

Cold Chain Management

May 2024

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Immunisation Team

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PHU Immunisation Programs

- ❖ Infant and children
 - monitor coverage
 - catch-up schedules
 - provide advice to immunisation providers
- ❖ School immunisation program
- ❖ Community influenza immunisation clinics
- ❖ Aboriginal community events
- ❖ Adverse event following immunisation review



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NSW Immunisation Schedule Updated October 2023



Vaccines funded under the National Immunisation Program

Childhood vaccines			
Age	Disease	Vaccine	Information
Birth	Hepatitis B	H-B-VAX II (IM) OR ENGERIX B (IM)	Within 7 days of birth (ideally within 24 hours)
6 weeks	Diphtheria, tetanus, pertussis, hepatitis B, polio, Haemophilus influenzae type b	INFANRIX HEXA (IM)	Rotarix: Dose 1 limited to 6-14 weeks of age Bexsero: Recommended for other children (see AHP*). Prophylactic paracetamol recommended
	Pneumococcal	PREVENAR 13 (IM)	
	Rotavirus	ROTARIX (Oral)	
	Meningococcal B (Aboriginal* children only)	BEXSERO (IM)	
4 months	Diphtheria, tetanus, pertussis, hepatitis B, polio, Haemophilus influenzae type b	INFANRIX HEXA (IM) OR VAXELIS (IM)	Rotarix: Dose 2 limited to 10-24 weeks Bexsero: Recommended for other children (see AHP*). Prophylactic paracetamol recommended
	Pneumococcal	PREVENAR 13 (IM)	
	Rotavirus	ROTARIX (Oral)	
	Meningococcal B (Aboriginal* children only)	BEXSERO (IM)	
6 months	Diphtheria, tetanus, pertussis, hepatitis B, polio, Haemophilus influenzae type b	INFANRIX HEXA (IM) OR VAXELIS (IM)	Children ≥ 6 months with at risk conditions for IPD† are recommended to receive an additional dose of Prevenar 13 (see AHP*) Aboriginal* children ≥ 6 months with certain at risk conditions may require an additional dose of Bexsero (see AHP*)
	Meningococcal ACWY	NIMENRIX (IM)	
	Pneumococcal	PREVENAR 13 (IM)	
	Measles, mumps, rubella	MMR II OR PRIORIX (IM or SC)	
* Annual influenza vaccination	Meningococcal B (NIP funded for Aboriginal† children only)	BEXSERO (IM)	Bexsero: Recommended for other children (see AHP*). Prophylactic paracetamol recommended
	Diphtheria, tetanus, pertussis	INFANRIX OR TRIPACEL (IM)	
	Measles, mumps, rubella, varicella	PRIORIX TETRA (IM or SC)	
	Haemophilus influenzae type b	ACT-HIB (IM or SC)	
4 years	Diphtheria, tetanus, pertussis, polio	INFANRIX-IPV OR QUADRACEL (IM)	Children with at risk conditions for IPD† are recommended to receive an additional dose of Pneumovax 23 (see AHP*)
At risk groups, adolescents and adults			
Age/group	Disease	Vaccine	Information
All people with asplenia, hyposplenia, complement deficiency and treatment with eculizumab	Meningococcal ACWY	NIMENRIX (IM)	See AHP* for required doses and timing. Additional groups are recommended to receive these vaccines but these are not funded
	Meningococcal B	BEXSERO (IM)	
≥ 5 years with asplenia or hyposplenia	Haemophilus influenzae type b	ACT-HIB (IM or SC)	If incompletely vaccinated or not vaccinated in childhood
≥ 18 years	Zoster	SHINGRIX (IM)	Only immunocompromised people ≥ 18 years with certain medical conditions (see AHP*)
Year 7	Diphtheria, tetanus, pertussis	BOOSTRIX OR ADACEL (IM)	
	Human papillomavirus	GARDASIL 9 (IM)	
Year 10	Meningococcal ACWY	NIMENRIX (IM)	
Pregnant	Influenza	INFLUENZA	Influenza: Any trimester Pertussis: each pregnancy between 20-32 weeks
	Pertussis	BOOSTRIX OR ADACEL (IM)	
Aboriginal* people ≥ 50 years	Pneumococcal	PREVENAR 13 (IM) then PNEUMOVAX 23 (IM)	Prevenar 13: ≥ 50 years Pneumovax 23: 2-12 months later (see AHP*) Pneumovax 23: at least 5 years later Shingrix: ≥ 50 years
	Zoster	SHINGRIX (IM)	
≥ 65 years	Zoster	SHINGRIX (IM)	Shingrix: Funded for people ≥ 65 years
≥ 70 years	Pneumococcal	PREVENAR 13 (IM)	Pneumococcal funded for people ≥ 70 years
People with at risk conditions for IPD†	See the online AHP* for conditions recommended to receive Prevenar 13 and Pneumovax 23		
Influenza			
Age/at risk condition	Recommendation	Information	
All children ≥ 6 months to < 5 years	ANNUAL INFLUENZA VACCINATION	Discuss influenza vaccination with other present family members	
Aboriginal* people ≥ 6 months	INFLUENZA VACCINATION	Children aged less than 9 years of age who are receiving the influenza vaccine for the first time should receive 2 doses of the vaccine, 4 weeks apart	
People with at risk conditions ≥ 6 months			
≥ 65 years			
Pregnant women		For vaccine brands and eligibility see: www.health.nsw.gov.au/immunisation/Pages/flu.aspx	

* The term Aboriginal† includes of Aboriginal and Torres Strait Islander people. † IPD: Invasive pneumococcal disease. AHP*: Online Australian Immunisation Handbook, October 2023. © NSW Health, Shingrix (IPV) 1201762.

Cold Chain Management

- ❖ What is a cold chain breach ?
- ❖ Cold chain breach response
- ❖ Cold chain audits



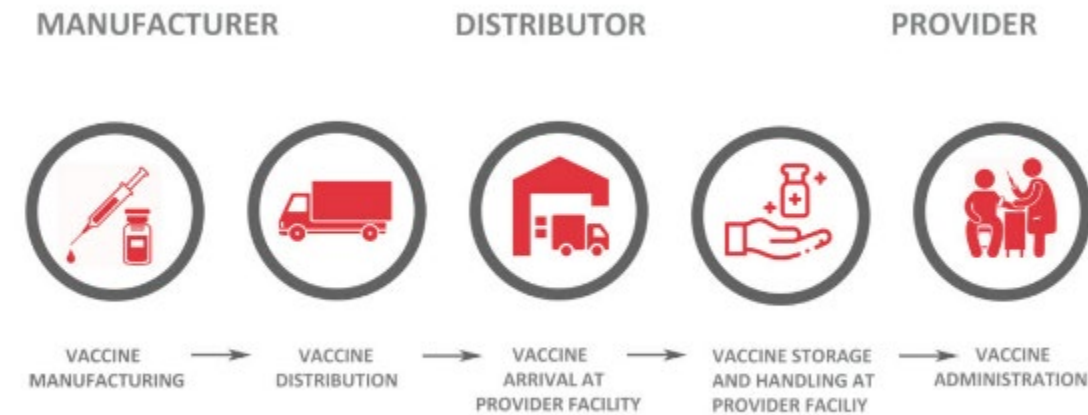
Cold Chain

❖ What is the cold chain

- The system of transporting and storing vaccines
- within the safe temperature range of +2°C to +8°C

❖ Why is cold chain important

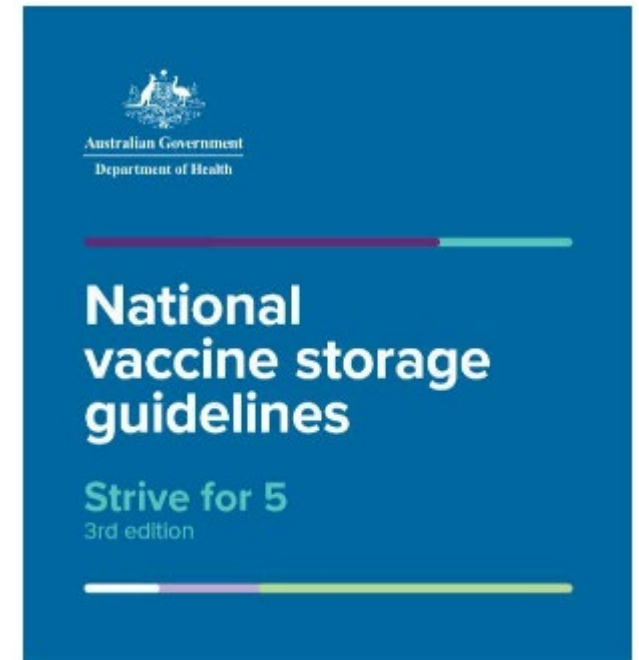
- Vaccines are delicate biological substances
- Failure to store and handle vaccines properly can reduce vaccine potency resulting in inadequate immune response and poor protection against disease.



Cold Chain

The National Vaccine Storage Guidelines: Strive for 5 provides best practice guidelines for storing vaccines and managing the cold chain.

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



A joint Australian, State and Territory Government Initiative



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Cold Chain

The safe vaccine storage checklist can be used to ensure safe and effective vaccines are given to patients



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Safe Vaccine Storage Checklist

Follow the principles of safe vaccine storage management to ensure safe and effective vaccines are given to your patients. Strive for 5°C and report ALL cold chain and light exposure breaches to your local public health unit on 1300 066 055.

- Vaccine refrigerators** **Purpose-built vaccine refrigerators (PBVR) are the only suitable option for vaccine storage.**
 - If your practice does not have a PBVR you will be required to order a new PBVR.
 - Domestic fridges and bar fridges are not built to store vaccines and must not be used for vaccine storage.
- Vaccine Storage** **Vaccines MUST be stored in their original packaging**
 - Store vaccines in their original cardboard packaging as they are sensitive to UV light and temperature fluctuations.
 - Vaccines must not touch the sides of the fridge
 - Vaccines must not be stored on the floor of the fridge
 - Annual vaccine storage self-audit completed and up to date.
- Temperature monitoring** **Vaccine fridge temperatures MUST be continuously monitored using a data logger**
 - Data loggers **MUST** be set at 5 minute intervals with a report downloaded weekly and when a potential cold chain breach has been identified.
 - Current, minimum and maximum temperatures **MUST** be manually recorded twice daily, every day the practice is open. Thermometer to be reset after temperatures are recorded.
 - Review temperature of fridge before removing vaccines for administration.
- Vaccine expiry** **Rotate stock and discard expired vaccines**
 - Check the vaccine expiry **before** administering vaccines and discard all expired vaccines.
 - Regularly review stock and bring vaccines with the shortest dates to the front of the refrigerator so they are used first.
- Staff education** **Ensure ALL staff are trained in vaccine management**
 - Provide regular vaccine management orientation and education training sessions for all staff.
 - Ensure one member of staff is responsible for vaccine management and a back up person.
 - The NSW Health Vaccine Storage and Cold Chain Management online training module may be used to train all staff that are responsible for vaccine storage and monitoring, visit https://nswhealth.seertechsolutions.com.au/public_content/HETICP/HETI/CCMWebv3/story_flash.html

Vaccine Refrigerator

- ❖ Must be a purpose built vaccine refrigerator
- ❖ Not overstocked
 - Vaccines must not touch sides of fridge
 - Vaccines must not be stored on floor of the fridge
- ❖ Data logger positioned on the middle shelf
- ❖ Vaccines must be stored in original packaging
- ❖ Stock must be rotated
- ❖ Discard expired vaccines



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Temperature monitoring

- ❖ Vaccine fridge must be continuously monitored by a data logger
 - Must be set to 5 minute intervals
 - Downloaded weekly
 - Ensure parameters set – 2-8 degrees
- ❖ The current minimum and maximum temperature must be manually recorded twice daily
- ❖ Review temperature of fridge before removing vaccines

Vaccine refrigerator temperature chart

Strive for 5

Minimum/maximum vaccine refrigerator temperature chart

Location of refrigerator *treatment room* Month *June* Year *2023*



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

Date _____
 Audited by _____
 Cleaning date _____

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)

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.
7. Record fridge temperature issues and actions on the flipside of this chart.
8. Determine if anyone has received compromised vaccine. Discuss your revaccination requirements with your state or territory health department.

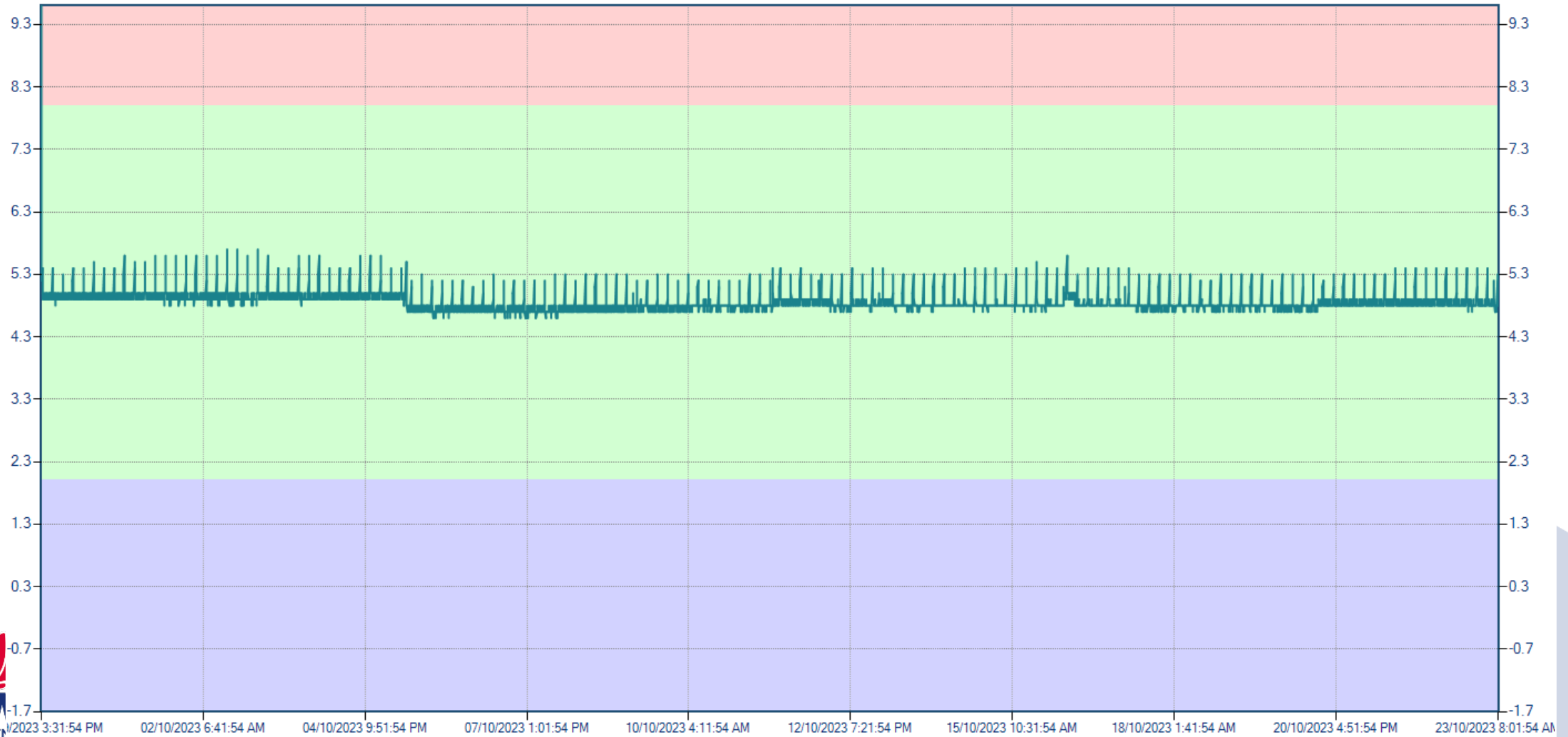
Temperatures above 8°C are too warm.

Correct range temperature 2°C to 8°C

Temperatures below 2°C are too cold.

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

Data logging



Staff education

- ❖ Provide regular vaccine management training for all staff
- ❖ Ensure one staff member responsible for cold chain management and that you have a back up person
- ❖ Vaccine storage and cold chain management online training module must be completed by one staff member



- ❖ <https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management.aspx>

What is a cold chain breach?

- ❖ Exposure of vaccines to temperatures outside the recommended range of +2°C to +8°C
- ❖ Excludes fluctuations up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking



What is the potential impact of a cold chain breach?

- ❖ Can result in revaccination
- ❖ Loss of confidence in vaccines and immunisations service providers
- ❖ Financial loss due to discarded vaccines and the cost of revaccination
- ❖ Litigation
- ❖ Staff hours spent on patient recall and management of the incident



Managing a cold chain breach

- ❖ Immunisation providers must report all cold chain breaches public health
- ❖ Isolate vaccines and place a 'DO NOT USE' sign on the fridge.
- ❖ Continue to store vaccines between +2°C to +8°C.
- ❖ Do not discard any vaccines.
- ❖ Download and review the data logging report
- ❖ Contact public health 47342022 as soon as possible during business hours.
- ❖ If transferring vaccines to a vaccine cooler (e.g. Esky), record temperatures on the Vaccine Cooler Temperature Chart.

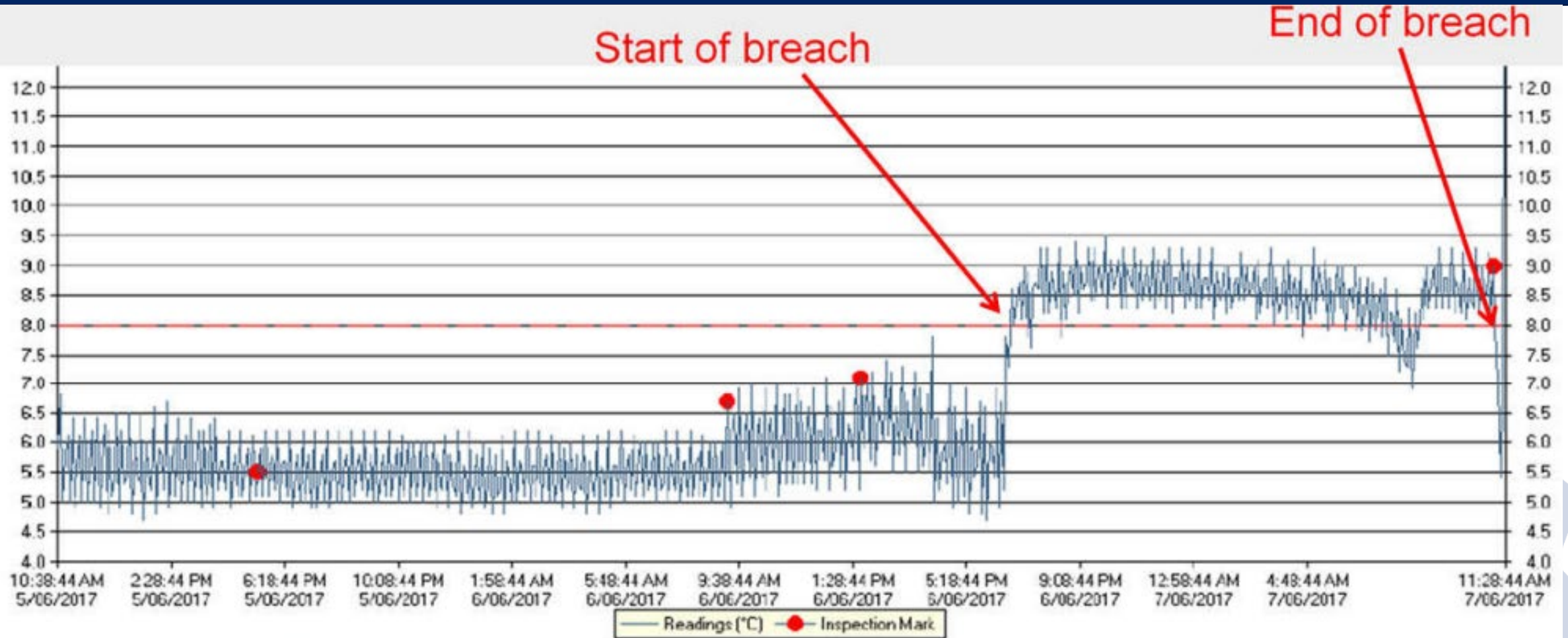


Reporting a cold chain breach

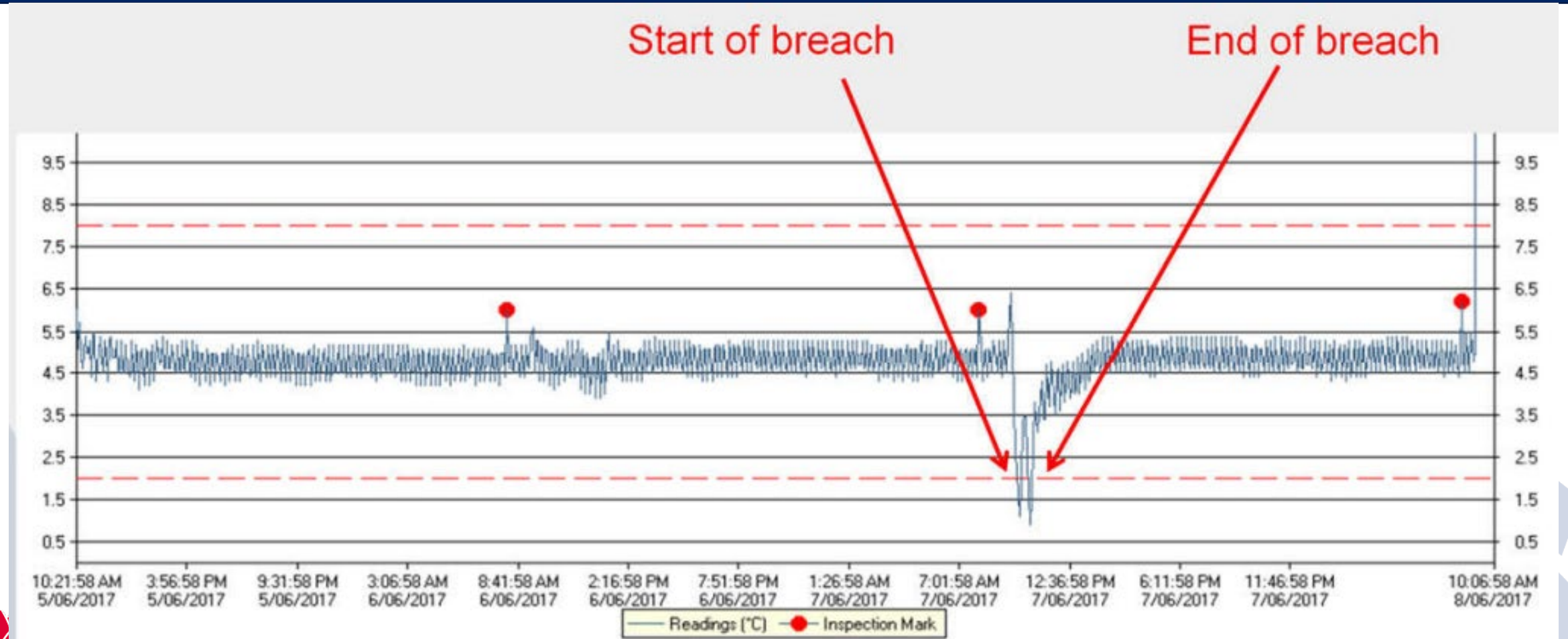
- ❖ You will need to provide the following
 - Completed cold chain breach reporting form
 - Data logging report
 - Min/Max temperature chart
- ❖ Public Health will then advise if the vaccines can be retained or must be discarded
- ❖ If there was a fridge malfunction 72 hrs of data logging will be required
- ❖ Put stickers on vaccines that can be retained
 - Better Health Centre - 98875450



Example of high cold chain breach



Example of low cold chain breach



Light exposure breach

- ❖ Vaccines may lose potency if exposed to direct sunlight or ultraviolet (UV) light
- ❖ To protect vaccines from light exposure they must be stored inside their original cardboard packaging.
- ❖ The original cardboard packaging ensures vaccines are protected against:
 - exposure to sunlight and ultraviolet (UV) light or fluorescent light
 - temperature fluctuations
 - vaccine administration errors
- ❖ If you become aware that vaccines have been exposure to light contact Public Health

on 4734 2022



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Ways of preventing cold chain breaches

- ❖ Do staff know what to look for in the data logging
- ❖ Make sure that the data logger is being cleared
- ❖ Is the data logging being saved
- ❖ Min / Max thermometer being reset
- ❖ Overstocking
- ❖ Check fridge is plugged directly into wall socket
- ❖ More than 1 person in the practice needs to know how to manage cold chain



Cold Chain Audit

NSW Health Cold Chain Audit for Immunisation Providers			
Public Health Unit details:			
Contact person:	Date audit issued:		
Contact number:	Email:		
Immunisation Provider details:			
Date audit completed:	Vaccine account number:		
Practice name:			
Practice address:			
Practice email address:			
Name, signature and position of person completing the audit:			
Instructions: Once completed, please forward the completed NSW Health Cold Chain Audit and required attachments (refer to section 5) to your local PHU at the email above within 14 days of receiving the audit.			
Audit Questions	Yes	No	Response/ Comment:
1. Is your facility accredited with a relevant industry body?	<input type="checkbox"/>	<input type="checkbox"/>	If yes date: _____
2. Does the facility report all administered vaccinations (childhood, adolescent & adult) including influenza vaccinations to the Australian Immunisation Register?	<input type="checkbox"/>	<input type="checkbox"/>	If no, are any vaccines reported to the AIR (Please specify) _____
Please submit the following to your local public health unit with the completed audit questionnaire			
3. A copy of the NSW Health Cold Chain Learning Module certificate of completion. Note: At least one staff member must complete the online learning module. However, it is recommended that all staff complete the online learning module to ensure staff are competent in cold chain management.	<input type="checkbox"/>	<input type="checkbox"/>	
4. Most recent annual vaccine storage self- audit Note: Refer to the "Strive for 5" vaccine storage self-audit .	<input type="checkbox"/>	<input type="checkbox"/>	Date: _____
5. Photo of the inside and outside of the vaccine fridge(s)	<input type="checkbox"/>	<input type="checkbox"/>	
6. 72 hrs data logging (for the 3 days prior to receiving the audit)	<input type="checkbox"/>	<input type="checkbox"/>	
7. A copy of the current twice daily temperature chart for each vaccine fridge. Note: Refer to the "Strive for 5" Vaccine Fridge Temperature Chart .	<input type="checkbox"/>	<input type="checkbox"/>	
Thank you for completing the NSW Health Cold Chain Audit. Your local public health unit may contact you if further information is required. If you have any questions about items in this audit please call your PHU on 1300 066 055.			
Outcome (PHU use only)			
Date Audit received:		Reviewer details:	
Facility compliant at time of audit: <input type="checkbox"/> Yes <input type="checkbox"/> No (consider site visit)			
Date of Site visit (if applicable): _____			
Facility now compliant (following support visit): <input type="checkbox"/> Yes <input type="checkbox"/> No			
Comments: _____			

Main Issues Identified

- ❖ Not completing Strive for 5 audit
- ❖ Not using the correct Strive for 5 min/max chart
- ❖ Not documenting on the back of the min/max chart
- ❖ Data logger stopped functioning
- ❖ Often practices do not have the equipment available for a salvage
- ❖ Equipment not maintained



Questions?



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