

# Daily

vaccine fridge temperature recordings



# Check list for cold chain breach



## Cold chain breach

1. Immediately isolate the vaccines until you have been in touch with your Regional/Metro Immunisation Coordinator or the Central Immunisation Clinic.
2. Keep vaccines refrigerated between +2°C and +8°C and label 'do not use'.
3. Do not discard any vaccine until advice has been sought from your your Regional/Metro Immunisation Coordinator or the Central Immunisation Clinic.
4. Contact your your Regional/Metro Immunisation Coordinator or the Central Immunisation Clinic as soon as possible (in business hours).
5. Take active steps to correct and prevent the problem recurring.
6. For privately purchased vaccines contact the manufacturer for advice.

## Management of cold chain problems

### Power failure

#### Domestic refrigerator

- During a power failure of 4 hours or less the refrigerator door should be kept closed.
- For power failures more than 4 hours store your vaccines in a cooler with conditioned ice packs/gel packs (see 'How to pack a cooler' Strive for 5, p 29-30). Continue to monitor the temperature of the vaccines by placing the thermometer probe inside a vaccine box inside the cooler.

#### Purpose-built vaccine refrigerator

- Monitor the temperature of your refrigerator. If vaccines are at risk use alternative storage arrangements (some refrigerators may not hold the temperature very long).

The following information will assist with rapid decision making about a suspected cold chain breach when you contact your state or territory health department

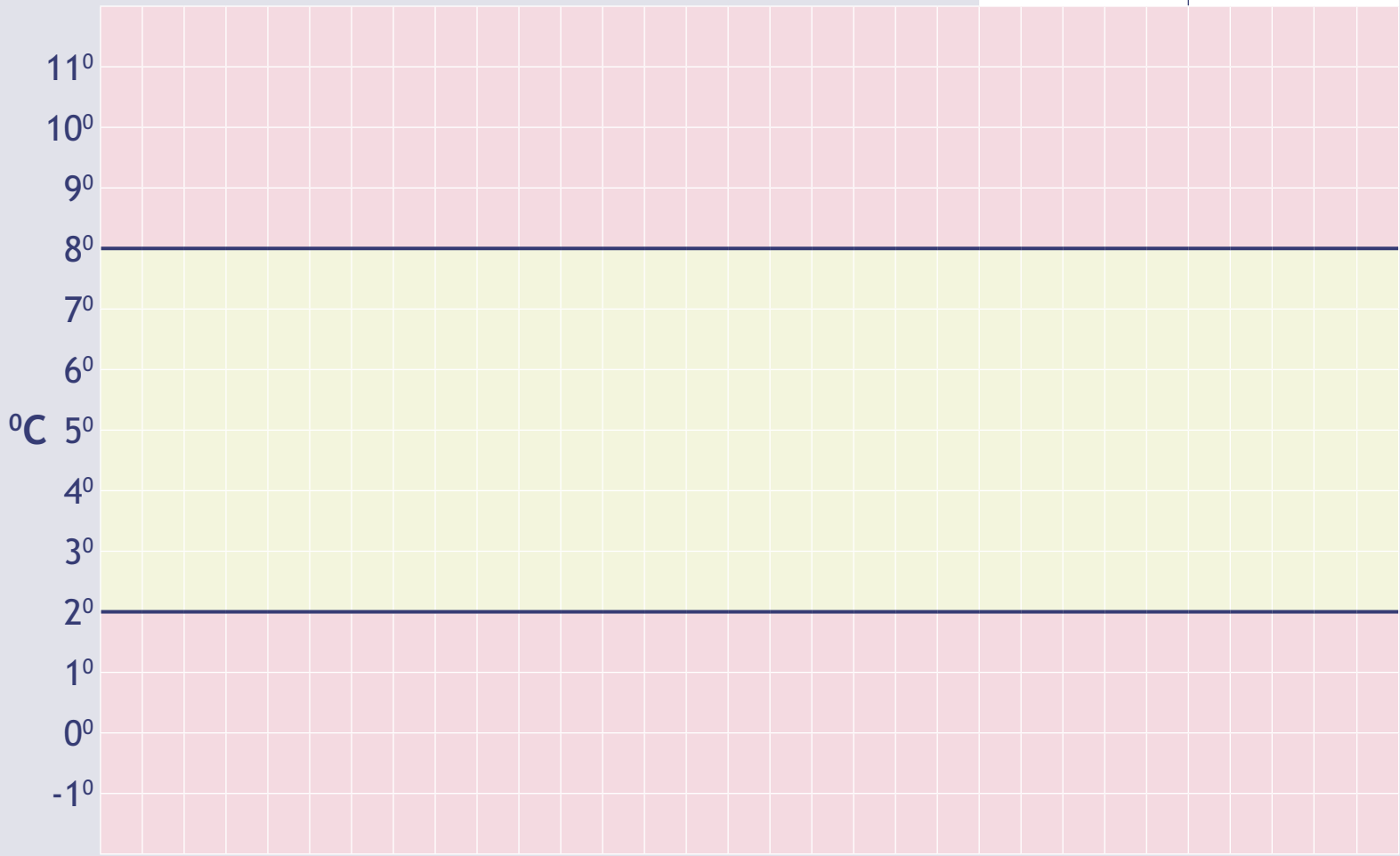
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Minimum and maximum temperature reading?	
Are Cold Chain Monitors (CCMs) stored with the vaccines? If 'yes', be ready to report the reading when breach was noticed.	
When was the thermometer last reset?	
When was the thermometer battery last changed?	
When was the last check on the accuracy of the thermometer done?	
How long do you think the temperature was outside +2°C to +8°C?	
How long do you think these problems have been occurring?	
Where is the temperature probe situated?	
Where are your vaccines stored in the refrigerator?	
What type and number of vaccines are in your current stock?	
What is the expiry date of your vaccines?	
Have vaccines been pushed up against the cooling plate or a cold air outlet?	
Are the vaccines in their packaging?	
If a domestic refrigerator—are the vaccines in enclosed plastic containers?	
Are there water bottles in the doors, unused shelves and drawers of the refrigerator?	
What do you think was the cause of the cold chain breach?	
Has the cause of the cold chain breach been rectified?	
Has anybody been vaccinated with potentially affected vaccines?	



# Cold Chain Points

vaccine fridge temperature recordings

Month: | Year:



1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th	11th	12th	13th	14th	15th	16th	17th	18th	19th	20th	21st	22nd	23rd	24th	25th	26th	27th	28th	29th	30th	31st	
Initials																															
Time*																															

Comments:

- Vaccines must be stored and transported in the recommended temperature range of +2°C to 8°C.
- Strive for 5! As this gives a greater leeway for protection from temperature fluctuation.
- A separate refrigerator should be used for vaccine storage only.
- Daily check and record temperatures at the same time each day.
- If problems occur, do not use vaccines or DESTROY THEM until advice has been sought from your State or Territory vaccine distribution centre, vaccine supplier, hospital pharmacy or local public health unit.
- In the event of a power failure of less than 4 hours keep the door closed and vaccines inside.
- Power failure more than 4 hours, transfer vaccine to another fridge or insulated esky (using ice, monitors and bubble wrap).
- Most vaccines are considered to be damaged at 0°C.

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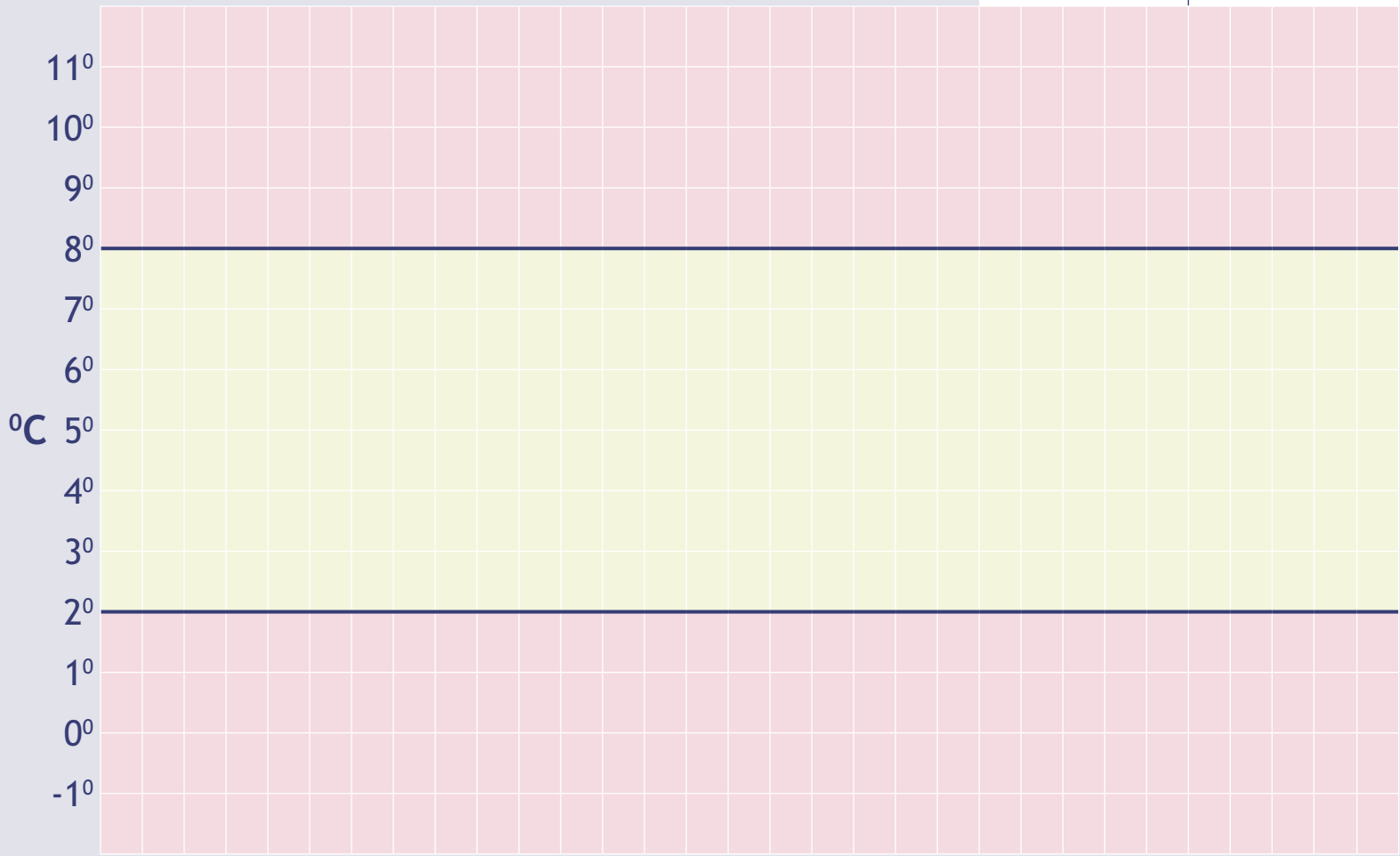
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#### Domestic refrigerator

- During a power failure of 4 hours or less the refrigerator door should be kept closed.
- For power failures more than 4 hours store your vaccines in a cooler with conditioned ice packs/gel packs (see 'How to pack a cooler' Strive for 5, p 29-30). Continue to monitor the temperature of the vaccines by placing the thermometer probe inside a vaccine box inside the cooler.

#### Purpose-built vaccine refrigerator

- Monitor the temperature of your refrigerator. If vaccines are at risk use alternative storage arrangements (some refrigerators may not hold the temperature very long).

The following information will assist with rapid decision making about a suspected cold chain breach when you contact your state or territory health department

Date of the breach.	
Do you store your vaccines in a domestic or purpose-built vaccine refrigerator?	
Minimum and maximum temperature reading?	
Are Cold Chain Monitors (CCMs) stored with the vaccines? If 'yes', be ready to report the reading when breach was noticed.	
When was the thermometer last reset?	
When was the thermometer battery last changed?	
When was the last check on the accuracy of the thermometer done?	
How long do you think the temperature was outside +2°C to +8°C?	
How long do you think these problems have been occurring?	
Where is the temperature probe situated?	
Where are your vaccines stored in the refrigerator?	
What type and number of vaccines are in your current stock?	
What is the expiry date of your vaccines?	
Have vaccines been pushed up against the cooling plate or a cold air outlet?	
Are the vaccines in their packaging?	
If a domestic refrigerator—are the vaccines in enclosed plastic containers?	
Are there water bottles in the doors, unused shelves and drawers of the refrigerator?	
What do you think was the cause of the cold chain breach?	
Has the cause of the cold chain breach been rectified?	
Has anybody been vaccinated with potentially affected vaccines?	



## Information on vaccines exposed to different temperatures

Vaccine (3) (4)	Stability at different temperatures (1) (2)				
	<0°C	2°C to 8°C	22°C to 25°C	35°C to 37°C	over 37°C
Diphtheria, tetanus and/or acellular pertussis - containing vaccines Includes DTPa, DTPa-hepB, DTPa-Hib, DTPa-IPV, DTPa-hepB-IPV, DTPa-IPV-Hib, DTPa-IPV/Hib, DTPa-hepB-IPV-Hib, dTpa, DT (CDT), dT (ADT)	DO NOT FREEZE Vaccines loses significant potency when stored at -5°C to -10°C. NB: Some vaccines may still remain as a liquid at <0°C. As little as 24 hours at <0°C or >25°C may cause antigens to fall from suspension and be very difficult to resuspend. Freezing point of tetanus is between -5°C to -10°C. The freezing point of pertussis is not known. Discard if exposed to temperature of 0°C or below.	Safe to store at 2°C to 8°C for 24 months in spite of continuous slow decrease in potency of the pertussis component.	The DT componets are stable for 4, possibly 6 months; the limiting factors are some of the other components. Some vaccines containing pertussis are stable for only 2 weeks at this temperature.	The DT componets are stable for weeks but the stability of the other components vary with different vaccines. Some vaccines containing pertussis lose 50% of potency after one week.	The DT componets are stable for 2 weeks at 45°C but much less at higher temperatures.. The other components are (where known) very unstable at high temperatures.
Freeze dried (lyophilised) monovalent PRP-T Hib vaccine	Freeze-dried or lyophilised vaccine PRP-T can be frozen.	Diluent - do not freeze (5). Store between 2°C and 8°C.	Not available.	Not available.	Not available.
Reconstituted monovalent PRP-T Hib vaccine	Reconstituted vaccine must NOT be frozen.	Store all components of the vaccine between 2°C and 8°C.	Not available.	Not available.	Not available.
Other Hib-containing vaccines (PRP-OMP, HbOC, Hib (PRP-OMP)-hepB	DO NOT FREEZE The precise freezing point is not established. Manufactures state freezing temperature of HbOC is -1.0°C. Discard if exposed to temperature of 0°C or below.	Store between 2°C and 8°C.	Stable for at least 24 months when stored at 25°C.	Not available.	Not available.
Monovalent hepatitis A vaccine	DO NOT FREEZE Discard if vaccine has been exposed to temperature of 0°C or below.	Store between 2°C and 8°C for many months (up to 36 months for some brands).	Stable for 15 months.	Stable for 15 months.	Not available.
Monovalent hepatitis B vaccine	DO NOT FREEZE Freezing point of hepatitis B vaccine is -0.5°C and vaccine is destroyed at this temperature. Discard if exposed to temperature of 0°C or below.	Retains satisfactory potency for 2 years.	Retains satisfactory potency for 30 days.	Stable for 1 week.	Stable for 3 days.
Inactivated poliomyelitis vaccine (IPV)	DO NOT FREEZE Discard if exposed to temperature of 0°C or below.	Store for up to 2 years between 2°C and 8°C.	Loses significant potency after 20 days.	Destroyed after 20 days.	Not available.
Influenza vaccine	DO NOT FREEZE Discard if exposed to temperature of 0°C or below.	Store between 2°C and 8°C.	Not available.	Not available.	Not available.
Measles-mumps-rubella (MMR) (freeze-dried or lyophilised vaccine) (4)	May be stored in freezer at 0°C or below. Protect from light, which may inactivate virus.	Safe storage for 2 years at 2°C and 8°C. Diluent - do not freeze (5). Store between 2°C and 8°C.	Retains satisfactory potency for 1 year.	Retains satisfactory potency for at least 1 week.	50% loss of potency after 2 to 3 days at 41°C, 80% loss of potency after 1 day at 54°C.
Reconstituted measles-mumps-rubella (MMR) (3) (4)	DO NOT FREEZE Protect from light.	Can be stored between 2°C and 8°C. Protect from light, which may inactivate the vaccine virus. Should be used in one vaccination session (8 hours) if kept cool and protected from sunlight. If not, discard after 1 hour.	Unstable: 50% loss of potency after 1 hour, 70% loss after 3 hours. Protect from light.	Very unstable: titre may be below acceptable level after 2 to 7 hours. Protect from light.	Inactivation within 1 hour.
Meningococcal C conjugate vaccine (MenCCV) NeisVac-C Meningitec (freeze-dried or lyophilised vaccine)	DO NOT FREEZE Discard if exposed to temperature of 0°C or below.	Store in refrigerator between 2°C and 8°C. Shelf life 18 months at this temperature.	Not available.	Not available.	Not available.

## Information on vaccines exposed to different temperatures

Vaccine (3) (4)	Stability at different temperatures (1) (2)				
	<0°C	2°C to 8°C	22°C to 25°C	35°C to 37°C	over 37°C
Pneumococcal conjugate vaccine (7vPCV)	DO NOT FREEZE Discard if exposed to temperature of 0°C or below.	Store between 2°C and 8°C.	Not available.	Not available.	Not available.
Pneumococcal polysaccharide vaccine, 23-valent (23vPPV)	DO NOT FREEZE Discard if exposed to temperature of 0°C or below.	Store between 2°C and 8°C.	Not available.	Not available.	Not available.
Varicella-zoster vaccine: Varivax Refrigerated, Varilrix (freeze-dried or lyophilised vaccine) (3) (4)	May be stored in frost-free freezer at an average temperature of -15°C or colder. Maintains potency for 24 months (Varilrix) or 18 months (Varivax Refrigerated). Protect from light.	Prior to reconstitution, varicella-zoster vaccine retains potency when stored between 2°C and 8°C for up to 2 years (Varilrix) or 18 months (Varivax Refrigerated). Diluent - do not freeze (5). Store between 2°C and 8°C.	Not available.	Not available.	Not available.
Reconstituted varicella-zoster vaccine: Varilrix and Varivax Refrigerated (3) (4)	DO NOT FREEZE Protect from light.	Administer immediately after reconstitution to minimise loss of potency. Discard if reconstituted vaccine is not used within 90 minutes (Varilrix) or within 30 minutes (Varivax Refrigerated) Diluent - do not freeze (5). Store between 2°C and 8°C.	Not available.	Not available.	Not available.

(1) For thermostability information on other vaccines not listed in this table, refer to The Australian Immunisation Handbook 8th ed.

(2) The information in this table is in many cases not consistent with the Australian product information documents. However, this table provides guidelines based on the WHO (1998) Thermostability of Vaccines, WHO/GPV/98.07.

(3) The vaccines that are most unstable at room temperature are reconstituted MMR and Varicella-zoster vaccines.

(4) Reconstituted MMR and Varicella-zoster vaccines must be protected from exposure to light.

(5) DO NOT FREEZE DILUENT AS THIS MAY CAUSE UNDETECTABLE CRACKS IN THE AMPOULE LEADING TO CONTAMINATION.

Produced by Immunisation Program  
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