

Cold Chain

*Protect your vaccines →
Protect our Community*

Kirsty Waller
Immunisation Clinical Nurse Consultant

03 April 2024

Key messages...

- Store vaccines between 2-8 degrees in a purpose-built vaccine fridge
- Light sensitive (store in original packaging)
- Can become less effective or destroyed if not stored correctly
- Loss of vaccine effectiveness is cumulative and cannot be reversed
- Vaccine management is the responsibility of ALL staff ordering and handling vaccines

(complete the NSW Health Vaccine Storage and Cold Chain Management online learning module- find on NSW Health website)

[Vaccine storage and cold chain management - Immunisation programs \(nsw.gov.au\)](https://www.nsw.gov.au/immunisation/vaccine-storage-and-cold-chain-management)



Why do we keep talking about vaccine storage?



Usually we get it right



Sometimes we get it wrong



Ordering vaccines →

- Order vaccines through NSW State Vaccine Centre
- Order appropriate amounts of stock, DO NOT exceed capacity of fridge

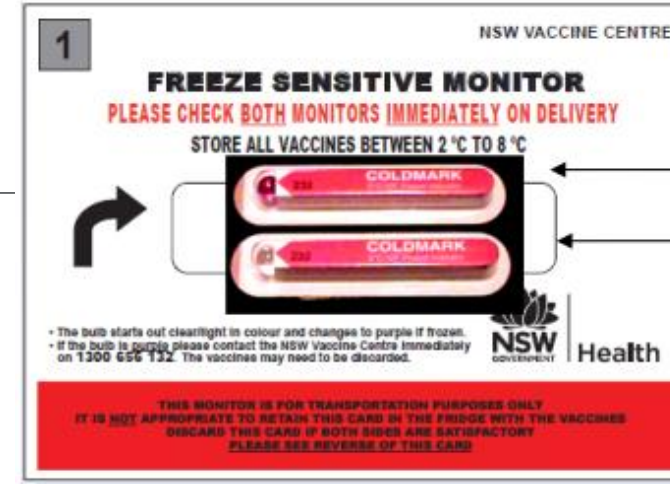
Helpful formula:

Quantity to be ordered = Quantity used since last delivery –
Quantity left over since last delivery + 10% of Quantity used
since last delivery

- It is the responsibility of the authorised practice provider to ensure the signed declaration is true AND the practice is compliant with mandatory vaccine storage and cold chain management requirements.
- Remember only 2 routine orders per month permitted

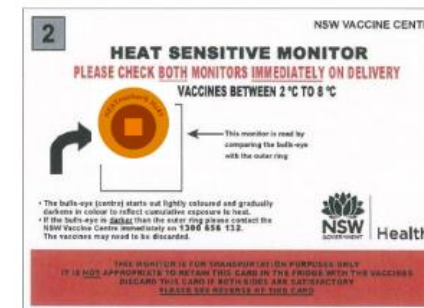
→ Receiving deliveries

- Before accepting a vaccine delivery- ensure cold chain has been maintained and vaccines were not compromised
- Check cold chain monitor prior to accepting delivery and transferring vaccines to fridge
- If cold chain monitor has been activated, contact NSW Vaccine Centre immediately
- Ensure stock is rotated and check for expiry
- No need to confirm receipt of delivery on SVC site



7.2 Heat indicators

This bioCSL Time Temperature Indicator changes from "satisfactory" to "unsatisfactory" as vaccines are exposed to temperatures over 8°C

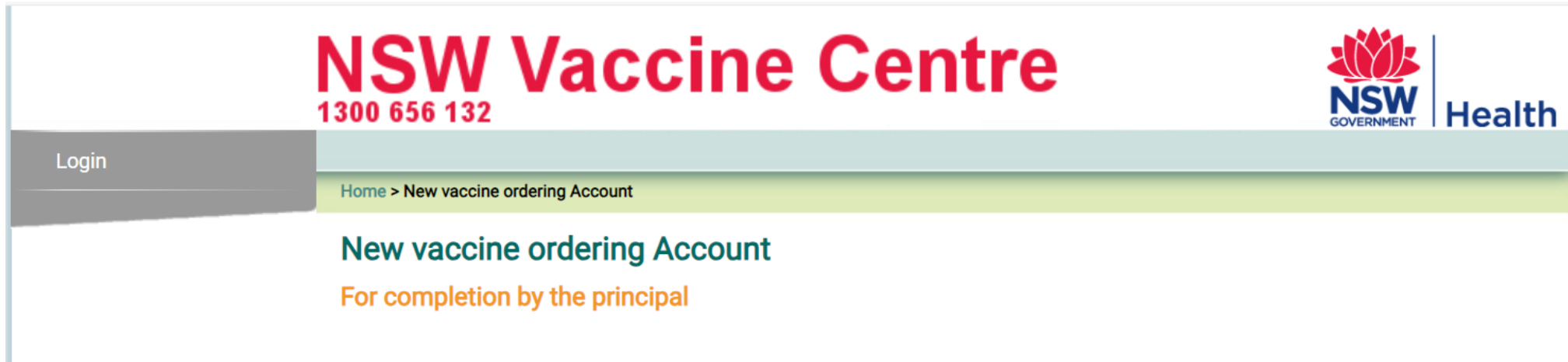


New Vaccine Account Number (VAN) Applications



- For all applications for a new VAN, the Principal provider of the service is required to complete the application found here

[NSW Vaccine Centre Online Ordering System - New vaccine ordering Account \(tollhealthcare.com\)](http://tollhealthcare.com)



- Your local Public Health Unit will then contact you with further information and a request for a list of documents to support your application showing your compliance with all Strive for 5 requirements.

Monitoring equipment

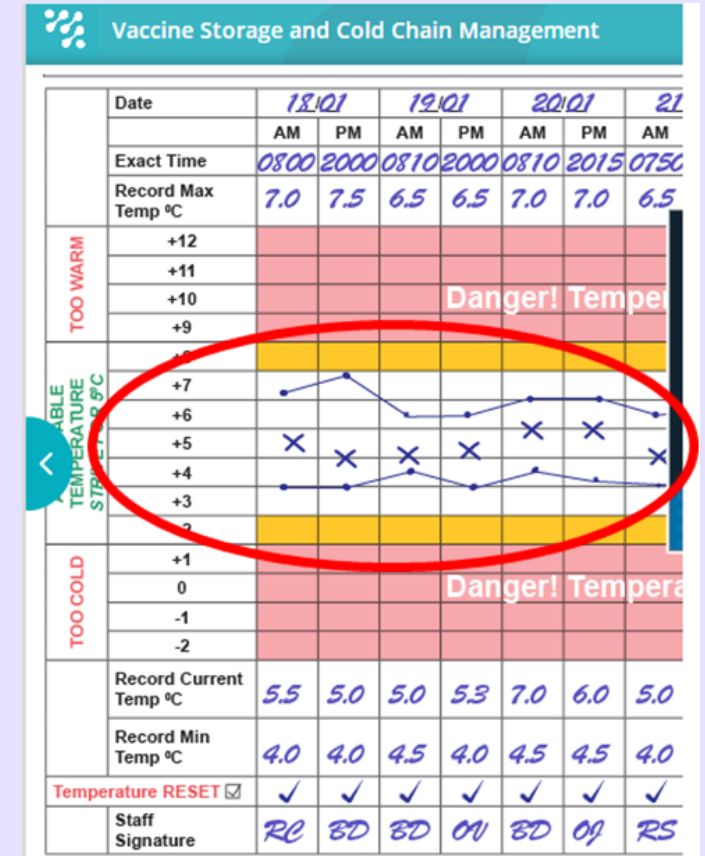
Data logger

- ✓ 5 minute recording intervals, run continuously
- ✓ Place logger/probe centrally in fridge
- ✓ Download and CHECK data weekly
- ✓ Save data on shared drive so can be accessed easily by all staff
- ✓ Service/ calibrate/ check accuracy every 12mths



Min/Max thermometer

- ✓ You **MUST** have a battery-operated min/max for each vaccine fridge and alternate cold storage (esbies)
- ✓ **This is in addition to the built-in min/max thermometer of your fridge**
- ✓ Current, minimum, maximum temperatures must be recorded and plotted twice daily
- ✓ Reset thermometer after recording each reading
- ✓ Battery must be changed when low or every 12mths



What else do you need?

Stickers

- ✓ On your fridge
- ✓ Power point
- ✓ Metre box



Regular maintenance

- ✓ Fridge
- ✓ Logger
- ✓ Min/max thermometer

→ check accuracy of ALL equipment every 12mths

Ice slurry test



- Leave the Min/Max probe in the Ice Slurry until it reaches 0°C (or -1°/+1°C)
- If 0°C is not achieved, replace battery again and repeat Ice Slurry test.
- If this then fails to reach 0°C - replace Min/Max Thermometer



Record the date of when Battery changed and ice slurry performed on the Min/Max thermometer.

Annual vaccine storage self-audit

APPENDIX 2: Vaccine storage self-audit

Immunisation service providers are required to use this checklist to carry out a self-audit at least once every 12 months, and more frequently if there have been problems with equipment or cold chain breaches. Documentation should be stored for future reference.

Print this checklist and use it as required.

Self-auditing is important because:

- it is part of routine quality assurance and risk management processes
- it enables staff to have confidence that they are providing a safe and effective vaccine.

Print or photocopy this page and keep it as a record of an audit.

Nominated person responsible for vaccine management	
Nominated back-up person for vaccine management	
Make and model of refrigerator	
Date of self-audit	
Person conducting audit	

In addition, for HNELHD facilities- annual QARS audit

Procedures

Checklist for safe vaccine handling and storage

- Have all staff received orientation and/or an annual update on vaccine management?
- Have vaccine management policies been reviewed in the past 12 months to ensure that procedures are up to date?

Date of last revision

- Is graph/logbook/chart for temperature recording readily available?
- Is the temperature of the vaccine refrigerator recorded twice a day when the facility is open?
- Are the contact numbers to report a cold chain breach easily accessible?
- Were all deviations outside the +2°C to +8°C range reported to the appropriate state or territory health department?
- Have the responses to all deviations outside the +2°C to +8°C range been documented and recommended actions taken?

Equipment

Vaccine refrigerator

- Has the refrigerator shown evidence of malfunction (eg poor seals so that the door opens too easily)?
- Is there an appropriate gap between the vaccines and the walls of the refrigerator?
- Can the refrigerator continue to store the required volume of vaccines safely according to these guidelines? (This includes times of increased demand such as the influenza program.) If 'No', what action is being taken?

Date refrigerator was last serviced

- If the refrigerator has a solid door, is a map or guide to where vaccines are stored located on the outside of the door?
- Does the power outlet have a sign 'Do not turn off or disconnect this refrigerator'?

Monitoring equipment

Date the minimum/maximum thermometer(s) was purchased

Date the battery for the minimum/maximum thermometer(s) was last changed

Date and results of thermometer accuracy check at 0°C
See *Strive for 5* Section 4.4 'How to check the accuracy of a thermometer ('slush test')'

- Is the minimum/maximum thermometer temperature probe(s) placed correctly?

Date the data logger(s) battery was last changed

Date data logger(s) was last serviced

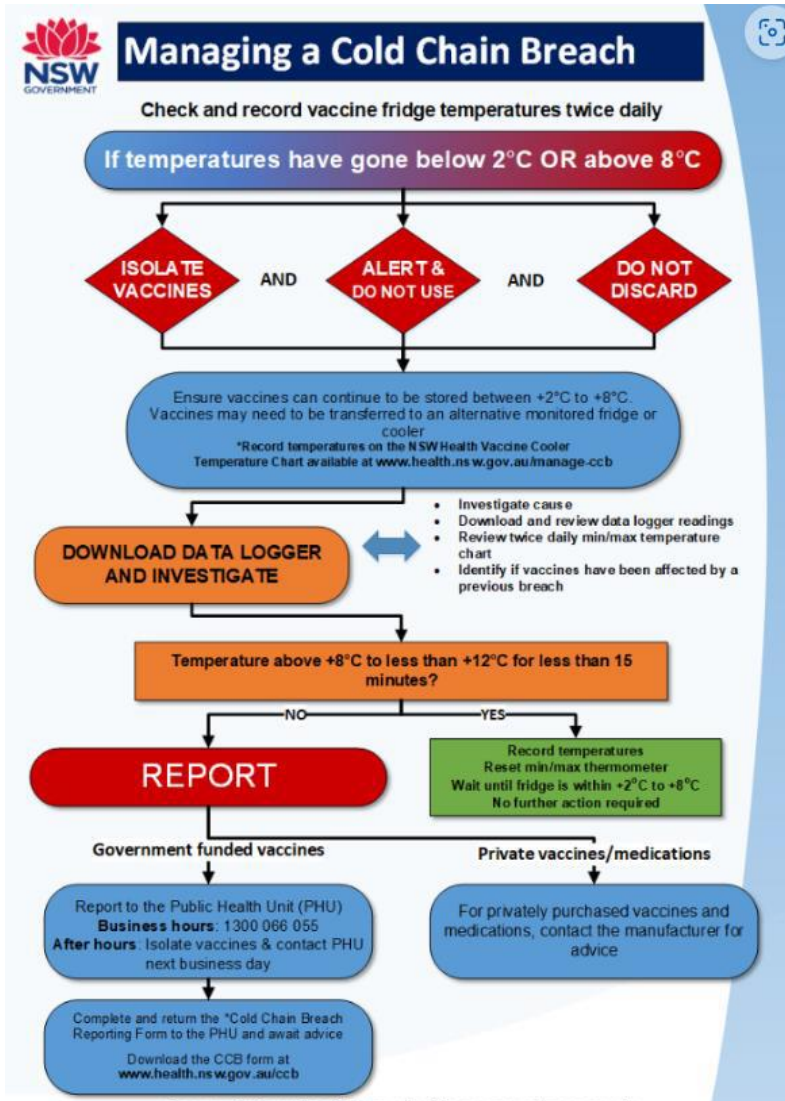
Alternative vaccine storage

- Is there a readily accessible written procedure for what to do during a power failure?
- Is enough alternative storage (eg cooler, other monitored refrigerator) available for vaccine storage, if necessary (eg vaccine refrigerator breakdown or power failure)?
- Are ice packs/gel packs at the correct temperature available?
- Is there one minimum/maximum thermometer for each cooler?
- Is there enough insulating material for each cooler?

Temperature monitoring requirements

How often	Action required
Before removing vaccines for administration	<ul style="list-style-type: none"> Check the vaccine fridge temperature before removing vaccines to ensure the temperature is in range.
Twice daily (every day the practice is open, including weekends)	<ul style="list-style-type: none"> Manually record current, minimum and maximum temperature of the vaccine refrigerator on the Strive for 5 - Vaccine Fridge Temperature Chart (Refer to Appendix 2) Record in the morning and in the evening, at opening and closing of practice Check that temperatures have remained between the +2°C to +8°C range, if out of range download the data logger or review automated temperature monitoring system Reset thermometer after recording each reading
Once a week	<ul style="list-style-type: none"> Download data logger (for practices which are not open daily, the data logger must be downloaded and reviewed prior to using vaccines) Save downloaded data to computer, and review data Check that temperatures have remained between the +2°C to +8°C range Relaunch data logger Ensure the logger is set to record at 5 minute intervals Practices with automated temperature monitoring systems must review the temperature readings at least weekly and document the weekly review on the Strive for 5 - Vaccine Fridge Temperature Chart (Refer to Appendix 2)
Annually	<ul style="list-style-type: none"> Perform vaccine storage self-audit (Appendix 2 of National Vaccine Storage Guidelines - Strive for 5). Service vaccine refrigerator– contact manufacturer Calibrate thermometers/data loggers and change batteries
If a potential breach is identified	<ul style="list-style-type: none"> Report temperatures outside the +2°C to +8°C range to your Public Health Unit (Refer to section 11: Managing a cold chain breach) Do not use and do not discard vaccines until advice is received from your local Public Health Unit

Reporting a Cold Chain Breach (CCB)




- Report ALL cold chain breaches or excursions
(this does not include temperature deviations in which the temperature reaches a maximum of up to +12°C for 15mins or less)
- DO NOT use and DO NOT discard vaccines until PHU advice received.
- In the event of a power outage, PHU require data logging for entire breach

TIP: For privately purchased vaccines and medications contact the manufacturer for advice

Reporting a Cold Chain Breach (CCB)

- Go to HNEH Immunisation website
- Download and complete reporting form ONLINE so it can be emailed to the PHU
- Section 1 & 2: complete carefully.
- Section 3: only required if there has been a fridge malfunction or reason for CCB is unknown.
- Section 4: note explanation at the top of the page.
- Don't forget to provide attachments as per page 4 on the reporting form.


COLD CHAIN BREACH AND VACCINE WASTAGE REPORTING FORM
Sections marked with an * are mandatory



*SECTION 1: IMMUNISATION PROVIDER DETAILS	
Facility Name	Vaccine Account Number
Address	Phone
Number of GPs in the practice	Person Reporting the breach
Email	

*SECTION 2: DETAILS OF COLD CHAIN BREACH	
1. Type of refrigerator	<input type="checkbox"/> Purpose Built Vaccine Specific Refrigerator <input type="checkbox"/> Domestic refrigerator
2. Date of breach	
3. Date breach identified	
4. Reason for breach	

COLD CHAIN BREACH AND VACCINE WASTAGE REPORTING FORM
Sections marked with an * are mandatory



*SECTION 4: VACCINE DETAILS					
Enter the number of vaccines involved in this breach as follows: First breach (Second breach)					
Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
MMRii	5 (7)	Retain 5 (Discard 7)	Infanrix	13 (2)	Retain 13 (Discard 2)

VACCINE DETAILS					
Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
Act-HIB		Select	MMR II		Select
Adacel		Select	MIRV (Rabies)		Select

Why might the PHU put a hold on your Vaccine Account?

- If we have not received a CCB Reporting Form, data logging or other attachments required to finalise the CCB
- In the event of a suspected CCB
- In the event of non-compliance with mandatory vaccine management and cold chain requirements
- In the event that a deadline is not met e.g. Random Cold Chain Audit

COLD CHAIN BREACH AND VACCINE WASTAGE REPORTING FORM

Sections marked with an * are mandatory

Attachments required

All providers are required to provide the following items on the checklist

- Data logging for the duration of the cold chain breach (graph and temp log required)
- Vaccine refrigerator twice daily min/max temperature chart
- Min/max temperature chart used during transfer of vaccines e.g. esky (if applicable)
- Last refrigerator service report (required if there has been a fridge malfunction)
- Certificates of completion of all staff that have completed the NSW Health Vaccine Storage and Cold Chain Management online training module

Key messages....

- Vaccines are special and need special care
- Cold chain management is everyone's responsibility
- Report ALL cold chain breaches or excursions

(this does not include temperature deviations in which the temperature reaches a maximum of up to +12°C for 15mins or less)

- Ensure vaccines are checked and put in the fridge when they arrive
- Ensure you have an independent battery-operated min/max thermometer
- Ensure your data logger is set for 5min recording AND multiple staff know how to download the logger AND attach to an email
- Ensure no vaccines are stored on the floor of the fridge and always left in their original packaging
- Complete your annual Strive for 5 Self Audit

Resources....make them a favourite!



[National Vaccine Storage Guidelines 'Strive for 5' | Australian Government Department of Health and Aged Care](#)

[Cold Chain Toolkit for Immunisation Providers \(nsw.gov.au\)](#)

[Immunisation | HNE Health \(nsw.gov.au\)](#)