HotDoc

Cold Chain Monitoring & Safe Vaccine Management

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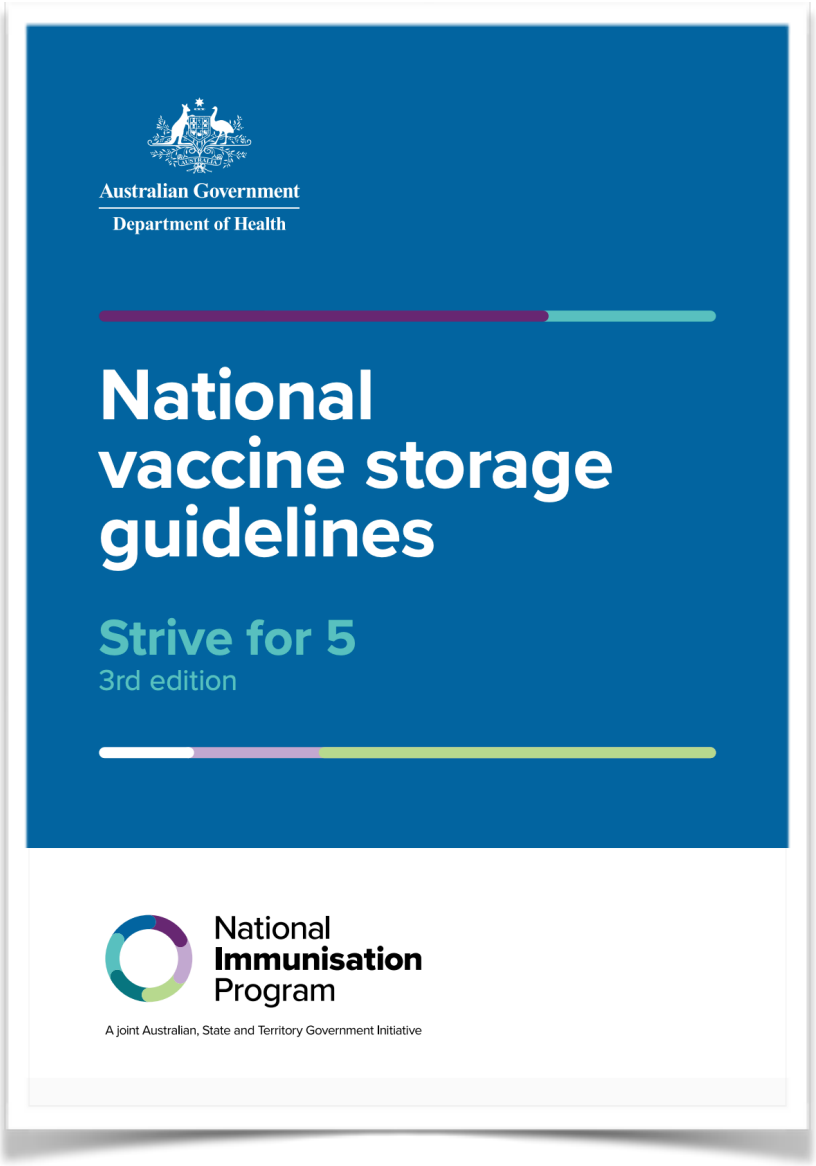
This session will cover

- Fundamentals of cold chain management and vaccine fridge temperature monitoring
- How to detect and manage cold chain breaches
- New resources and changes to recommendations from the updated Strive for 5 National Vaccine Storage Guidelines
- Our preferred templates and tools to help you manage and protect vaccine potency

National Vaccine Storage Guidelines: Strive for 5



What is cold chain?

The '**cold chain**' is the **system of transporting and storing vaccines within the safe temperature range** of

+2°C to +8°C

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

Source: National vaccine storage guidelines – Strive for 5

Why bother with cold chain?

Vaccines are **very sensitive** biological substances and they can **become less effective or** even be **destroyed** if:

- **Frozen** (reach zero degrees, even if they don't 'look' frozen)
- Allowed to get **too warm**, or
- **Exposed** to direct **sunlight, UV light, or fluorescent light**

Most vaccines will be destroyed if they reach zero degrees!

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

This is why in some cases, the advise from the State Health Department may be to 'use within the month' for certain vaccines and to discard others.

Source: National vaccine storage guidelines – Strive for 5

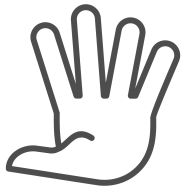
Why bother with cold chain?

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

- Health professionals have a responsibility to ensure **patients receive effective vaccines**
- **Vaccines are expensive** and can be in **short supply**. The combined cost of vaccines in a fridge can be significant.
- **Good management eliminates the need to revaccinate**
- Cold chain **breaches can occur even with good procedures**, **but this way, problems can be detected quickly** and **before an ineffective vaccine is given**

Source: National vaccine storage guidelines – Strive for 5

Key principles and why we ‘strive for 5’



- Always store vaccines in **purpose-built vaccine refrigerators**
- **Nominate a staff member** to be responsible for vaccine management
  (and a back-up staff member to be responsible in their absence)
- Have **policies and procedures** for vaccine management
- Ensure **all staff involved** in vaccine transport, storage and handling are adequately **trained**
- Perform a **self-audit** at least every 12 months
- Check and **record fridge max/min temperature twice daily**
- **Using a data logger and downloading a report at least weekly**
- Have a **plan for cold chain breaches** & power failures
- Report temperatures **outside the +2°C to +8°C** range to your state health department. **Always strive for *5°C!*** *(middle of safe range)*
- **Do not use or discard** vaccine until advice is given
- Follow the **guidelines for packing and monitoring vaccines in coolers**
  (see Section 9 of Strive for 5)

Source: National vaccine storage guidelines – Strive for 5

Types of refrigerators for vaccine storage

Never use domestic refrigerators as they are not suitable for vaccines

Purpose-built vaccine refrigerators

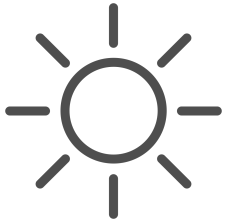
Specifically designed to store vaccines, these are the best-practice storage option because they have:·

- **A stable, uniform, and controlled** cabinet **temperature**
- **Alarms and safety features** to alert or prevent temperature fluctuations
- **Inbuilt monitoring and/or data logging** (depending on the model)
- **Good temperature recovery** after the refrigerator has been opened
- **Nearly all of the internal space** can be used for vaccine storage **(don't let vaccines touch the walls or back of the fridge)**

Note:
An **additional refrigerator with a freezer section will be required** for storing ice packs/gel packs

Source: National vaccine storage guidelines – Strive for 5

Tips for placement of the vaccine fridge



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

Source: National vaccine storage guidelines – Strive for 5

Power source reliability

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

Source: National vaccine storage guidelines – Strive for 5

Monitoring fridge temperature

- **Check and record** the vaccine refrigerator **temperature (minimum, maximum and current) twice daily**
- **Reset the data logger or thermometer after each reading**
- Also **record refrigerator temperature**:
  - **On receipt of vaccines**
  - **Following a power failure**
- **Make sure temperature** readings are **set to Celsius** not Fahrenheit.
- **Each refrigerator needs its own** temperature monitoring **chart**

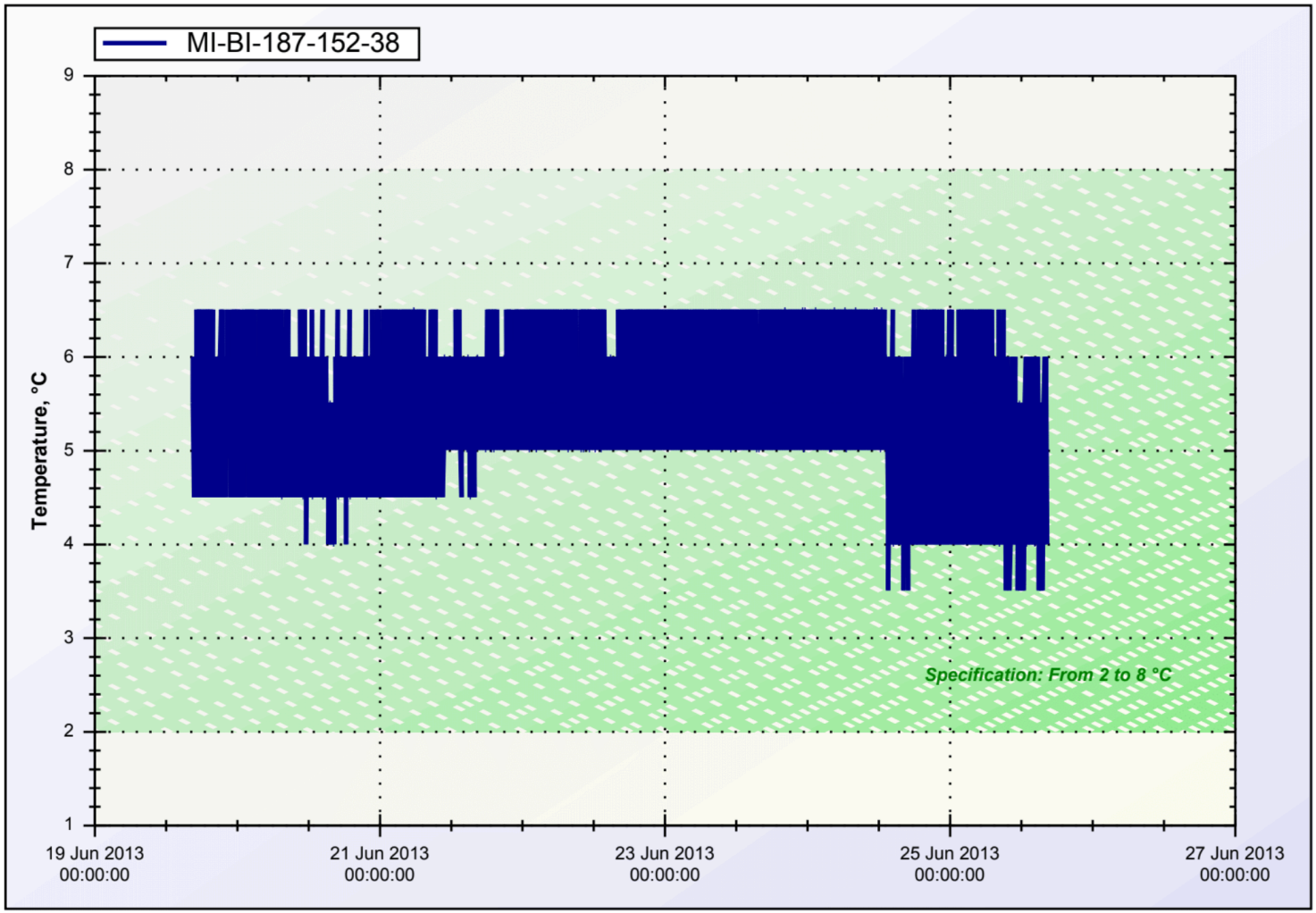
Source: National vaccine storage guidelines – Strive for 5

Data Loggers

- Data loggers are usually set to record temperatures at pre-set intervals. **5 minute intervals** is what is currently recommended for logging.
- Each logger is a **self-contained miniature computer**
- **Once programmed via a computer, they are placed in the fridge** near the temperature probe or vaccines
- **Some purpose-built vaccine refrigerators have an inbuilt data logger**
- **Twice daily minimum/maximum temperatures must still be manually recorded** in addition to longer term tracking with a data logger

Source: National vaccine storage guidelines – Strive for 5

Data Logger Reports



Dealing with cold chain breaches

A ‘cold chain breach’ is when vaccine fridge temperatures have been outside the recommended range of +2°C to +8°C

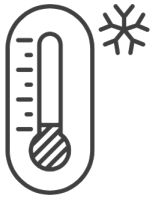
This **excludes fluctuations up to +12°C lasting less than 15 minutes** (e.g. stock taking or restocking fridge)

Steps to follow in the event of a breach

1. Immediately **isolate the vaccines**
2. **Keep refrigerated** between + 2°C and +8°C and **label ‘Do not use’**
3. **Contact your state or territory health department** as soon as possible
4. **Do not discard any vaccine until advised** to do so by the health department
5. Take steps to **correct the problem** and to prevent it from recurring
6. For **private vaccines, contact the manufacturer** for advice

Source: National vaccine storage guidelines – Strive for 5

Tips for using coolers

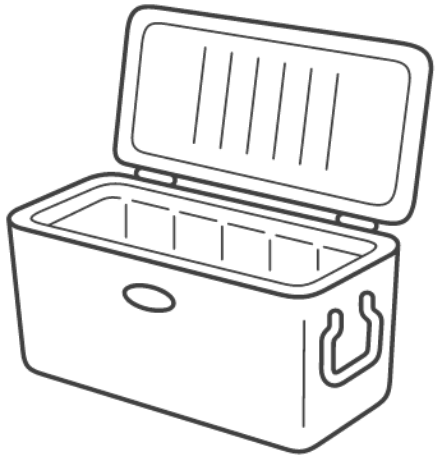


- **Freezing episodes can occur in all coolers (usually in the first 2 hours)**
- The **minimum size cooler** recommended is **10 litres**
- **Polystyrene coolers provide limited insulation** and are **only suitable for** storing vaccines for **short periods (up to 4 hours)**
- **Condition the ice packs/gel packs** (Section 9.2 of Strive for 5)
- **Pre-chill** the cooler before use
- **Insulate the vaccines** so they are not in direct contact with ice packs/ gel packs. (e.g. Polystyrene chips or loosely wrap in bubble-wrap, allowing cool air to circulate)
- **Monitor and record the temperature every 15 minutes for the first 2 hours, then at least hourly** using a **battery-operated minimum/ maximum thermometer**

Source: National vaccine storage guidelines – Strive for 5

Tips for using coolers

- The **thermometer should be reset after each reading** for accuracy
- Keep the cooler **out of the direct sun**
- **Only remove vaccines** from the cooler **as they are needed**
- **Check that the temperature** has **remained between +2°C and +8°C** before administering



Source: National vaccine storage guidelines – Strive for 5

Packing a cooler

Figure 2: Ice packs/gel packs placed in bottom of cooler to chill cooler

Figure 3: Insulating material placed in bottom of cooler

Source: National vaccine storage guidelines – Strive for 5 p.66

Figure 4: Vaccines packed in cooler

Figure 5: Minimum/maximum thermometer placed in centre of vaccine stock

Note: A data logger (if available) can also be placed with the minimum/maximum probe.

Packing a cooler

Figure 6: Insulating material placed on top of vaccine stock followed by ice packs/gel packs

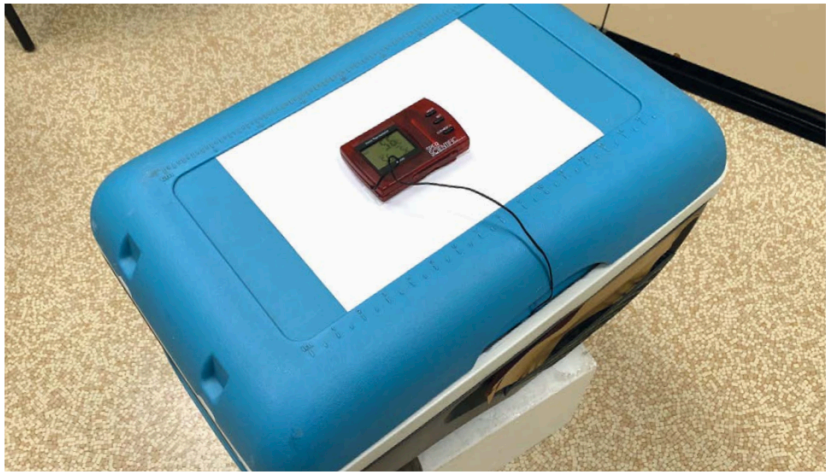


Figure 7: Minimum/maximum thermometer display placed outside cooler

Source: National vaccine storage guidelines – Strive for 5

Accreditation Standards

GP6.1 A Our practice has at **least one team member who has primary responsibility for cold chain management** in the practice.

You must:

- Have a **team member** who has **primary responsibility** for cold chain management
- **Educate the team member** with primary responsibility for cold chain management about their role
- **Inform the practice team** so they know who is responsible for cold chain management
- Have a **process** to transfer cold chain management **when the team member with primary responsibility is unavailable.**

You could:

- Include education about cold chain management in **induction and ongoing training** for the practice team.

Source: RACGP Standards for General Practice, 5th ed

Procedures are in line with Strive for 5

GP6.1 B The team member who has primary responsibility for cold chain management ensures that the **process used complies with the current edition of the National vaccine storage guidelines: Strive for 5**.

You must:

- Maintain a **cold chain management policy and procedure**
- Have a team member who is responsible for the practice **complying with the current edition of the National vaccine storage guidelines: Strive for 5.**

You could:

- **Conduct an audit** of vaccine storage to determine whether it complies with the National vaccine guidelines: Strive for 5.

Source: RACGP Standards for General Practice, 5th ed

Have set cold chain procedures

GP6.1 C The team member who has primary responsibility for cold chain management **reviews the following processes** to ensure potency of our vaccine stock:

- **Ordering and stock rotation** protocols
- **Maintenance of equipment**
- **Annual audit** of our vaccine storage procedures
- **Continuity of the cold chain**, including the handover process between designated members of the practice team
- **Accuracy of our digital vaccine refrigerator thermometer**

You must:

- Maintain a **cold chain management policy and procedure**
- Have procedures that require a **written record of all monitoring of refrigerators** in which vaccines are stored, including the temperature.

You could:

- Create a template to make monitoring and recording of refrigerator temperatures easier.
- Create a roster for monitoring cold chain compliance.

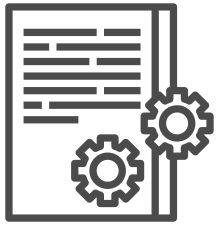
Source: RACGP Standards for General Practice, 5th ed

Have a cold chain policy

GP6.1 D Our practice has a **written, practice-specific policy** that outlines our cold chain processes.

You must:

- Maintain a cold chain management **policy and procedure**.

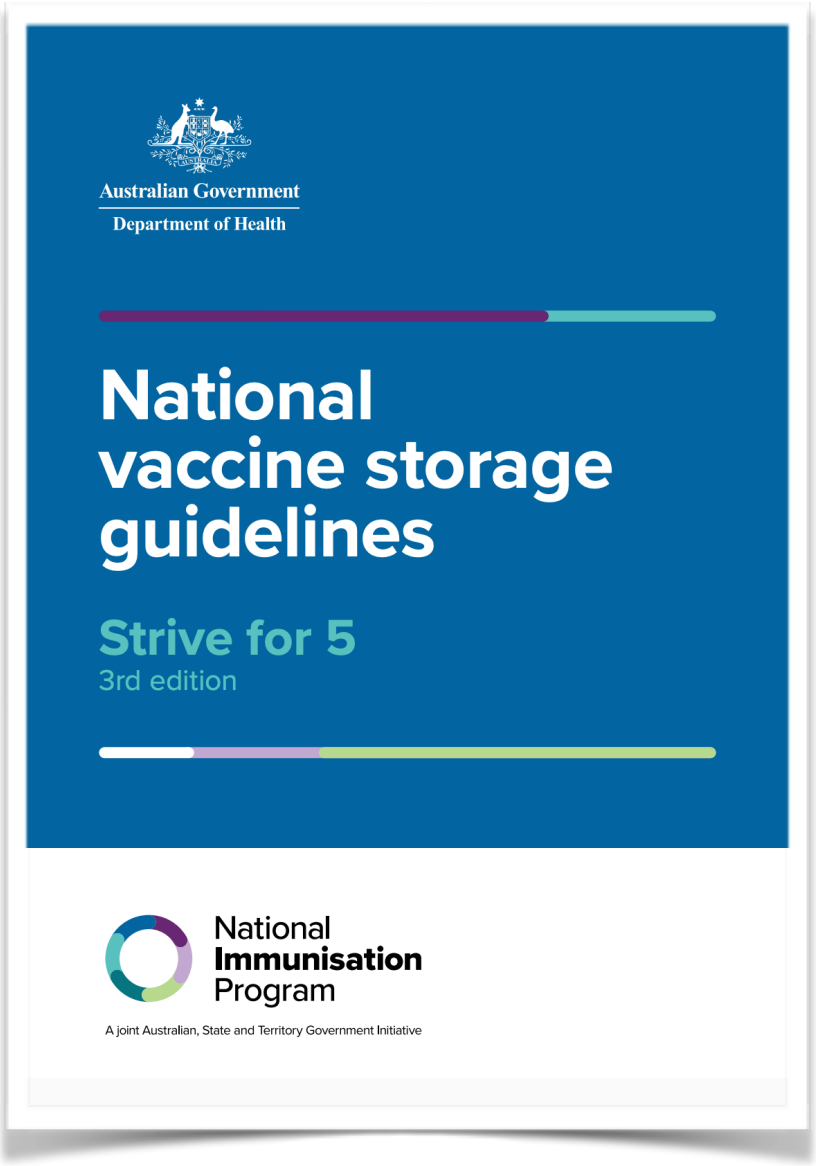


You could:

- **Review** the cold chain management policy **once a year**
- **Discuss** the cold chain management policy in **team meetings**.

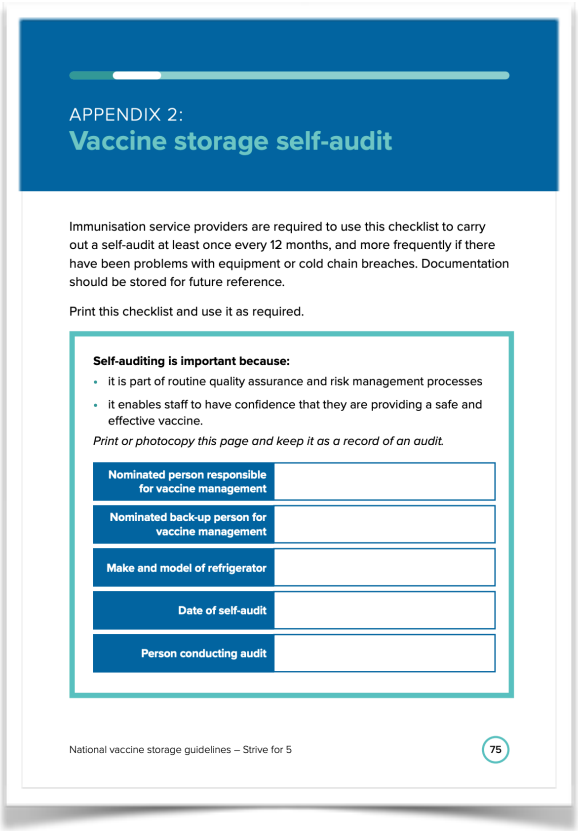
Source: RACGP Standards for General Practice, 5th ed

Resources: Strive for 5 Guide



Resources: Self-audit

A vaccine storage self-audit should be undertaken by each practice at least every 12 months or more frequently if you've experienced cold chain problems



APPENDIX 2:

Vaccine storage self-audit

Immunisation service providers are required to use this checklist to carry out a self-audit at least once every 12 months, and more frequently if there have been problems with equipment or cold chain breaches. Documentation should be stored for future reference.

Print this checklist and use it as required.

Self-auditing is important because:

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

Print or photocopy this page and keep it as a record of an audit.

Nominated person responsible for vaccine management	
Nominated back-up person for vaccine management	
Make and model of refrigerator	
Date of self-audit	
Person conducting audit	

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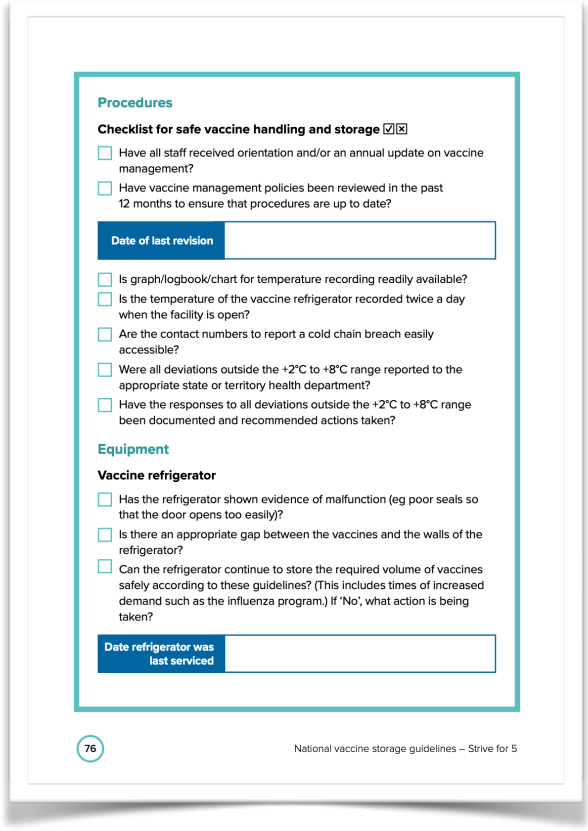

Procedures

Checklist for safe vaccine handling and storage ☑☒

- ☐ Have all staff received orientation and/or an annual update on vaccine management?
- ☐ Have vaccine management policies been reviewed in the past 12 months to ensure that procedures are up to date?

Date of last revision	

- ☐ Is graph/logbook/chart for temperature recording readily available?
- ☐ Is the temperature of the vaccine refrigerator recorded twice a day when the facility is open?
- ☐ Are the contact numbers to report a cold chain breach easily accessible?
- ☐ Were all deviations outside the +2°C to +8°C range reported to the appropriate state or territory health department?
- ☐ Have the responses to all deviations outside the +2°C to +8°C range been documented and recommended actions taken?

Equipment

Vaccine refrigerator

- ☐ Has the refrigerator shown evidence of malfunction (eg poor seals so that the door opens too easily)?
- ☐ Is there an appropriate gap between the vaccines and the walls of the refrigerator?
- ☐ Can the refrigerator continue to store the required volume of vaccines safely according to these guidelines? (This includes times of increased demand such as the influenza program.) If 'No', what action is being taken?

Date refrigerator was last serviced	

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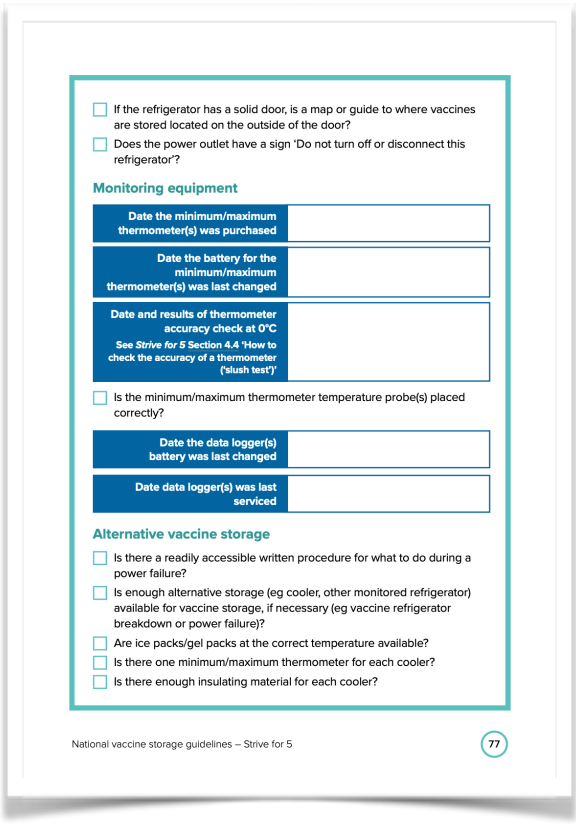

- ☐ If the refrigerator has a solid door, is a map or guide to where vaccines are stored located on the outside of the door?
- ☐ Does the power outlet have a sign 'Do not turn off or disconnect this refrigerator'?

Monitoring equipment

Date the minimum/maximum thermometer(s) was purchased	
Date the battery for the minimum/maximum thermometer(s) was last changed	
Date and results of thermometer accuracy check at 0°C See *Strive for 5* Section 4.4 'How to check the accuracy of a thermometer ('slush test')'	

- ☐ Is the minimum/maximum thermometer temperature probe(s) placed correctly?

Date the data logger(s) battery was last changed	
Date data logger(s) was last serviced	

Alternative vaccine storage

- ☐ Is there a readily accessible written procedure for what to do during a power failure?
- ☐ Is enough alternative storage (eg cooler, other monitored refrigerator) available for vaccine storage, if necessary (eg vaccine refrigerator breakdown or power failure)?
- ☐ Are ice packs/gel packs at the correct temperature available?
- ☐ Is there one minimum/maximum thermometer for each cooler?
- ☐ Is there enough insulating material for each cooler?

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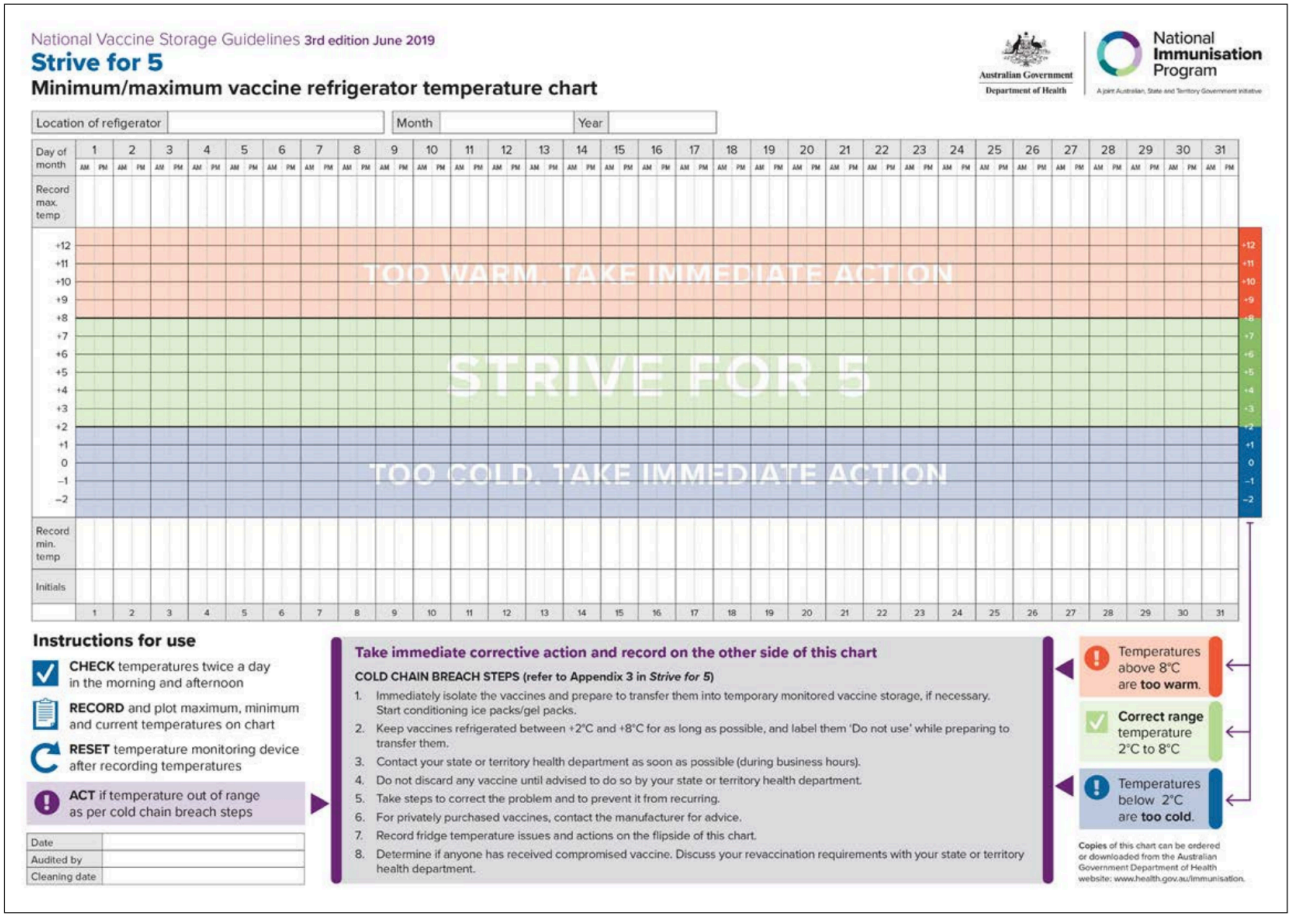
Source: National vaccine storage guidelines – Strive for 5 - Appendix 2

Resources: Fridge Temperature Chart

Copies of this chart can be ordered or downloaded from the Australian Government Department of Health website: www.health.gov.au/immunisation.



Source: National vaccine storage guidelines – Strive for 5 - Appendix 5

Resources: Posters and Stickers

National Vaccine Storage Guidelines
3rd edition June 2019
Strive for 5

Australian Government
Department of Health

National Immunisation Program
A joint Australian, State and Territory Government Initiative

! STOP

Do not open door until you know which vaccines you need and where they are located.

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

Read and record the refrigerator temperature twice daily and reset the thermometer.

Is the refrigerator temperature between +2°C and +8°C?

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

Do not use or discard vaccines
unless advised to do so by your state or territory health department.

Person responsible for vaccine management	
Back-up person for vaccine management	
Number for reporting a cold chain breach	
Number for state or territory health department	

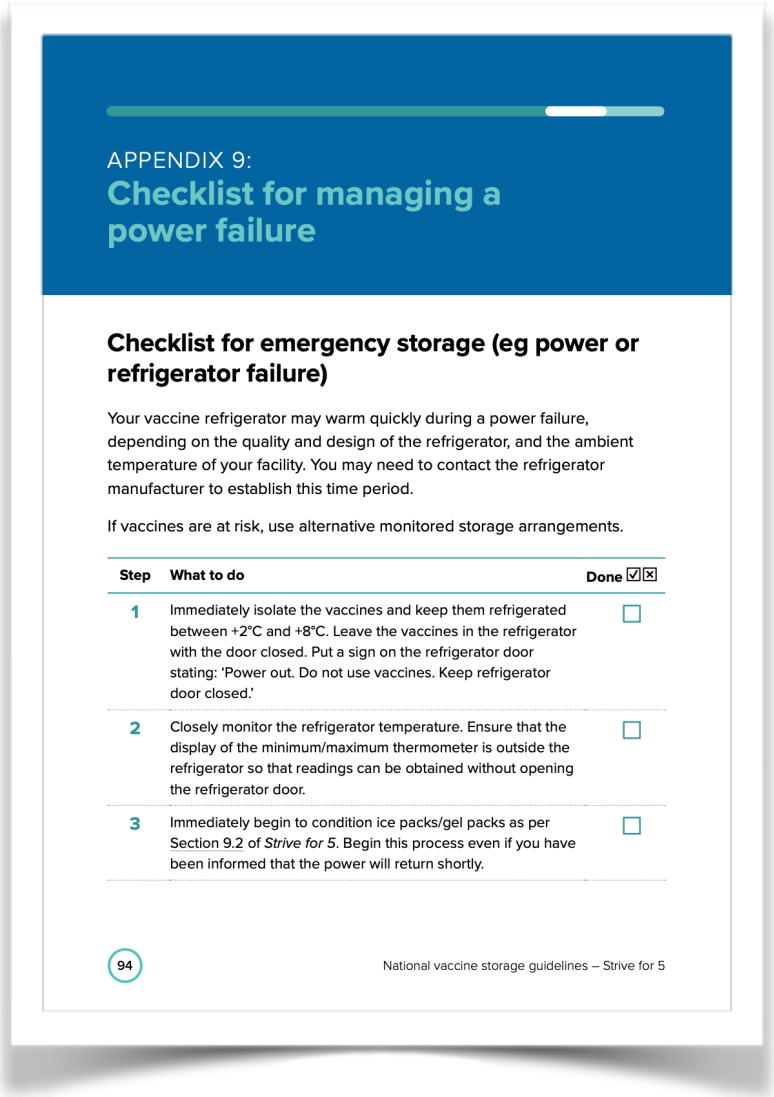
Date updated

Copies of this poster can be ordered or downloaded from the Australian Government Department of Health website: www.health.gov.au/immunisation.

These stickers can be ordered from the Australian Government Department of Health website: www.health.gov.au/immunisation

Source: National vaccine storage guidelines – Strive for 5 - Appendix 6

Resources: Managing a Power Failure



APPENDIX 9:

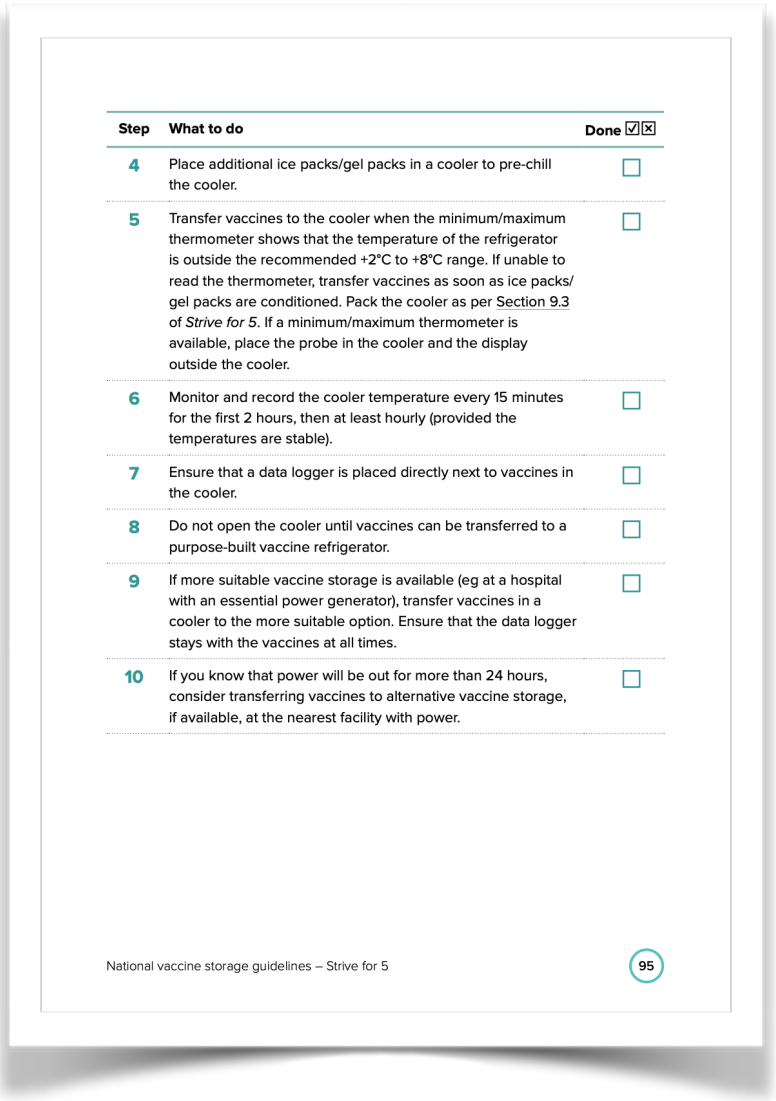
Checklist for managing a power failure

Checklist for emergency storage (eg power or refrigerator failure)

Your vaccine refrigerator may warm quickly during a power failure, depending on the quality and design of the refrigerator, and the ambient temperature of your facility. You may need to contact the refrigerator manufacturer to establish this time period.

If vaccines are at risk, use alternative monitored storage arrangements.

Step	What to do	Done ☑☒
1	Immediately isolate the vaccines and keep them refrigerated between +2°C and +8°C. Leave the vaccines in the refrigerator with the door closed. Put a sign on the refrigerator door stating: 'Power out. Do not use vaccines. Keep refrigerator door closed.'	☐
2	Closely monitor the refrigerator temperature. Ensure that the display of the minimum/maximum thermometer is outside the refrigerator so that readings can be obtained without opening the refrigerator door.	☐
3	Immediately begin to condition ice packs/gel packs as per Section 9.2 of *Strive for 5*. Begin this process even if you have been informed that the power will return shortly.	☐



Step	What to do	Done ☑☒
4	Place additional ice packs/gel packs in a cooler to pre-chill the cooler.	☐
5	Transfer vaccines to the cooler when the minimum/maximum thermometer shows that the temperature of the refrigerator is outside the recommended +2°C to +8°C range. If unable to read the thermometer, transfer vaccines as soon as ice packs/gel packs are conditioned. Pack the cooler as per Section 9.3 of *Strive for 5*. If a minimum/maximum thermometer is available, place the probe in the cooler and the display outside the cooler.	☐
6	Monitor and record the cooler temperature every 15 minutes for the first 2 hours, then at least hourly (provided the temperatures are stable).	☐
7	Ensure that a data logger is placed directly next to vaccines in the cooler.	☐
8	Do not open the cooler until vaccines can be transferred to a purpose-built vaccine refrigerator.	☐
9	If more suitable vaccine storage is available (eg at a hospital with an essential power generator), transfer vaccines in a cooler to the more suitable option. Ensure that the data logger stays with the vaccines at all times.	☐
10	If you know that power will be out for more than 24 hours, consider transferring vaccines to alternative vaccine storage, if available, at the nearest facility with power.	☐

Source: National vaccine storage guidelines – Strive for 5 - Appendix 9

Resources: Mobile/Outreach clinics

APPENDIX 8:

Checklist and temperature chart for mobile or outreach immunisation clinics, or emergency storage of vaccines

Checklist for mobile/outreach immunisation clinics or emergency storage of vaccines

Print this checklist and store it along with the following items for your cooler:

- minimum/maximum thermometer
- temperature chart
- packing material.

Step	What to do	Done ☑☒
1	Remove ice packs/gel packs from the freezer: • Place the number of packs you require for your cooler on the bench to 'sweat' (see *Strive for 5* Section 9.2 for information about conditioning ice packs/gel packs). • Place the ice packs/gel packs in your cooler to chill the inside of the cooler.	☐ ☐
2	Remove the ice packs/gel packs from the cooler and place insulating material (bubble-wrap or polystyrene chips) in the bottom of the cooler.	☐
3	Reset the minimum/maximum thermometer and insert the thermometer probe inside an empty vaccine box with the product information intact.	☐
4	Make sure the minimum/maximum temperature is between +2°C and +8°C at the time the vaccines are placed in the cooler.	☐
5	**YOU ARE NOW READY TO MOVE YOUR VACCINES INTO THE COOLER.** Place the vaccine stock in the cooler with the box containing the thermometer probe in the centre. **Note:** All vaccines should remain in their original packaging until they are administered or returned to a purpose-built vaccine refrigerator — this prevents damage from exposure to light and ambient temperature. Surround the vaccines with packing material and place conditioned ice packs/gel packs on the top before closing the cooler. Ensure that vaccine stock is not in direct contact with the ice packs/gel packs, to minimise risk of freezing. Close the cooler lid and fix the digital thermometer display to the outside of the cooler. Keep the cooler out of direct sunlight.	☐ ☐
6	Record the date, time, and minimum and maximum temperatures on the temperature chart now. Then record temperatures at the following times: • every 15 minutes for the first hour • hourly thereafter, provided the temperatures are stable. **Note:** Freezing vaccines occurs most commonly in the first 2 hours of storage in a cooler.	☐
7	Ensure that ice packs/gel packs do not become displaced and have direct contact with vaccines — this may freeze the vaccines and render them unviable. Remove vaccines from the cooler only as they are required	☐
8	Only move vaccines back to a purpose-built vaccine refrigerator in which the temperature is between +2°C and +8°C.	☐

Source: National vaccine storage guidelines – Strive for 5 - Appendix 8

Resources: Mobile/Outreach clinics

Temperature chart for mobile or outreach immunisation clinics, or emergency storage of vaccines

Date	Monitoring times P = vaccines packed A = arrived at clinic D = during clinic B = arrived at base	Time	Minimum temperature	Maximum temperature	Temperatures outside +2°C to +8°C Yes/No If yes, must be notified*	Signature

*State or territory health department contact number	

Source: National vaccine storage guidelines – Strive for 5 - Appendix 8

Resources: RACGP Standards 5th Edition

Continue the conversation….

There will be a hot Topic post in the group's feed to ask further questions

Join our Facebook Group **"For the Love of Healthcare"**

Request to join here https://www.facebook.com/groups/346537095914349/

APNA National Conference Sponsorship

21- 23 May, Sydney International Convention Centre

We will be sponsoring 3 x members of ***For the Love of Healthcare*** to attend the APNA National Conference in 2020.

Be sure to join our group as details on how to enter will be announced in the group's feed in the coming weeks.

Further details to be posted in **"For the Love of Healthcare"** group

Request to join here https://www.facebook.com/groups/346537095914349/

Special Guest Webinar Series

Wednesday April 1st, 2020 at 12:30pm AEDT

Understanding Your Employment Foundations in Private Practice

Hosted by George Sotoris

HEALTH INDUSTRY EMPLOYMENT SERVICES

Further details to be posted in **"For the Love of Healthcare"** group

Request to join here https://www.facebook.com/groups/346537095914349/

Thank you for participating!

Got a question?
Email: md@hotdoc.com.au