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COLD CHAIN BREACH

To ensure clients receive effective and potent vaccines, immunisation providers must follow the principles of safe vaccine storage management.

Cold chain is the system of transporting or storing vaccine within the safe temperature range of +2°C to +8°C (strive for +5°C – the midway point).

A cold chain breach is:

- exposure of vaccines to temperatures outside the recommended range of +2°C to +8°C, excluding fluctuations up to +12°C lasting no longer than 15 minutes when restocking, cleaning the fridge or stock taking
- exposure to light as vaccine has been removed from the packet and the glass fridge door allows light to penetrate.

Impact of Cold Chain Breach on the Primary Care System.	Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in the community and poor protection against disease. If community members have to be revaccinated after receiving vaccines that may have been compromised and have reduced efficacy, it can lead to a loss of confidence in vaccinations and immunisation providers.
Cold chain breach protocol (what to do if you have a cold chain breach)	Immunisation providers must report all cold chain breaches for all government funded vaccines that have been exposed to temperatures outside the recommended range of +2°C to +8°C. This excludes fluctuations up to +12°C lasting no longer than 15 minutes when restocking, cleaning the fridge or stock taking. 1. Immediately isolate the vaccines and prepare to transfer them into temporary monitored vaccine storage, if necessary. Start conditioning ice packs/gel packs. 2. 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. 3. Contact your state or territory health department as soon as possible (during business hours). 4. Do not discard any vaccine until advised to do so by your state or territory health department. 5. Take steps to correct the problem and to prevent it from recurring. 6. For privately purchased vaccines, contact the manufacturer for advice.
Where to report a cold chain breach	Cold Chain Breach Reporting Form

Information required when reporting a cold chain breach	• Date and time of the breach • Reason for the cold chain breach (if known) and whether it has been rectified • Brand and size of refrigerator in which the vaccines are stored (e.g. ABC brand; 381 litres) • Information for the breach period downloaded from your data logger. All refrigerators should have continuous data logging. Download the data before contacting your state or territory health department • Minimum and maximum temperature readings while the vaccines were exposed to temperatures outside the +2°C to +8°C range • Length of time the refrigerator temperature was outside the +2°C to +8°C range • Date the refrigerator was last serviced • Whether the vaccine refrigerator has had any maintenance issues recently • Length of time that these issues have been occurring • Type and number of vaccines in the current stock • Expiry date of the vaccines • Whether any vaccines have bee • Whether all vaccines are in their original packaging • Whether anybody has been vaccinated with potentially affected vaccines • Whether the vaccines have previously been exposed to temperatures outside the +2°C to +8°C range • Whether there is any visible damage to vaccines (e.g. wet or soggy packaging).
What to do if power failure occurs	Power failures occur for many reasons. How a power failure is managed in your organisation may depend on the cause of the power outage, whether prior notice was given and the time of day the outage occurs. The safety and wellbeing of staff should always be considered when managing power failures, particularly when they occur outside business hours. Some power networks send letters or provide text message alerts for power outages. Check with your local power networks whether this service is available in your state or territory. Always have a back-up plan and alternative storage if a power failure occurs. This will allow vaccines to continue to be stored between the recommended temperatures of +2°C and +8°C, thereby minimising vaccine loss and disruption to your facility's activities. Alternative vaccine storage in the event of a power failure may include any of the following: • a back-up power supply (e.g. generator or battery/solar back-up) • a monitored refrigerator offsite (e.g. at a local hospital or pharmacy) — ensure that an agreement has been put in place with the relevant organisation before the event, and also consider that this organisation may be affected by the same power failure • a cooler — each facility should ensure that they have enough coolers for an emergency. If using a cooler, ensure that it will be large enough to accommodate: • all vaccines, loosely packed • ice packs or gel packs

	• insulating material (e.g. polystyrene chips or bubble-wrap) • a minimum/maximum thermometer or data logger. Each immunisation facility should practise implementing its back-up plan, including practising packing vaccines into alternative storage, to ensure that the plan will work in a real power failure situation. Keep in mind that there may be only a short window of time before the vaccine refrigerator temperature rises above +8°C — suitable alternative storage must be ready quickly. Ensure that the back-up plan is clearly documented in the vaccine management protocol. The information provided here is a general guide only and may not be applicable to each facility — careful planning and practice will ensure that your back-up plan will work for your facility.
Additional resources	• National Vaccine Storage Guidelines "Strive for 5" • Australian Immunisation Handbook • Victoria Cold chain breach reporting (health.vic.gov.au) • NSW Vaccine storage and cold chain management - Immunisation programs (nsw.gov.au) • Procedure - Notifiable Event Reporting Requirement's for Commissioned Providers Procedure • notifiable event - Clinical Reporting (murrayphn.org.au)
Education for Clinical and non-clinical staff	Department of Health Victoria Immunisation eLearning Modules Victorian Immunisation Learning Hub (vic-immunisation-learning.com)

For further information or support please contact the Primary Health Care Response team email: primarycareresponse@murrayphn.org.au or visit the immunisation page on Murray PHN's website.

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