.

- Keep 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.

Correctly packing a cooler reduces the risk of freezing.

How to pack a cooler

Option one: This option can be used for storing vaccines up to 8 hours (see Figures 2 and 3 on the following pages).

- Chill the inside of the cooler prior to use by placing ice packs/gel packs in it for a few hours.
- Place polystyrene chips, shredded paper 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 which stops air from circulating near the vaccine. However if using bubble-wrap avoid wrapping the vaccines tightly.
- Pack the freeze-sensitive vaccines in the centre of the container and the freeze-tolerant vaccine closest to the ice packs/gel packs.
- Place a minimum/maximum thermometer and a freeze indicator (or a dual time-temperature indicator if either is used in your state or territory) in the centre of the vaccine stock.
- Surround the vaccines with packing material which allows cold air to circulate.
- Place the conditioned ice pack/gel pack(s) (see p 32–33) on top, close and seal the lid of the cooler. If you are using a larger cooler, place conditioned ice packs/gel packs around the sides of the cooler as well as on top. You will need to experiment to find the correct combination for your needs.
- Ensure vaccine stock is not in direct contact with the ice packs /gel packs to minimise risk of freezing.
- Monitor the temperature before you leave, when you arrive, prior to administering vaccine and regularly throughout the immunisation session (at least hourly).

Pre-chill the cooler before use.

Danger: incorrect conditioning of ice packs/gel packs may cause vaccines to freeze easily because incorrectly or unconditioned ice packs/gel packs are too cold for safe vaccine storage.

Incorrectly conditioned or unconditioned ice packs/gel packs are too cold for safe vaccine storage and may easily cause vaccines to freeze.

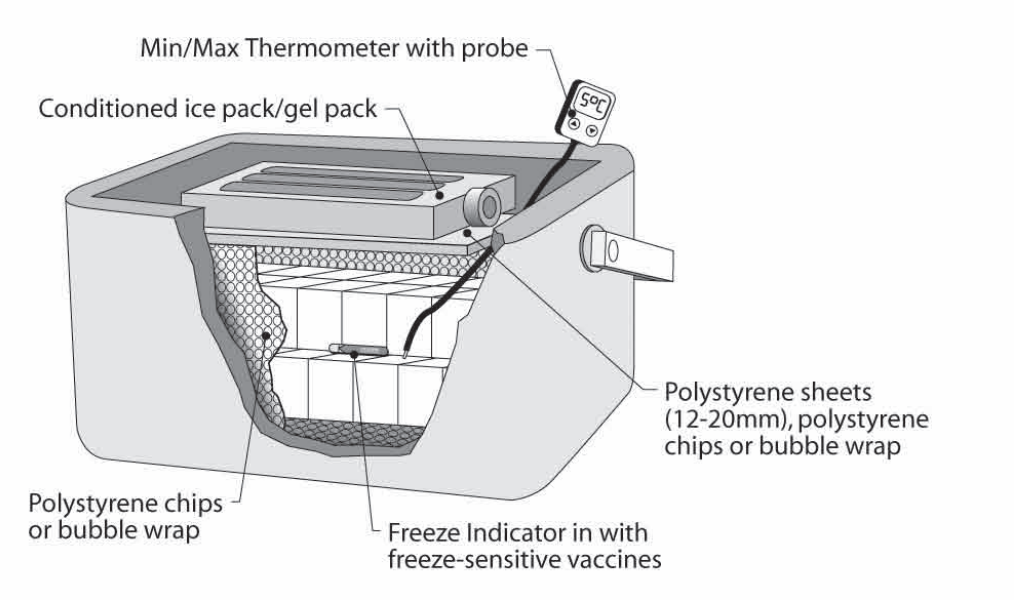

Figure 2: Example of a packed 10L cooler

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

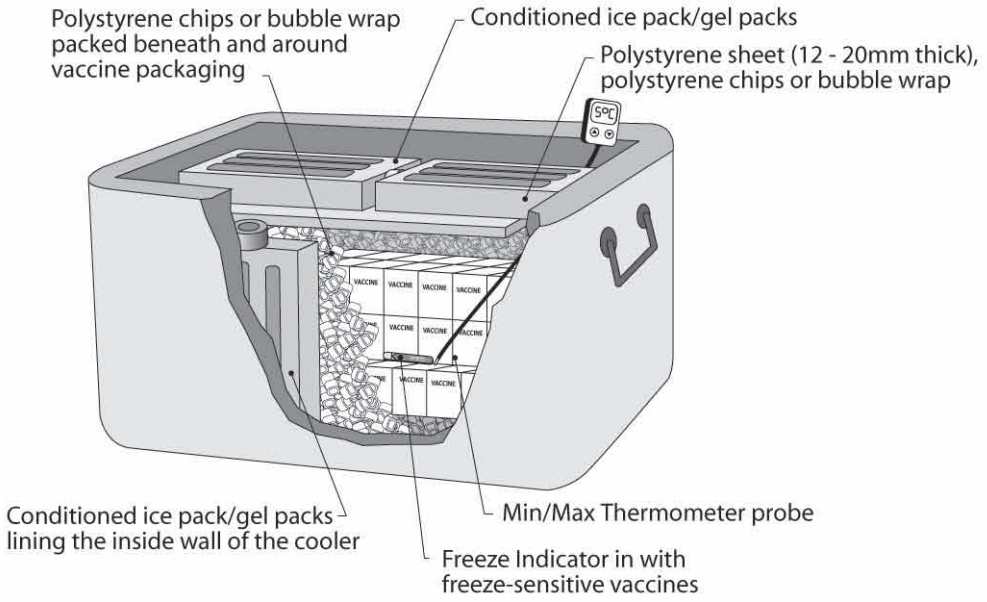

Figure 3: Example of a packed 30L cooler

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

- Choose a polystyrene container large enough for your needs and chill the inside of it by placing some 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 either is 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 you leave, when you arrive, prior to administering vaccine and regularly throughout the immunisation session (at least hourly).

High quality coolers cost several hundred dollars and are available from large boating, fishing or camping suppliers. They may have thick refrigerator-grade insulation and fibreglass or plastic walls. Some may have small 'feet' so that the bottom of 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.

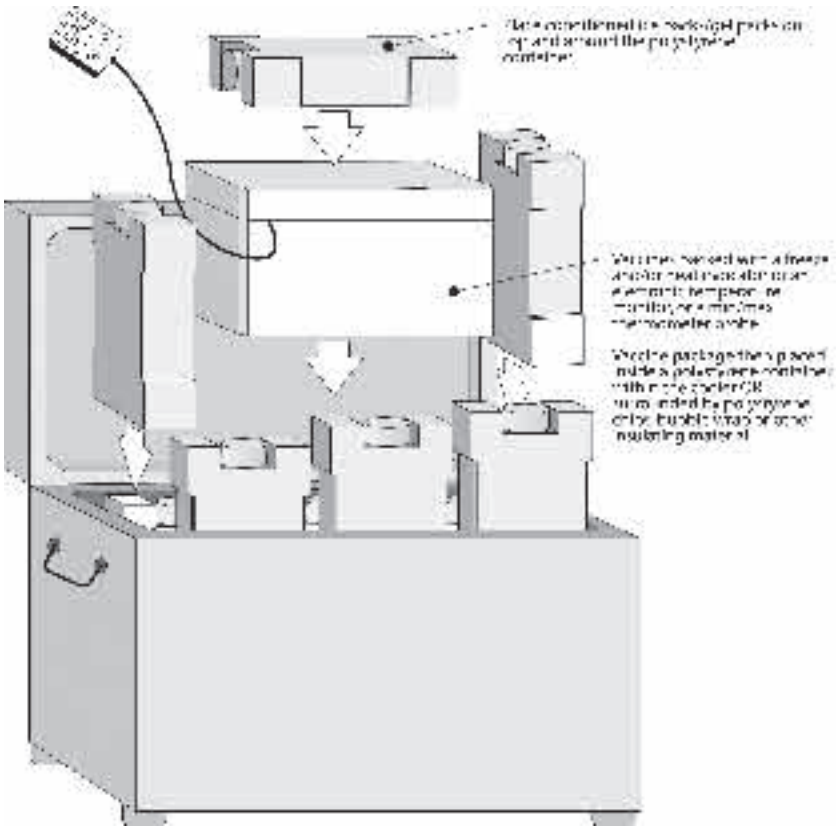

Figure 4: Example of packing a polystyrene container inside a large cooler

Freezing and conditioning of ice packs and gel packs

Ice packs and gel packs must be correctly conditioned before use. The risk of freezing vaccines increases if the ice packs/ gel packs are not correctly 'conditioned.'

Ice packs are water-filled and come out of the freezer at a temperature of about –18°C. It normally requires at least 12 hours in a freezer or 24 hours in a freezing compartment of a domestic refrigerator for an ice pack to be frozen and brought down to the temperature in the freezer (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.

There are a number of different types of gel packs that contain chemicals that depress the melting point and ensure the gel remains colder than 0°C for longer than water-filled ice packs. There is an increasing range of gel and phase-change materials becoming available that are also used to maintain the temperature of coolers. They tend to have freezing points below 0°C and present a risk of freezing vaccines unless they are appropriately conditioned for use in the cooler or cold box. Before purchasing gel packs, request current documentation from the manufacturer that:

i. Validates their claims about the product's cold life.

ii. 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.

Incorrect use of gel packs is even riskier than ice packs because the gel packs remain colder than 0°C for longer than ice packs.

Gel packs will take longer than ice packs to freeze. Generally it will take around 24 hours in a freezer and longer in a domestic refrigerator freezer to completely freeze gel packs.

One of the greatest risks to vaccines from freezing occurs when they are transported in a cooler or cold box and this risk increases if the ice packs/ gel packs are not correctly 'conditioned'.

Conditioning is a term which refers to leaving the ice pack(s)/gel pack(s) at room temperature to allow the ice or gel at the core to rise to about 0°C. This minimises the risk of damaging vaccines from freezing.

How to condition ice packs

Condition the ice packs as follows:

- Remove ice packs from the freezer.
- Lay out ice packs in single row on their sides (where possible) leaving a 5cm space around each ice pack to allow maximum air exposure to reduce the 'conditioning' time.
- Wait until ice pack(s) begins to sweat. This will take up to one hour at +20°C and a lot less at higher temperatures.
- 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 so that they are safe to use for vaccine transport.
- Follow the manufacturer's instructions on correct conditioning of the gel pack. There is no 'one rule fits all' approach to conditioning all the available gel packs. However 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 of frozen gel packs for the times prescribed in the Table on the next page enables the initial chill factor to be removed from the packs.

Gel packs will usually take longer than ice packs to condition.

Guide to time needed to condition small and large gel packs

Gel packs weighing *less* than 750gm	**Gel packs weighing *more* than 750 gm**
• If ambient (room) temperature is *over* +15°C, condition for <u>45 minutes</u> before use. • If ambient temperature is less than +15°C, condition for <u>1 hour</u> before use.	• If ambient (room) temperature is *over* +15°C, condition for <u>1 hour</u> before use. • If ambient temperature is less than +15°C, condition for <u>1½ hours</u> before use.
 Examples of gel packs weighing *less* than 750gm	 Examples of gel packs weighing *more* than 750gm

Specialised vaccine cold box

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

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

For longer term storage or extreme conditions (storage environment is <0°C or >40°C or) a specialised cold box is needed. 'Longer term' generally refers to more than 8 hours (one working day). Specialised cold boxes are available that meet WHO recommendations. A large cold box should have a minimum cold life of 120 hours at an air temperature of 43°C without openings. Specialised vaccine cold boxes need to be imported.

WHO has a list of specifications at: http://www.who.int/vaccines-access/vacman/pis/e04.pdf and product information sheets at http://www.who.int/vaccines-documents/DocsPDF00/www518.pdf

For more information on specialised vaccine cold boxes refer to the 'Proceedings of the National Vaccine Storage Workshop' (p 79) available on website http://immunise.health.gov.au/vaccinestorage.htm

Portable refrigerators

Portable refrigerators have a high propensity to freeze vaccines and should not be used unless they have been rigorously appraised (e.g. their controls cannot be inadvertently changed; a correct temperature can be set and will be maintained throughout the vaccine storage areas). If transporting vaccines for three days or more you need to use a specialised vaccine cold box.

APPENDIX 1
VACCINE STORAGE SELF-AUDIT

Self-auditing is important because:

- It is part of routine quality assurance and risk management processes.
- It enables you to have confidence that you are providing a safe and effective vaccine.

You can photocopy these pages and keep as a record of an audit. It is suggested that auditing is done at least every 12 months.

Date of self-audit / /

Person conducting Audit: _____

PROCEDURES

Checklist for safe vaccine handling and storage when using a domestic refrigerator or a purpose-built refrigerator

Have **all** staff received training to enable them to possess adequate knowledge in performing their role in cold chain procedures?	Y	N	
Is a record available that shows monitoring of the temperatures at the beginning of each working day? (before the vaccine is used)	Y	N	
Is a record available that shows monitoring of the temperatures at the end of each working day (minimum requirement is daily prior to commencing vaccination)?	Y	N	
Is there a valid documented reason if monitoring has been missed?	Y	N	N/A
Were all deviations outside +2°C and +8°C reported to the appropriate state or territory health department?	Y	N	N/A
Have the responses to all deviations outside +2°C and +8°C been documented and recommended actions taken?	Y	N	N/A

EQUIPMENT

Domestic refrigerators

When was the battery for the thermometer(s)/data logger(s) changed?	/ /		
Date and the results of checking the accuracy of your thermometer (do at least 12 monthly) (see 'How to check the accuracy of your thermometer' p 22)?	/ /		°C
If a cyclic defrost refrigerator, when was the refrigerator last defrosted?	/ /		
Has the refrigerator shown evidence of malfunction (e.g. poor seals so that the door opens too easily, ice build up)? If 'Yes', what action was taken?	Y	N	
Is the temperature probe placed correctly as recommended (see Step 10 p 14)?	Y	N	
Is there an appropriate gap between the vaccines and the walls, element, air outlets and a buffer (if necessary) in place?	Y	N	
Are the vaccines stored in enclosed plastic containers prepared according to these guidelines (see Step 7 p 12)?	Y	N	
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 are you taking?	Y	N	
Are there enough water bottles and/or ice packs/gel packs in the shelves of the door, lower drawer and empty shelves?	Y	N	

Purpose-built vaccine refrigerators

Has the refrigerator shown evidence of malfunction (e.g. poor seals so that the door opens too easily)?	Y	N
Is there an appropriate gap between the vaccines and the walls?	Y	N
If using a thermometer or data logger, when was the battery changed?	/	/
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 are you taking?	Y	N

Alternative vaccine storage

Is there an alternative (e.g. cooler, other monitored refrigerator) available for vaccine storage, if necessary (e.g. vaccine refrigerator breakdown)?	Y	N
Are ice packs/gel packs at the correct temperature available?	Y	N

APPENDIX 2

Common misconceptions about vaccine storage management

1. **Myth: Vaccines are robust products that tolerate heat and cold.**

   Fact: Most vaccines are considered damaged with temperatures of 0°C or below. Some vaccines are sensitive to high temperatures. Generally the lower temperatures are more dangerous to vaccine potency than slightly high temperatures.

2. **Myth: Vaccines are free (or cheap).**

   Fact: Vaccines range in price from a few dollars (e.g. tetanus) to about $180 (e.g. privately purchased conjugate pneumococcal vaccine). Even a small general practice can be storing vaccines worth about $4,000.

3. **Myth: Warming of vaccines is more harmful than freezing.**

   Fact: In Australia, most vaccines are destroyed by freezing. There are some vaccines that are particularly heat sensitive e.g. reconstituted MMR.

4. **Myth: Vaccines that have been frozen look frozen, solid or changed.**

   Fact: Most vaccines do not appear different even when they have been frozen. At cold temperatures that would damage the vaccine, they may not appear 'frozen' and can be easily drawn up.

5. **Myth: Vaccine refrigerators look after themselves. Domestic refrigerators storing vaccine require a low level of care.**

   Fact: Domestic refrigerators are designed for food storage and are not designed to meet the specialised needs of vaccines and place the safety of vaccines at risk. Careful monitoring and knowledge of your refrigerator is required to minimise risk to the vaccine.

6. **Myth: Cold chain management is someone else's responsibility.**

   Fact: All people handling vaccines are responsible for maintaining the cold chain. It is recommended that a key person is nominated to oversee vaccine management.

7. **Myth: If the thermometer shows a temperature outside +2°C to + 8°C, there must be something wrong with the thermometer.**

   Fact: If refrigerator temperatures are outside the recommended range, the thermometer reading should be assumed to be correct until proven otherwise. Always take action to report it straight away.

8. **Myth: Temperature monitoring equipment and some thermostat override devices eliminate the need for staff intervention and monitoring of the cold chain.**

   Fact: Temperature monitoring equipment and thermostat override devices do not guarantee safety of vaccines and should not be considered a substitute for good vaccine storage management.

9. **Myth: The temperature throughout the refrigerator is the same.**

   Fact: Temperatures vary throughout the refrigerator, between the shelves and even on the same shelf.

10. **Myth: If the temperature increases in the refrigerator for any reason, you should alter the thermostat dial for a short time until the required temperature is reached.**

    Fact: If you have cooled water bottles (for 'cold mass') and an adequately functioning refrigerator the refrigerator should revert to the normal operating temperature fairly quickly. Haphazard changing of the dial can destabilise the temperature and put the vaccines at risk.

11. **Myth: Refrigerators cannot get to freezing.**

    Fact: Domestic refrigerators can drop to temperatures below 0°C depending on the location within the refrigerator (e.g. near the cooling plate or cold air outlets) and the temperature control settings.

APPENDIX 3

Case study

This GP works in a busy four doctor medical centre in an inner metropolitan area. The refrigerator used to store vaccines in the practice is a domestic frost-free refrigerator which had been difficult to stabilise between the required +2°C to +8°C range despite being a 'modern' electronic model. Before modification the refrigerator temperatures varied between +1°C and +10°C.

After attending the National Vaccine Storage Workshop in June 2004 as the RACGP representative, the GP went through the following steps:

- Initial monitoring of the refrigerator to 'get to know it'.
- Assessed that the best place for freeze sensitive vaccines was away from the air vents at the back of the refrigerator.
- Placed maximum number of cooled water bottles in the shelves in the refrigerator door to add 'cold mass' and assist in stabilising refrigerator temperatures.
- Placed ice packs (on their side with a gap between each) in the freezer.
- Purchased a set of enclosed plastic drawers to store vaccines. In each drawer placed a gel pack at the back to act as a buffer against cold air vents and assist in stabilising temperatures in those drawers containing fewer vaccines.
- Labelled each drawer with the contents.
- Confirmed temperatures by monitoring with two thermometers with probes placed at varying places within the refrigerator. The temperatures have also been confirmed by data logging. Since modification, the refrigerator temperatures have remained within a 4°C to 6°C range.

Total cost of equipment for modification was $160.00. Equipment was purchased from a large department store. Similar equipment is readily available.

Figure 1: Refrigerator after monitoring and modification

- Vaccines stacked in plastic boxes each with separate drawers. Drawers are labelled for easy identification of vaccine required.
- Air circulation possible between stacks and into front of containers.
- The rear of each container is sealed.
- Warning sticker over the thermostat.

Note: there are medications, not vaccines or diluents in the drawer at the bottom of the refrigerator.

Figure 2: Water bottles in refrigerator door

Door filled with bottles of water to provide 'cold mass' and to reduce temperature loss on opening the refrigerator.

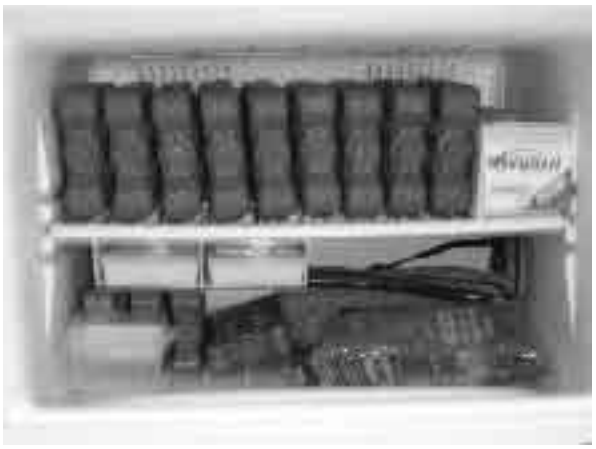

Figure 3: Packing of freezer

- If you need the ice packs/gel packs to freeze quickly ensure there is a space between them to allow cold air circulation.
- Ice packs and gel packs can be placed in the door of the freezer but these packs will take longer to freeze completely.
- Storing ice packs/gel packs in the freezer will assist in stabilising the temperature in your refrigerator compartment as in most frost-free refrigerators cold air is distributed from the freezer to the fresh food compartment.

Figure 4. Vaccines packed in a pull out drawer (enclosed plastic container)

- Vaccines stacked in their original boxes to preserve temperature buffer. Labelled drawers slide out for easy selection.
- Vaccine boxes clearly marked with expiry date.
- Temperature probe placed within a vaccine box placed at the back of the drawer.
- Gel pack fixed to back of the container. This provides some temperature stability as well as protection (a buffer) from cold air vents at back of refrigerator unit.
- Individual pull out drawers can be removed from the refrigerator for restocking to minimise door opening time.

APPENDIX 4

HOW TO IDENTIFY AND MANAGE SITUATIONS WHEN THINGS GO WRONG

Report all variations outside +2°C and +8°C to the relevant state or territory health department unless:

- Short term elevated temperatures from opening the door during routine use or unpacking a new vaccine order.

Coping with your domestic refrigerator

These are a few examples of what can go wrong!

Issue:

You have a cyclic defrost refrigerator where there is a cooling plate or a frost free refrigerator with cold air outlet(s). This places the vaccines in close proximity at risk of freezing.

Potential solution:

Store your vaccines in a enclosed plastic container with a strip of polystyrene at least 12mm to 20mm thick glued to the area of the container at risk of having the greatest exposure to cold temperature from the cooling plate or the cold air outlet.

Do not use glass or metal containers as they provide less buffering to temperature deviations.

Issue:

Refrigerator temperatures can become unstable if there is a small volume of vaccines stored in the refrigerator or there is a power failure. Refrigerator contents need to have sufficient 'cold mass' to assist in maintaining stable temperatures. This applies to domestic and purpose-built vaccine refrigerators.

Potential solution:

Store cooled water bottles in the empty areas of your refrigerator e.g. refrigerator door, any empty shelves and the lower drawers to stabilise the temperature. Water bottles increase the 'cold mass' in the refrigerator.

When placing more water bottles in the refrigerator ensure they are filled with cool water to avoid destabilising the vaccine refrigerator environment. Monitor the refrigerator temperatures closely until they have stabilised.

Issues:

- Small volume of vaccines
- Difficulty stabilising the refrigerator temperature

Potential solution:

Store your vaccines in an enclosed polystyrene box within the refrigerator and place the thermometer probe inside a vaccine package, inside the polystyrene box. Increase the 'cold mass' of refrigerator contents (see previous box and Step 10 p 14).

A polystyrene box within the refrigerator can be used to store vaccines if you do not know how your refrigerator behaves or are concerned it may have significant fluctuations (but not having temperatures ≤ 0°C) e.g. a new refrigerator, change in weather conditions such as seasonal changes or in extremes of heat or cold weather.

Issue:

The thermometer's minimum or maximum temperature shows that your vaccines have been stored outside the recommended safe range of +2°C to +8°C. This is a cold chain breach.

Potential solution:

Isolate the vaccines, keep them refrigerated, do not use or discard them and contact your state or territory health department at the earliest opportunity in business hours to seek advice.

If they are privately purchased vaccines contact the vaccine manufacturer.

If people are vaccinated with suspect/frozen vaccine you may need to recall them for revaccination.

Sometimes a refrigerator mechanic will say the refrigerator compartment cannot get to freezing. This is incorrect information.

Issue:

The refrigerator temperature keeps going up or is difficult to cool down.

Potential explanation:

Power failure.

Refrigerator door left open.

Load shedding of electricity.

Thermometer probe placed in the wrong position.

Refrigerator accidentally turned off or unplugged.

Over-filled refrigerator.

Refrigerator malfunctioning.

Faulty thermostat.

More than one person adjusting the refrigerator thermostat (poor communication channels).

APPENDIX 5

1. Frost free refrigerators

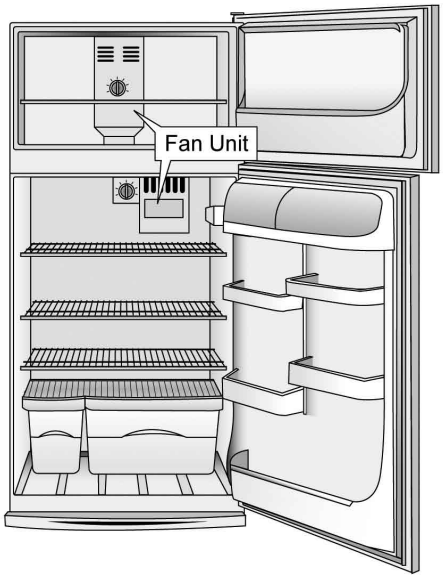

Figure 1.
Frost free refrigerators with fan unit for circulation of cold air.

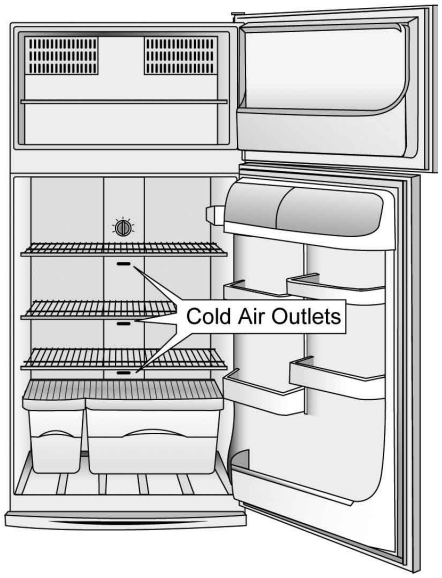

Figure 2.
Frost free refrigerators with cold air outlets for circulation of cold air.

In frost-free refrigerators, the air emitted into the fresh food section of the refrigerator comes from the freezer compartment. Generally accepted temperature for a freezer is –18°C for correct storage of frozen food.

In this frost free refrigerator (Figure 2) there are a number of cold air outlets down the back of the refrigerator to allow cold air to be blown into the refrigerator from the freezer and this can be seen as dark vents on the back wall of the refrigerator. Other refrigerators can have cold air coming from the top, from numerous points or from a specific outlet (as with the refrigerator to the left).

2. Cyclic defrost refrigerators

In cyclic defrost refrigerators similar to the one pictured below, the 'cooling plate' is usually a vertical plate at the back of the refrigerator. Most models as in this particular instance have a manual defrost freezer combined with a cyclic defrost fresh food compartment.

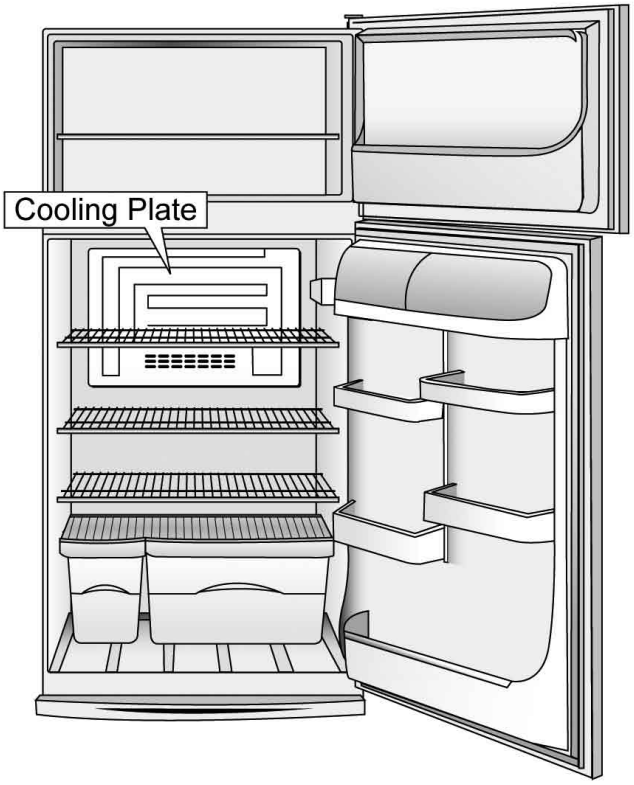

Figure 3. Cyclic Defrost Refrigerator

APPENDIX 6

DATA LOGGERS

What is a data logger?

Temperature data loggers are small, electronic devices that measure temperatures and keep a record of the results over a period of time.

Each logger is a self-contained miniature computer. They 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 in close proximity to the temperature probe. The logger then operates independently on its own battery until the recording is downloaded to the computer.

A print out of results is obtained and is most easily seen as a graph. Also provided is information of times the temperature was recorded outside +2°C to +8°C and the minimum and maximum temperatures.

Many data loggers can be programmed to alarm when the temperature is recorded outside the NHMRC parameter of +2°C to +8°C. The replaceable battery has a typical life of 1 to 2 years (see manufacturer's guidelines). Advances in technology are producing more features in data loggers, the information in this section refers to basic models.

Periodic logging

This activity is usually undertaken to verify cold chain efficacy and provide documentation for accreditation purposes. Data logging is also useful in getting to 'know your refrigerator' (see Step 5 p 11).

Data logging is also useful in getting to 'know your refrigerator' (see Step 5 p 11).

Permanent logging

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

1. You still need to be able to visually access the minimum/maximum temperatures daily and record them.
2. A daily minimum/maximum temperature recording is still required. Twice daily temperature recording is highly recommended.
3. It is also recommended that the data loggers have their alarm systems activated to alarm outside +2°C to +8°C.
4. **All** staff need to be trained to recognise the alarm.
5. Downloading and recording of information should occur at all times when an alarm is activated.
6. Your state or territory health department should be notified if recordings are outside of +2°C to +8°C.
7. Regular checking of the accuracy of the data logger and battery change needs to occur according to the manufacturer's recommendation.
8. Ensure this process of accuracy checking is recorded.

Benefits of logging

Logging:

1. Confirms the cold chain has been maintained and provides accurate knowledge of the vaccine refrigerator temperature.
2. 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.
3. Supplements a cold chain audit and assists staff to understand the functioning of the refrigerator.
4. Identifies the temperature fluctuations within the shelves and the location of 'cold spots' on each shelf.
5. Provides feedback on the effects of changes made to the refrigerator.
6. Confirms efficacy of modifications made to domestic refrigerators.
7. Supports accreditation documentation.
8. Helps to assess the refrigerator thermometer's accuracy, if it is placed next to the temperature probe.

Limitations of logging

1. **All** staff need to be trained about the purpose of the logging, and their responsibility for managing the data logger when it is in the refrigerator. This can be time consuming, especially when part-time staff are involved.
2. When the data logger and the thermometer are not co-located in the refrigerator different recordings can occur, resulting in confusing data on the maintenance of the cold chain.
3. All data logger manufacturers identify a degree of error in the recordings. This needs to be known by all staff otherwise your state or territory health department may advise vaccines to be discarded, when they may still be used.
4. This adds another layer of work to vaccine management in the practice and increases the knowledge, skill and time requirements of practice staff.

Points to consider

- How easy is it to set up and download data (usually to a computer) and to create and retain a record of data?
- What is the accuracy of the data logger (is it ±1°C or, more usually, ±0.1°C)?
- Can checking the accuracy be done by you or does it need a technician?
- If using the logger as a permanent method of monitoring temperatures, does it have a visual minimum/maximum temperature display? Can you see what the current temperature is?
- The objective of data logging is to build up a 'temperature map' (see 'know your refrigerator' Step 5 p 11) of the vaccine storage areas within the refrigerator to identify the safest areas and the most dangerous areas for vaccine storage. You are particularly looking for areas where vaccine could freeze.

REFERENCES

Proceedings of the National Vaccine Storage Workshop 2004 available on the:

- Immunise Australia website
  http://immunise.health.gov.au/vaccinestorage.htm

These proceedings provide extensive background information but it should be noted that there have been developments in knowledge and policy since the publication of the Proceedings document.

Keep it Cool 2nd Edition.

The Australian Immunisation Handbook 8th Edition.

A Guide to Effective Vaccine Management for Practice Staff. Queensland Division of General Practice.

Queensland Division of General Practice document on Data Logging Version 1 2004.

Useful contact details

Australian Divisions of General Practice for details of your local division
Tel: 02 6228 0800

AGPAL (Australian General Practice Accreditation Limited)
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Free Fax: 1300 362 110
Email: info@qip.com.au
Web: www.qip.com.au

GPA ACCREDITATION *plus*
Free Phone: 1800 188 088
Free Fax: 1800 644 807
Email: gpa@gpa.net.au
Web: www.gpa.net.au

State and Territory Health Department contact details for immunisation

Australian Capital Territory	02 6205 2300
New South Wales	Contact the local Public Health Unit (Look under 'Health' in the White Pages)
Northern Territory	08 8922 8044
Queensland	07 3234 1500
South Australia	08 8226 7177
Tasmania	03 6222 7724 or 1800 671 738
Victoria	1300 882 008
Western Australia	08 9321 1312