

Cold chain breaches

Immunisation Unit
Health Protection NSW

What is the cold chain?

The 'cold chain' is the system of transporting and storing vaccines within the temperature range of +2°C and +8°C.

The cold chain begins from the time the vaccine is manufactured, continues through storage at the NSW State Vaccine Centre and ends when the vaccine is administered.

What is a cold chain breach?

A breach occurs when the vaccines are stored outside of +2°C and +8°C. Excursions of up to +12°C for no longer than 15 minutes, may occur whilst restocking the refrigerator and are acceptable

Principles of Safe Vaccine Storage Management

- All vaccines should be stored and managed according to National Vaccine Storage Guidelines *Strive for 5* 2nd Edition
- Vaccines should be stored in a purpose-built vaccine refrigerator (bar or cyclic defrost refrigerators **MUST NOT BE USED**)
- Nominate a person (and delegate) to be responsible for vaccine and cold chain management
- Monitor fridge temperatures twice daily and report any temperature breaches outside +2°C to +8°C to the Public Health Unit (PHU) on 1300 066 055
- All fridges must be continuously data logged, with the report downloaded weekly
- Develop cold chain management policies and procedures
- Ensure staff are trained in cold chain management as required
- Perform annual checks of all vaccine storage equipment

Steps when a cold chain breach is detected

1. Quarantine the vaccines in the fridge and label 'do not use'
2. Notify the practice manager/principal/relevant staff member
3. Download the data logging report for the past week, including the cold chain breach
4. Contact the PHU on 1300 066 055 as soon as possible during business hours and forward data logging report
5. DO NOT discard vaccines until advice from PHU is provided
6. You may be required to have the fridge serviced and provide 3 days of data logging before restocking

Power outages

To salvage vaccines:

1. Immediately isolate the vaccines, keep the fridge door closed and attach a sign stating *'Power out. Do not use vaccines. Keep fridge door closed.'*
2. Closely monitor fridge temperature with battery powered min/max thermometer
3. If the temperatures gradually progress towards 8°C, make arrangements to transfer to a cooler.
4. Pack vaccines in a cooler (as per Strive for 5)
5. Return vaccines to fridge when power has returned and fridge is stable, between +2°C to +8°C degrees

Salvage equipment

- Cooler (types include Esky® , Willow® , Coolman®)
- Ice/gel packs
- Polystyrene chips/bubble wrap
- Battery powered min/max thermometer

(NSW Health does not endorse any particular brand of cooler)

Coolers:

- Are a solid-walled insulated container with a tightly fitting lid
- Should be selected based on your needs
- Generally have limited cold life and are not adequate for vaccine storage over prolonged periods (more than 8hrs) or in extreme conditions (eg. very hot or very cold weather)
- Minimum size cooler for storing vaccines is 10L
- Polystyrene coolers are only suitable for storing vaccines for up to 4 hours

How many ice/gel packs are required?

This will depend on:

- The ambient temperature
- Type and size of cooler
- Number of vaccines
- Cooler capacity
- Size and type of ice/gel packs

Ice packs

- Are filled with water and can be removed from the freezer at a temperature as low as -18°C

Conditioning ice packs:

- Remove ice packs from freezer
- To condition the ice packs, lay them in a single row on their side with 5cm space between packs to allow maximum air exposure.
- Wait until ice packs begin to sweat (can take 1 hour @ $+20^{\circ}\text{C}$)
- An ice pack is conditioned as soon as water begins to 'slosh' about slightly inside ice pack

Gel packs

Gel packs contain chemicals that depress the freezing point of the pack and ensures the gel remains $< 0^{\circ}\text{C}$ for longer than water-filled packs (check with manufacturer before purchasing)

Conditioning gel packs:

Gel packs usually take longer to condition than ice packs. It is recommended that the manufacturer's instructions are followed to condition gel packs, however below is a guide to conditioning gel packs

Gel Pack Size	Ambient Temperature	Conditioning Time
Gel Packs $< 750\text{g}$	Temp $> +15^{\circ}\text{C}$	45mins
	Temp $< +15^{\circ}\text{C}$	1 hour
Gel Packs $> 750\text{g}$	Temp $> +15^{\circ}\text{C}$	1 hour
	Temp $< +15^{\circ}\text{C}$	1½ hours

How to pack a cooler

Freezing is the greatest risk to vaccines when packed in a cooler.

There are two storage options available - depending on how long the vaccines need to be stored for and the ambient temperature

- **OPTION ONE** – can be used for storing vaccines for up to 8 hours (see slide 13)
- **OPTION TWO** – packing vaccines into a polystyrene container which is then placed into a larger cooler (see slide 16)

OPTION ONE (Store vaccines for up to 8 hours)

Step 1 – If time permits chill the inside of the cooler prior to use by placing ice/gel packs inside for a few hours and then remove. Place conditioned ice/gel packs on bottom if needed.



Step 2 – Place polystyrene chips, bubble wrap or other suitable insulating material at the bottom of the cooler. This eliminates ‘hot and cold spots’. Polystyrene chips are preferred as it promotes air circulation. If using bubble-wrap, avoid wrapping vaccines tightly.



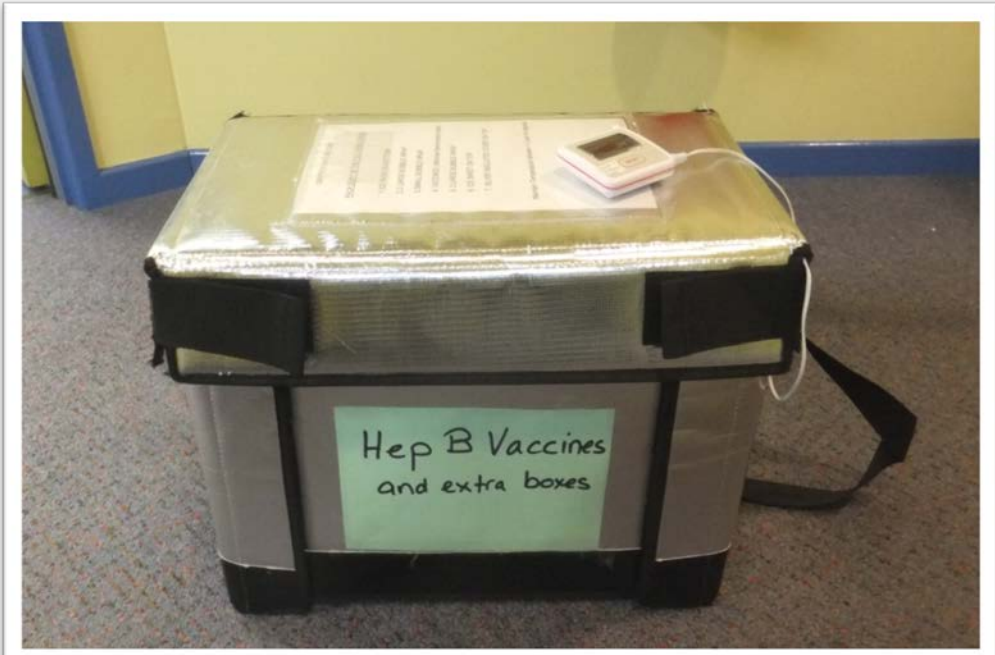
Step 3 – Place vaccines in cooler with a battery powered min/max thermometer probe in the centre of the vaccine stock.

Step 4 – Surround the vaccines with packaging material which allows cold air to circulate

Step 5 – Place the conditioned ice/gel pack(s) on top, close and seal the lid of the cooler. If using a larger cooler, place conditioned ice/gel packs around the sides of the cooler as well as on top

Step 6 – Secure min/max thermometer on outside of cooler and monitor the temperature every hour

Ensure vaccine stock is not in direct contact with the ice/gel packs to minimise risk of freezing



OPTION TWO

Pack vaccines into a polystyrene container then into a larger cooler.

Steps:

1. Collect polystyrene container and chill inside by placing ice/gel packs inside for a few hours
2. Place vaccines and a battery powered minimum/maximum thermometer (in centre of vaccines) inside polystyrene cooler and secure lid
3. Pack polystyrene container inside a larger cooler and surround it with ice/gel packs and secure lid
4. Monitor the temperature every hour

Ensure vaccine stock is not in direct contact with the ice/gel packs to minimise risk of freezing

Monitoring temperature of vaccines in a cooler

Temperatures must be recorded hourly to ensure it is maintained between +2°C to +8°C. Ensure temperature is monitored closely in the first 2 hours (due to increased risk of freezing)

Ice/gel packs may need to be added or removed, depending on how long vaccines are in the cooler and the external ambient temperature



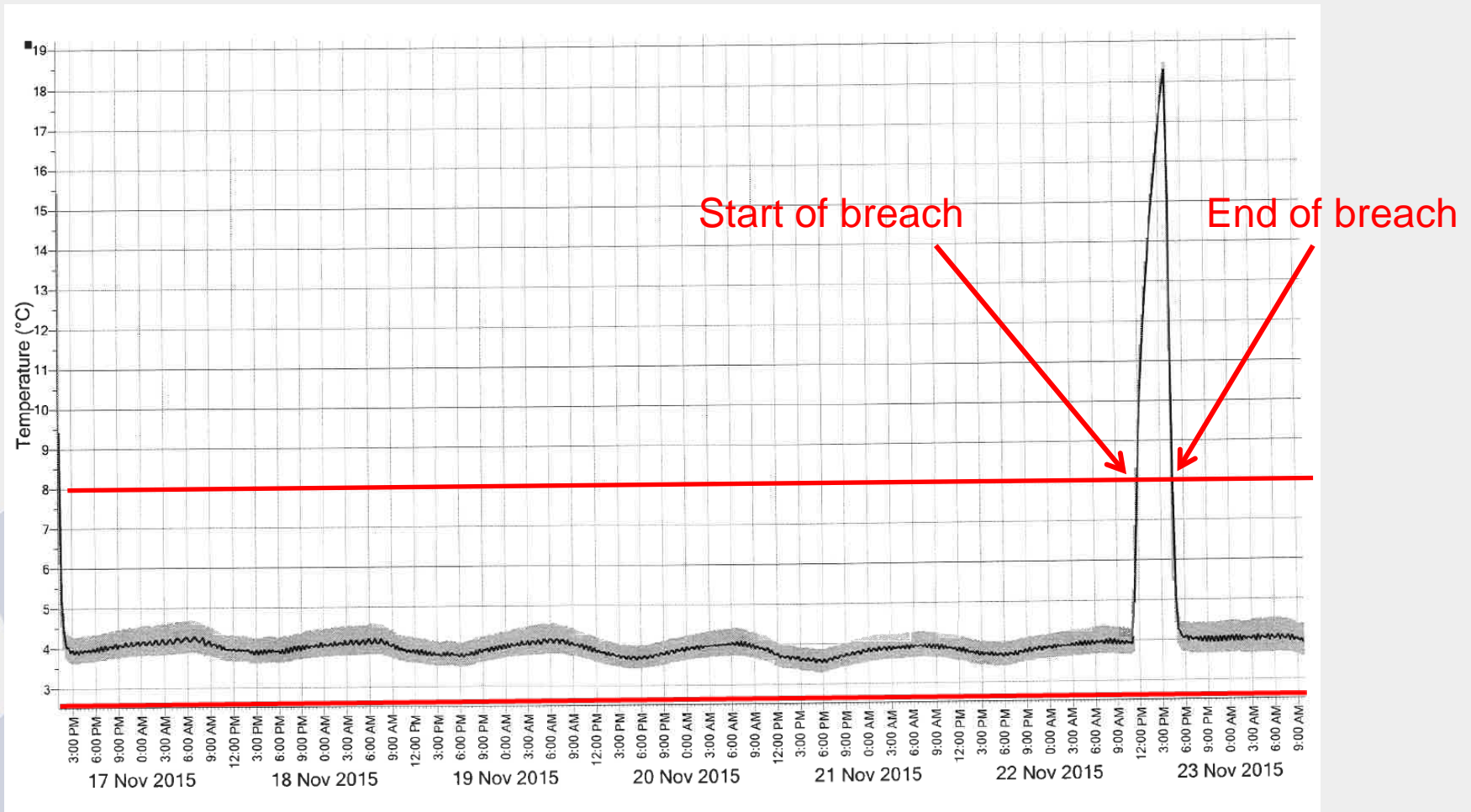
Reset min/max thermometer after each reading

When the power returns

All vaccines that have been continuously stored between +2°C to +8°C can be returned to the fridge when the power resumes and the fridge temperature has been stable for one hour (between +2°C and +8°C)

Remember to reset the fridge min/max thermometer after fridge has been restocked and the temperature has returned to +2°C and +8°C. Document all activity on the Fridge Temperature chart/graph

Example data logging graph of a cold chain breach



If a breach occurs, contact your Public Health Unit on 1300 066 055

Acknowledgement

- Barbara Wilson, Immunisation Coordinator, Albury Public Health Unit, for providing cold chain information and images