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VICTORIAN-TASMANIAN ALLIANCE

An Australian Government Initiative

Vaccine and Cold Chain Management

The content is current at the time of presentation – August 2019

We acknowledge the Aboriginal and Torres Strait Islander Peoples as the Traditional Owners of the lands. We wish to pay our respects to their Elders – past, present and emerging – and acknowledge the important role Aboriginal and Torres Strait Islander people continue to play within our community.

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This webinar has been developed by Eastern Melbourne PHN on behalf of the Victorian and Tasmanian PHN Alliance, which is a collective platform for the seven PHNs in Victoria and Tasmania.

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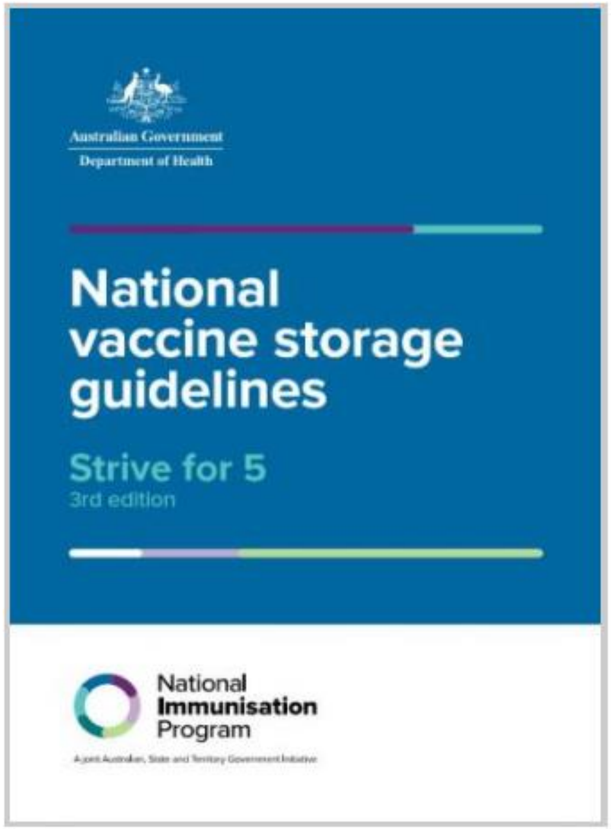
RACGP Standards for general practice 5th edition and

the National vaccine storage guidelines: Strive for 5 (3rd edition) .

Objectives

- Recognise and apply the principles of safe vaccine storage management
- Identify the processes required to ensure that cold chain is maintained
- Implement a cold chain breach or power failure protocol including undertaking the required processes and reporting

National Vaccine Storage Guidelines



https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5

What is cold chain?

- A system of transporting and storing vaccines within the safe temperature range of 2 to 8 °C
- Begins from point of manufacture until administration to the patient
- Vaccines become less effective or destroyed if they are:
  - frozen
  - affected by heat
  - exposed to direct sunlight or UV light

Why is cold chain important?

- Health professionals have a responsibility to ensure that clients receive effective vaccines
- Vaccines are expensive and may need to be discarded if cold chain is not maintained
- Reducing risk and liability

Principles of safe vaccine storage

- Store vaccines in a purpose built vaccine fridge (PBVF) with data logger
- Nominate a clinical staff member with primary responsibility for vaccine management plus a back-up person
- Have documented practice policies and procedures
- Always **store vaccines in original boxes** in the vaccine fridge
- Have alternative temporary cooler storage and monitoring equipment
- Complete an annual vaccine storage self-audit
- Ensure twice daily vaccine fridge min/max temperature monitoring and recording
- Do not discard vaccines until advice is obtained

Practice policies and procedures

- Ordering and receipt of vaccines
- Packing of the vaccine fridge
- Daily monitoring and recording of the vaccine fridge temperature
- Managing a power failure
- Packing a portable cooler
- Actions in event of cold chain breach
- Appropriate disposal of vaccines
- Maintenance of vaccine fridge and monitoring equipment, and
- Annual audit of processes and equipment

Practice policies and procedures-Strive for 5 (3rd Ed.)

- Downloading and storing of data logger records
- Monitoring of vaccines when packed in a cooler
- Staff education of vaccine management
- Strive for 5 checklists
    - Appendix 8- packing and transporting vaccines to a clinic or in an emergency
    - Appendix 9- managing cold chain in a power failure

Accreditation requirements

Criterion GP6.1 – Maintaining vaccine potency

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

- **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*

Accreditation requirements

Criterion GP6.1 – Maintaining vaccine potency

- **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

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

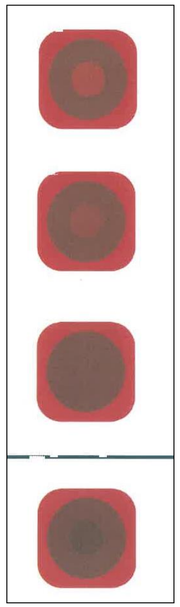
Vaccine delivery

- Delivery of government stock will have single use cold chain indicators with alarm profiles
- All staff should know their responsibilities for vaccine delivery
  - Check correct delivery
  - Check cold chain indicator and record display
  - Transfer vaccines to vaccine fridge
  - Discard single use cold chain indicator
- Person responsible for vaccine management should be made aware of delivery
- Vaccines must be kept in original packaging and new stock rotated to back

Victoria - cold chain indicator

Tasmania – cold chain indicators

Time-temperature indicator label



Satisfactory for use

Satisfactory for use

Satisfactory for use

Do not use (Centre will continue to darken even beyond this point; until it becomes black)

Batch numbers

- Practices must have a record of batch numbers of vaccines
- Records can include
    - complete a manual spreadsheet
    - keep delivery docket
    - enter batch number in the immunisation screen of the patient’s file

Vaccine storage requirements

“ Purpose-built vaccine refrigerators are the only suitable option for vaccine storage”

“At a minimum, all vaccine refrigerators must have a basic data logger and thermometer to continuously monitor refrigerator temperatures.”

Strive for 5 (3rd edition)

Vaccine storage – No domestic fridges

Purpose built

Not domestic

Not bar

Vaccine storage – digital thermometers

- Use a portable digital thermometer if fridge min/max does not have battery support
- Always use when packing a cooler
- Place the probe in a used vaccine box with product information leaflet

Data Loggers

Data Loggers

- Set to record at 5 minute intervals
- Download weekly or in the event of a temperature fluctuation
- Retain data logger records as per medical record policy
- Use downloaded data when reporting a cold chain breach
- Map variations in PBVF internal temperatures
- Compare data to assess accuracy of other data loggers and thermometers

Vaccine fridge requirements

- A reliable, well-maintained PBVF of adequate size
- Minimum and maximum temperatures of the fridge must be recorded twice daily. Reset the thermometer after each reading
- Temperature records are retained for the same time as medical records
- Use the fridge for vaccine and medication storage only

Vaccine fridge requirements

- Do not overstock the fridge.
- The fridge must be in a secure area and away from direct sunlight and heat
- Consider power source reliability
- Store vaccines with the earliest expiry at the front
- A vaccine map may be useful

Vaccine transportation

- Vaccines may need to be moved due to offsite vaccinations or power outage
- Cold chain of 2 to 8 °C must be maintained during transportation. See Strive for 5 guidelines on coolers and ice packs
- Conditioning of ice packs is required to decrease the risk of freezing vaccines
- Consider a mock run. Keep a list of instructions and bubble wrap in the cooler. Consider cooler space
- A probe thermometer, and preferably a data logger, is needed to monitor the cooler temperature hourly
- Temperatures monitored and recorded every 15 minutes for the first 2 hours and then at least hourly

Cold chain breach

- Exposure of vaccines to temperatures outside the range of 2 - 8 °C
- A temperature up to 12°C is acceptable for periods less than 15 minutes
- Common causes of cold chain breaches:
  - Fridge door left open
  - Vaccine left on bench
  - Fridge plug disconnected
  - Fluctuating internal fridge temperatures
  - Poor staff training
- Report a cold chain breach if in doubt

Single-event breach exception – Victoria

- In Victoria, you do not need to complete a Cold Chain Breach Report form for:
  - vaccine that is exposed, on a **single occasion**, to a temperature of **greater than 8°C** and **less than 25°C for less than 6 hours**
- BUT, the following actions must be taken:
  - determine the cause of the breach and reduce the risk of a recurrence
  - record the date and duration of the breach and any actions taken
  - identify the vaccine exposed to a single-event breach by **marking it with a pen**
- For a subsequent breach:
  - report immediately
  - alert staff and
  - put a 'Do NOT Use Vaccines' sign on fridge.

Cold Chain Breach (CCB) Protocol

- Isolate the vaccines and place a ‘Do NOT Use Vaccines’ sign on the vaccine fridge. Do not discard any vaccines. Wait on advice from the health department.
- Keep vaccines refrigerated between 2 to 8°C.
- **In Victoria** complete the CCB report form as soon as possible and email immunisation@dhhs.vic.gov.au or fax 1300 768 088 to the Immunisation Section Victoria. For urgent advice telephone 1300 882 008.
- **In Tasmania** contact the Department of Health & Human Services, Communicable Diseases Prevention Unit Public Health Hotline 1800 671 738 as soon as possible.
- For privately purchased vaccines, contact the manufacturer.
- Determine the cause of the breach and reduce the risk of recurrence.

Power failure contingency plan

- Practices must have a contingency plan including alternative storage for vaccines
- The plan needs to be documented in the vaccine and cold chain management policy
- Practice the contingency plan

Power failure

- Check with the power company
- Keep vaccines refrigerated at 2 - 8 °C and put a sign on the refrigerator: '***Power out. Do not use vaccines. Keep refrigerator door closed***'
- Closely monitor the fridge temperature
- Glass fridge doors can be covered with an insulating material
- Cold mass placed in empty spaces, not touching vaccines
- If power is likely to be off for more than 4 hours, the power failure contingency plan may need to be implemented quickly.
- Contingency plans may involve an emergency power source, eskies or off-site fridge
- You may need a battery operated probe thermometer

Power restoration

- Record the refrigerator temperature
- Reset the temperature
- Ensure the refrigerator temperature is 2 - 8 °C before returning vaccines
- If a cold chain breach has occurred, report as soon as possible
- Monitor refrigerator closely until stable
- Document the incident including the cause, duration and action taken
- Review the incident
- Strive for 5 Appendix 8 & 9 checklists for packing and monitoring a cooler and managing a power failure

Patients bringing vaccines into the practice

- Patients need to be educated on the safe storage of purchased vaccines at a temperature between 2 and 8°C to maintain vaccine effectiveness.
- Privately purchased vaccines should be:
    - handed to reception staff as soon as possible
    - labelled with the patient's name
    - placed in the vaccine fridge
- Any vaccine stored for a patient should NOT be swapped and administered to another patient

Frequently asked questions

1. Is the temperature uniform throughout the refrigerator?
2. If I have a purpose-built vaccine refrigerator do I still need a minimum/maximum thermometer?
3. Can a receptionist record the fridge temperature?

Check Strive for 5 Appendix 4: FAQs

Summary

- Cold chain is important as it can affect the potency of vaccines
- Observe the *Strive for 5* National Vaccine Storage Guidelines
- Ensure your practice has effective, current, documented vaccine cold chain storage policies and procedures including:
    - vaccine delivery
    - cold chain breach processes
    - a contingency plan for a power outage
    - staff orientation and training

Resources

- National vaccine storage guidelines: Strive for 5 (3rd edition)

  https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5
- RACGP Standards for general practice 5th edition

  https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition
- Tasmanian Department of Health and Human Services – Immunisation

  https://www.dhhs.tas.gov.au/publichealth/communicable_diseases_prevention_unit/immunisation/information_for_immunisation_providers
- Victorian Department of Health & Human Services – Immunisation including Cold Chain Breach Form

  https://www2.health.vic.gov.au/public-health/immunisation
- Melbourne Vaccination Education Centre (MVEC)

  https://mvec.mcri.edu.au/

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