

Cold Chain Monitoring in General Practice



HOSTED BY
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**aapm**

Australian Association of
Practice Management
excellence in healthcare management

AAPM Approved 2024
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Wed 4th September
12:30pm AEST

The background is an abstract composition of textures. On the left, there is a vibrant green area with a fine, pebbled texture. On the right, there are warm orange and brown tones with a more fluid, marbled appearance. A large, semi-transparent white rectangular area is centered over the image, serving as a backdrop for the text.

**In the spirit of reconciliation, HotDoc
acknowledges the Traditional Custodians of
country throughout Australia and their
connections to land, sea and community.**

**We pay our respect to their elders past and
present and extend that respect to all
Aboriginal and Torres Strait Islander peoples
today.**

Before we begin -

- This session is being recorded & you will be sent a link 4-6 hours after this session has concluded with the recording & resources.
- Use the Q&A tool on your screen to submit a questions through the session & we will address at the end. If we don't get a chance to address during the LIVE session, we will reach out to you afterwards to discuss further.
- In the “related content” you'll find our further feedback form.
- Your CPD certificate will be accessible at the 40 minute mark, you can access via the certificate icon on your console.
- Have a play around with the console/ icons on your screen, it's an interactive experience.
- Please take some time to complete our feedback survey to let us know what you thought of today's session.



The background of the slide is a light gray gradient with several realistic water droplets of various sizes scattered across it. The droplets have highlights and shadows, giving them a three-dimensional appearance. The main title is centered in a large, bold, black sans-serif font.

COLD CHAIN MONITORING IN GENERAL PRACTICE

PRESENTED BY SARA DREW

RN | IPN | GRAD CERT IPC |
DIP BUSINESS | DIP MANAGEMENT | CERT IV TAE |

GRAD DIP NEONATAL NURSING

ACKNOWLEDGEMENT


We would like to acknowledge the traditional owners of country throughout Australia and their continuing connection to land, sea and community.

We pay our respects to them, their cultures, and to elders past and present.





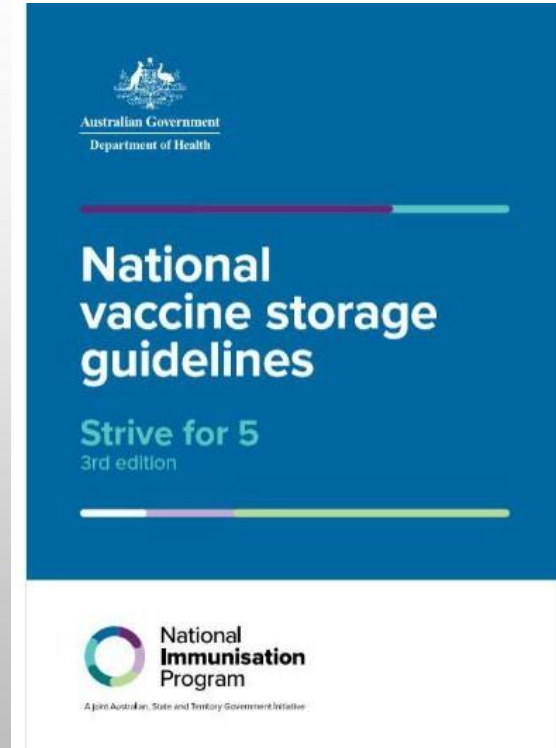
OBJECTIVES

- Recognise and apply principles of safe vaccine storage management
 - Identify processes to ensure cold chain monitoring and management
 - Implement protocol to manage any suspected cold chain breach
- 

NATIONAL VACCINE STORAGE GUIDELINES

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

Link is in the “related content” section on your screen



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

NOTE: THE COLD CHAIN IS ONLY AS STRONG AS THE WEAKEST LINK

WHY IS COLD CHAIN MANAGEMENT IMPORTANT?

- Health professionals have a responsibility to ensure clients receive effective vaccines
- Vaccines are expensive and can be in short supply. If cold chain is not maintained, they may need to be discarded
- To reduce risk and liability



WHAT IS A COLD CHAIN BREACH?

- A 'cold chain breach' occurs when vaccine storage temperatures deviate outside the recommended range of +2°C to +8°C. The optimal storage temperature for vaccines is +5°C.
- Vaccines are delicate substances that can become less effective or destroyed if:
 - Frozen
 - Exposed to direct sunlight or UV light, including fluorescent light
 - Allowed to get warm

IF WE DON'T PROTECT OUR VACCINES, THEY WON'T PROTECT OUR COMMUNITY!

WHAT IS THE POTENTIAL IMPACT OF A COLD CHAIN BREACH?

- Patient recall and revaccination
- Administration of ineffective medications
- Loss of faith in the organisation
- Litigation
- Staff hours spent on patient recall and management of incidents
- Reduction in supply of potent vaccines available for use
- Significant cost of replacement of inactive vaccines



SAFE VACCINE STORAGE MANAGEMENT

- All vaccines must be stored and managed according to National Vaccine Storage Guidelines 'Strive for 5' (3rd edition)
- Store vaccines in a purpose-built vaccine fridge with data logger
- Always store vaccines in original boxes in the vaccine fridge
- Have documented practice policies and procedures
- Have alternative temporary cooler storage and monitoring equipment
- Monitor fridge temperatures twice daily during operating hours and record on an approved temperature chart
- Complete an annual vaccine storage self-audit
- Do not discard vaccines until advice obtained

COLD CHAIN MANAGEMENT IS **EVERYONE'S** RESPONSIBILITY



PRACTICE POLICIES & PROCEDURES

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

STRIVE FOR 5 (3RD EDITION)

- Downloading and storage 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

DELIVERY OF VACCINES

- **All staff** need to know their responsibilities for vaccine delivery. This includes:
 - Checking correct delivery
 - Checking cold chain indicator and record display
 - Transferring vaccines to vaccine fridge
 - Discarding single use cold chain indicators
- Delivery of government stock contains a single use cold chain indicator
- Persons responsible for vaccine management in practice should be made aware of delivery
- Vaccines must be kept in original packaging with older stock rotated to the front and new to the back



COLD CHAIN INDICATORS

TagAlert



Cold chain indicator



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)

RECORDING BATCH NUMBERS

- General practices must have a record of batch numbers of all vaccines
- Records can include:
 - Delivery dockets
 - A manual spreadsheet
 - Entering batch numbers into the immunisation screen in the patient's file

VACCINE STORAGE



- 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 REQUIREMENTS

- No not overstock
- Air gaps around all walls
- Ensure within temperature range
- Data logger positioned in the middle of the refrigerator
- Baskets used to facilitate air flow
- No stock on bottom shelf
- 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
- Consider a vaccine map



DIGITAL THERMOMETERS

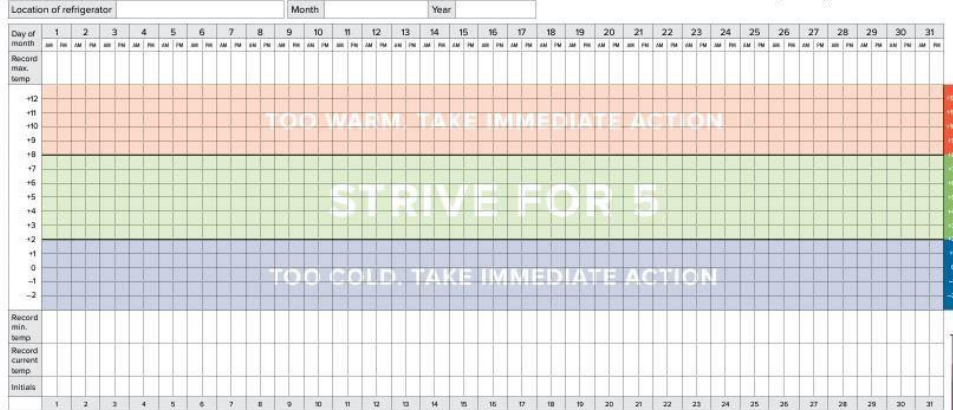


- Record min and max temperatures twice daily
- Reset the min/max thermometer after reading
- Record any events, e.g. deliveries on the temperature monitoring chart
- Follow cold chain breach protocol if temperature outside 2 to 8 degree Celsius
- Use a portable digital thermometer if fridge min/max does not have battery support
- Always use when packing a cooler
- Place portable in a used vaccine box with the product information leaflet

VACCINE FRIDGE MONITORING CHART

National Vaccine Storage Guidelines 3rd edition June 2019

Strive for 5 Minimum/maximum vaccine refrigerator temperature chart



Instructions for use

- CHECK** temperatures twice a day in the morning and afternoon
- RECORD** and plot maximum, minimum and current temperatures on chart
- RESET** temperature monitoring device after recording temperatures
- ACT** if temperature out of range as per cold chain breach steps

Take immediate corrective action and record on the other side of this chart

COLD CHAIN BREACH STEPS (refer to Appendix 3 in Strive for 5)

- Immediately isolate the vaccines and prepare to transfer them into temporarily monitored vaccine storage, if necessary. Start conditioning ice pack/gel packs.
- Keep vaccines refrigerated between +2°C and +8°C for as long as possible, and label them 'Do not use' while preparing to transfer them.
- Contact your state or territory health department as soon as possible (during business hours).
- Do not discard any vaccine until advised to do so by your state or territory health department.
- Take steps to correct the problem and to prevent it from recurring.
- For privately purchased vaccines, contact the manufacturer for advice.
- Record fridge temperature issues and actions on the flipside of this chart.
- Determine if anyone has received compromised vaccine. Discuss your revaccination requirements with your state or territory health department.

- Temperatures above 8°C are too warm.
- Correct range** temperature 2°C to 8°C
- Temperatures below 2°C are too cold.

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

Vaccine storage troubleshooting

Date	Time	Max./min. temperatures	Problem	Action taken	Results	Initials

<https://www.health.gov.au/sites/default/files/documents/2022/07/national-vaccine-storage-guidelines-strive-for-5-vaccine-fridge-temperature-chart-poster-strive-for-5-vaccine-fridge-temperature-chart-poster.pdf>

DATA LOGGERS

- All vaccine fridges must have a data logger and are continuously monitored via the logger
- 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
- Compare data to assess accuracy of other data loggers and thermometers

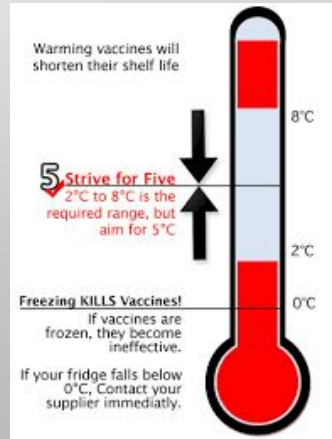


VACCINE TRANSPORTATION

- Clinics may conduct off site vaccinations or have power outages requiring vaccines to be moved
- Cold chain of 2 to 8 degree Celsius must be maintained during transportation
- Strive for 5 has guidelines on coolers and ice packs
- Conditioning of ice packs is required to decrease the risk of freezing vaccines
- Keep a list of instructions and bubble wrap in the cooler
- Coolers must be large enough to fit all vaccines
- A probe thermometer, and preferably a data logger is needed to monitor the cooler temperature hourly
- Temperatures are monitored and recorded **every 15 minutes for the first 2 hours, then hourly**

COLD CHAIN BREACH

- Cold chain breach occurs when vaccines are exposed to temperatures outside the 2-8 range
- A temperature up to 12 degree Celsius is acceptable for periods of less than 15 minutes
- Ensure your clinic has a CCB protocol in place



POWER FAILURE

- Practices must have a contingency plan including alternative storage for vaccines and document in the vaccine and cold chain management policy
- Immediately quarantine vaccines, keep fridge door closed and attach sign ***'Do Not Use Vaccines, power out- keep door closed'***
- Closely monitor fridge temperature via the data logger readings
- Glass fridge doors can be covered with an insulating material
- Place cold mass in empty spaces-not touching vaccines
- Check with the power company, if power is likely to be off more than 4 hours, contingency plan may need to be implemented
- If temperatures progress towards 8-degree Celsius, implement contingency plan
- Plan may involve an emergency source cooler or off-site fridge
- A battery-operated probe thermometer may be needed
- Practice!



WHEN POWER RETURNS



Adapted from: [unreadable]

- Record the fridge temperature
- Reset the temperature
- Ensure fridge temperature is 2 to 8 degree Celsius before returning vaccines
- If CCB has occurred report ASAP
- Monitor fridge closely until stable
- Document incident including cause, duration and actions taken
- Refer to Strive for 5 appendix 8 and 9 for packing and monitoring a cooler and managing a power failure

COMMON ISSUES RESULTING IN COLD CHAIN BREACHES

- Overstocking
- Variety of fridges and data loggers
- Irregular servicing of vaccine fridges
- Staff unsure of quarantine procedures
- Transporting from pharmacy to clinic
- Fridge door left open
- Vaccines left on the bench
- Fridge plug disconnected
- Poor staff training
- Fluctuating internal fridge temperature

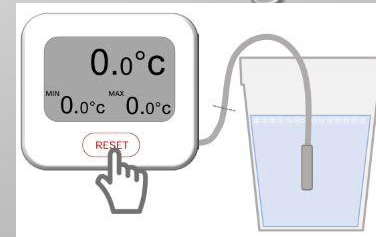
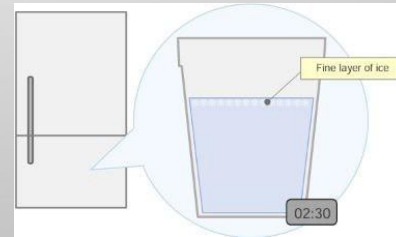
If in doubt- report a cold chain breach

TEMPERATURE MONITORING REQUIREMENTS

- Before removing vaccines for administration
- Twice daily (every day the practice is open, including weekends)
- Once a week
- Annually –slush test

https://nswhealth.Seertechsolutions.Com.Au/public_content/HETICP/HETI/ccm_minmax_batterychange_v02/ccm_minmaxbatterychange_v02.Pdf

- If a potential breach is identified



PATIENT VACCINES AND COLD CHAIN



- Patient education is essential regarding the safe handling and storage of purchased vaccines
- Privately purchased vaccines must be:
 - Handed to reception staff asap
 - Labelled with patients name
 - Placed in vaccine fridge
- Vaccines stored for a patient should not be swapped or administered to another patient

STATE AND TERRITORY REQUIREMENTS

Victoria has updated the cold chain management policy (Aug 23)

- Immunisation providers must report all cold chain breaches for government funded vaccines
- Use the new cold chain breach report form to report vaccine cold chain breaches.
- Exposed to light (if removed from packaging and exposed to direct sunlight or ultraviolet (UV) light, including fluorescent light).
- Additional training required:
[HTTPS://VIC-IMMUNISATION-LEARNING.COM/IMMUNISATION/](https://vic-immunisation-learning.com/immunisation/)
- NSW <https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management.aspx>
 - additional training required
 - https://nswhealth.seertechsolutions.com.au/public_content/HETICP/HETI/CCMWebv3/story.html



RACGP ACCREDITATION REQUIREMENTS

Maintaining vaccine potency

Criterion GP6.1

- **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*.
- **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.

TIPS & TRICKS



- If in doubt...quarantine
- Ensure the fridge door is always closed
- Angle the fridge up slightly at the front to facilitate auto-closing of the door
- Only remove vaccines for immediate use
- Check temperature before opening door every time
- Check expiry dates and use oldest first
- Ensure a valid vaccine order is in place prior to removing vaccine
- FAQ in Strive for 5 appendix 4

TAKE HOME MESSAGES

*REMEMBER:
COLD CHAIN
MANAGEMENT IS
EVERYONE'S
BUSINESS*



Observe *Strive for 5* National Vaccine Storage Guidelines



State and Territory requirements



Implement mock runs and test procedures



Cold chain is essential to ensure potency of vaccines



Ensure documented, current and effective vaccine cold chain storage policies and procedures are in place including:

Vaccine
delivery CCB
processes
Contingency plans 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>
- State and territory health departments:
 - 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>
 - Queensland - <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/immunisation/service-providers/cold-chain-breaches>
 - NSW - <https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management.aspx>
 - SA- <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs+and+practice+guidelines/immunisation+for+health+professionals/vaccine+ordering+and+storage/vaccine+storage>
 - WA - www.health.wa.gov.au/~media/Corp/Documents/Health-for/Communicable-Diseases/Guidelines/OD355-Vaccine-Cold-Chain-Guidelines.pdf
 - NT - <https://health.nt.gov.au/professionals/centre-for-disease-control/immunisation-program>
 - ACT - <https://www.act.gov.au/health/providing-health-care-in-the-act/treatment-and-clinical-information/vaccination/cold-chain-monitoring>

 **HotDoc** | WEBINAR

Team Collaboration in General Practice: Mastery & Purpose

HOSTED BY



Dr Jaspreet Saini
GP & CEO, Healthicare



Riwka Hagen
Medical Business Services

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Tuesday
24th September
7:30pm AEST

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Team Collaboration in General Practice: Culture & Leadership

HOSTED BY



Dr Jaspreet Saini
GP & CEO, Healthicare



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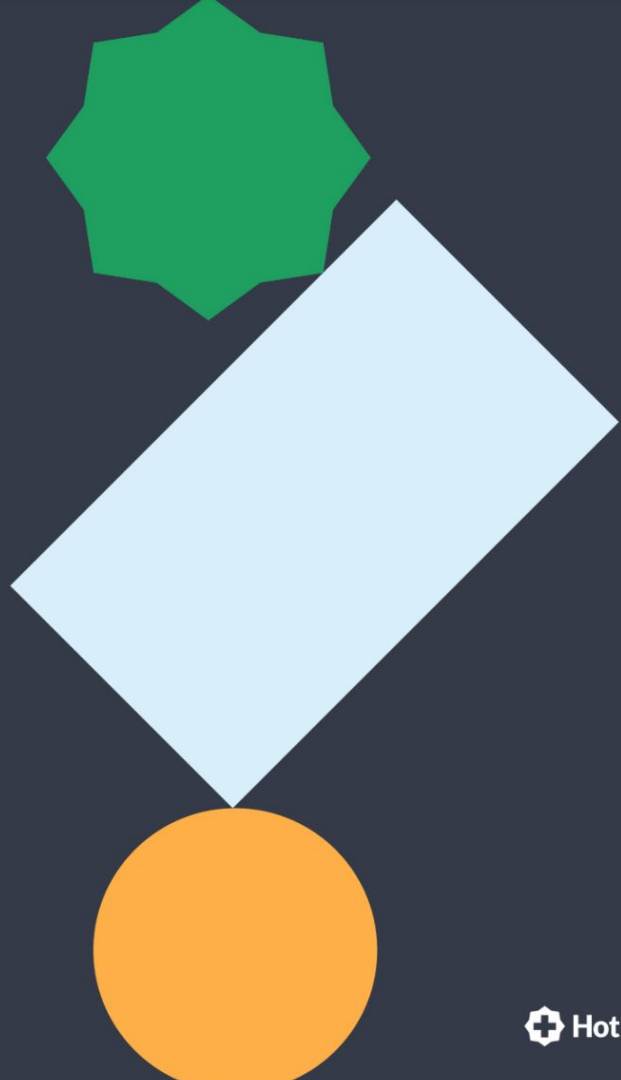
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Thursday
31st October
7:30pm AEDT

Questions





Thanks for watching!

Find out more about HotDoc here:
practices.hotdoc.com.au