

Vaccine Storage and Cold Chain Management

Summary This Policy Directive provides mandatory requirements for the storage and management of vaccines and aims to ensure consistent and effective vaccine storage and monitoring processes. The Policy aims to ensure that all clients receive potent vaccines and that vaccine cold chain breaches are identified and managed consistently, efficiently and effectively

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VACCINE STORAGE AND COLD CHAIN MANAGEMENT

POLICY STATEMENT

All NSW facilities must adhere to mandatory vaccine storage and cold chain management requirements to ensure vaccine are stored in accordance with best practice guidelines, vaccine cold chain breaches are identified and managed consistently and efficiently, and all patients receive potent and effective vaccines.

SUMMARY OF POLICY REQUIREMENTS

All facilities must ensure that policies, procedures and protocols are in place for effective vaccine storage and cold chain management according to the current editions of the *National Vaccine Storage Guidelines 'Strive for 5'* and the digital *Australian Immunisation Handbook*.

All vaccines must be stored in a purpose-built vaccine refrigerator that is continually data logged. The data logging report is downloaded and reviewed at least weekly.

All refrigerators must have an audible alarm preferably with a back-to-base alarm or automated temperature monitoring system.

A base-line vaccine storage self-audit is conducted initially and annually in March thereafter (available on the Quality Audit Reporting System – QARS).

Local procedures must be in place to respond to cold chain breaches and power failures, including reporting temperatures outside +2°C to +8°C range to the local public health unit (PHU) on 1300 066 055 within the same working day. Vaccines must be quarantined until advice is received from the PHU.

Cold chain breaches resulting in vaccine wastage or recall and revaccination of patients must be reported in the Incident Management System to facilitate investigation, resolution and minimise the risk of future incidents.

All vaccine refrigerator current/minimum/maximum temperatures are visualised and manually recorded twice daily on the NSW Health vaccine refrigerator monitoring chart.

Staff education should be facilitated through the MyHealth 'Vaccine Storage and Cold Chain Management' module and cold chain management resources available on the NSW Health cold chain webpage.

REVISION HISTORY

Version	Approved by	Amendment notes
August - 2020 (PD2020_028)	Deputy Secretary Population and Public Health and Chief Health Officer	Inclusion of automated temperature monitoring systems Monitoring and reporting requirements Education and training requirements Appendix 1: Vaccine Refrigerator and Cold Chain Breach Protocol Appendix 2: Cold Chain Breach and Vaccine Wastage Reporting Form Appendix 3: Recall and Revaccination Report Appendix 4: NSW Health Vaccine Refrigerator Temperature

		Chart Appendix 5: Vaccine Cooler Temperature Chart
June -2017 (PD2017_014)	Deputy Secretary Population and Public Health and Chief Health Officer	Initial Document

ATTACHMENTS

1. Vaccine Storage and Cold Chain Management: Procedures

CONTENTS

1	BACKGROUND.....	1
1.1	About this document.....	1
1.2	Key definitions.....	1
1.3	Legal and legislative framework	2
2	VACCINE COLD CHAIN MANAGEMENT	3
2.1	Cold Chain Management Principles	3
2.2	Governance	4
2.3	Implementation	4
3	EQUIPMENT.....	5
3.1	Purpose-built Refrigerators.....	5
3.2	Temperature Monitoring Equipment.....	6
3.2.1	Data Loggers.....	6
3.2.2	Minimum/maximum Thermometers	7
3.2.3	Automated Temperature Monitoring Systems.....	7
3.2.4	Disposable Cold Chain Monitors	7
4	REFRIGERATOR MONITORING	8
5	MANAGEMENT OF COLD CHAIN BREACHES	9
5.1	Cold Chain Breach Protocol	9
5.2	Patient Recall and Revaccination.....	10
5.3	Incident Notification	10
6	VACCINE MANAGEMENT AND STORAGE SELF AUDIT.....	10
7	MONITORING AND REPORTING	10
8	EDUCATION.....	11
9	VACCINE ORDERING	11
10	VACCINE DELIVERIES	12
11	RECORD MANAGEMENT	12
12	REFERENCES.....	13
13	APPENDIX LIST.....	13
13.1	Vaccine Refrigerator and Cold Chain Breach Protocol.....	14
13.2	Cold Chain Breach and Vaccine Wastage Reporting Form	15
13.3	Recall and Revaccination Report	16
13.4	NSW Health Vaccine Refrigerator Temperature Chart.....	17
13.5	Vaccine Cooler Temperature Chart.....	18

1 BACKGROUND

1.1 About this document

This Policy Directive provides specified procedures for the storage and monitoring requirements of vaccines that are either funded by NSW Health or purchased by facilities. Self-auditing requirements are also detailed in this Policy which aims to:

- Ensure consistent and effective vaccine storage, monitoring and reporting processes in all public health facilities;
- Facilitate the administration of viable vaccines to vaccine recipients;
- Ensure vaccine cold chain breaches are identified and managed consistently, efficiently and effectively;
- Reduce vaccine wastage as a result of vaccine cold chain mis-management, and;
- Inform providers of requirements for ordering, storing and monitoring vaccines.

This Policy should be read in conjunction with the current edition of the [National Vaccine Storage Guidelines: Strive for 5 \(referred to as 'Strive for 5'\)](#) and the digital [Australian Immunisation Handbook](#).

1.2 Key definitions

Ambient temperature

Temperature of the surrounding environment in which the vaccine refrigerator is operating.

Automated temperature monitoring systems

Wireless temperature-monitoring systems that provide real-time temperature readings, and email or text message alerts when a temperature excursion outside the recommended +2°C to +8°C range occurs.

Salvage plan

A plan of action that ensures that vaccines will continue to be stored between +2°C to +8°C during power supply or refrigerator failures.

Cold chain

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

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, for example, when stock taking or restocking). A cold chain breach may also be referred to as an 'adverse vaccine storage event'.

Cold chain monitors (CCMs)

Transport monitors that accompany vaccines during transit from the NSW Vaccine Centre to the immunisation provider. CCMs must be discarded after delivery and not used for routine temperature monitoring.

Data logger

A small electronic device that continuously measures temperatures and stores an electronic record of the refrigerator temperatures during a monitored period.

Public Health Unit (PHU)

A team of health professionals based within a local health district who are responsible for a range of health protection issues, including immunisation. The PHU contact number is 1300 066 055.

Purpose built vaccine refrigerators

Refrigerators designed and constructed specifically for vaccine storage at temperatures between +2°C and +8°C.

Thermostability

Capability of withstanding moderate heat without loss of characteristic properties.

Vaccines

Complex biological products designed to induce a protective immune response effectively and safely.

Vaccine management

The storage and monitoring of vaccines, including stock rotation, effective management of cold chain breaches and nomination of a staff member responsible for cold chain management to ensure timely reporting to the local PHU when required.

1.3 Legal and legislative framework

[NSW Health Medication Handling in NSW Public Facilities \(PD2013 043\)](#)

[NSW State Records Act \(1998\) General Disposal Authority](#)

2 VACCINE COLD CHAIN MANAGEMENT

Health professionals have a legal and professional obligation to ensure their patients receive effective health products, for example, vaccines that have been stored appropriately and not adversely affected by heat, cold or light.

Vaccines must be transported and stored within the recommended temperature range +2°C to +8°C at all times.

Effective vaccine storage and cold chain management are essential as:

- Freezing of vaccines can cause loss of potency which can never be restored.
- Effective cold chain management ensures patients are vaccinated with potent vaccines to reduce their risk of disease. Patients vaccinated with ineffective vaccines may need to be recalled, counselled and revaccinated. In addition to the inconvenience of this, the total cost of a cold chain breach can be significant.

2.1 Cold Chain Management Principles

- Store vaccines in a purpose-built vaccine/medication specific refrigerator (*refer to section 3 Equipment*).
- Nominate a staff member responsible for vaccine storage and cold chain management within their area, and a back-up staff member(s) in their absence. (*refer to section 2.1.2 Governance*).
- Ensure policies, procedures and protocols are in place for vaccine management in each facility (*refer to the Vaccine Management Protocol in Appendix 1 of 'Strive for 5' for detailed information*).
- Develop procedures for orientating new staff and staff with new roles who are responsible for cold chain management. Staff education records must be maintained for ongoing education as required (*refer to section 8 Education for detailed information*).
- Ensure local procedures are in place and essential equipment is readily available for responses to cold chain breaches and power failures in each facility (*refer to Management of Power Failure in Section 8 of 'Strive for 5'*). A local procedure could include a salvage plan that provides a reference guide/chart for display on the front of the refrigerator that contains the contact details for the local public health unit (PHU) to seek advice following a cold chain breach (*example of a refrigerator protocol is provided at Appendix 1*).
- Report temperatures outside the +2°C to +8°C range (excludes fluctuations up to +12°C, lasting no longer than 15 minutes) to the local PHU on **1300 066 055** using the Cold Chain Breach and Vaccine Wastage Reporting Form (*refer to Appendix 2*). The facility pharmacist are to also be contacted as appropriate for advice on temperature sensitive medications that are stored in the refrigerator.
- Vaccines must not be discarded until PHU advice is received (*refer to Cold Chain Breach Protocol in Appendix 3 of 'Strive for 5', current edition and Appendix 1*).

- Follow the guidelines for using ice packs/gel packs and monitoring vaccines in coolers and cold boxes (*refer to Checklist for Managing a Power Failure in Appendix 9 of 'Strive for 5'*) as required during power outages. Record the vaccine temperatures on the 'Vaccine Cooler Temperature Chart' when storing vaccines in a cooler (*refer to Appendix 5*).
- Refer to *Caring for Vaccines During Immunisation Sessions* in Section 7 of 'Strive for 5', if outreach and/or community clinics are conducted.
- Perform vaccine storage self-audits at least annually in March each year (*refer to section 6 Vaccine Management and Storage Self-Audit and section 7 Monitoring and Reporting*).

2.2 Governance

In some health facilities vaccines may be stored in the central pharmacy, ward or clinic. In this situation, the following governance arrangements must be followed:

- the on-duty pharmacist or delegate is responsible for the cold chain management of vaccines that are stored in a central pharmacy, and;
- the Nursing Unit Manager (NUM)/Midwifery Unit Manager (MUM) or delegate is responsible for the cold chain management of vaccines that are removed from the central pharmacy and stored in the ward or clinic refrigerator until they are administered.
- Vaccines must be transferred from the pharmacy to the ward in a monitored cooler using a battery-operated minimum/maximum thermometer or data logger (*refer to Coolers in section 9 of 'Strive for 5' for detailed information*).
- The person who transfers the vaccine (may be pharmacy or ward staff, as determined by local protocols) is responsible for ensuring the cooler is packed appropriately, the temperature of the cooler is recorded during transfer and at arrival to the ward. Vaccine temperatures can be recorded on the 'Vaccine Cooler Temperature Chart', (*refer to Appendix 5*). The person receiving the vaccines must record their receipt and that the cold chain was maintained during transfer on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH700227) or on a locally developed vaccine register. The vaccines must be unpacked and stored immediately in the ward/clinic purpose-built refrigerator.
- The nurse administering the vaccine is responsible for maintaining the cold chain from the time it has been removed from the refrigerator to administration. It is good practice to check the refrigerator display temperature each time before removing vaccines.

2.3 Implementation

Effective vaccine storage and management requires a coordinated approach by key personnel as follows:

Public facilities must:

- Ensure that vaccines are stored and managed according to the National Vaccine Storage Guidelines – Strive for 5 and this Policy Directive.

- Ensure that all staff are aware of the requirements of this Policy Directive.
- Report all vaccine storage and cold chain management issues to the local public health unit for advice and management.

Health Protection NSW will:

- Provide ongoing vaccine storage and cold chain management support to public health units and facilities as required.
- Provide recall and revaccination advice following cold chain breaches as required.
- Ensure that updated vaccine storage and cold chain management advice is provided to local health districts and public health units.

3 EQUIPMENT

Regular maintenance of cold chain equipment must be conducted as specified in *Key Recommendations for Effective Vaccine Storage Management in 'Strive for 5'* and includes the following:

- Service the refrigerator (including a thermostat and calibration service) every 12 months and following any refrigerator malfunction;
- Recalibrate the portable data logger annually or as indicated by the manufacturer; if annual calibration is not recommended by the manufacturer perform accuracy checks as required or annually as a minimum (refer to Strive for 5, current edition);
- Change the portable data logger battery at least every 12 months or as indicated by the manufacturer;
- Check the accuracy of the battery operated minimum/maximum thermometer at least annually or as indicated by the manufacturer (as appropriate);
- Change the battery operated minimum/maximum thermometer battery at least every 12 months or as indicated by the manufacturer (as appropriate).
- Back to base alarm and automated temperature monitoring systems are to be serviced according to the manufacturer recommendations.

Local procedures must include an equipment maintenance log or similar process to document maintenance of cold chain equipment. The document must be readily accessible to staff to assist in the investigation of cold chain incidents.

3.1 Purpose-built Refrigerators

Purpose-built vaccine refrigerators (including medication specific refrigerators) are the only suitable option for vaccine storage as they are designed to store vaccines and temperature sensitive medications. They have a stable, uniform and controlled cabinet that maintains the temperature between +2°C to +8°C, however they must be monitored as specified in *section 4 Refrigerator Monitoring*. The following principles must be followed:

- Each refrigerator must have an audible alarm (preferably with a back to base alarm or automated temperature monitoring system) with preset parameters set

outside +2°C to +8°C (to activate when temperature reaches less than +2°C and greater than +8°C and is maintained until the alarm is manually deactivated). A visual temperature display must accompany the auditory alarm.

- The refrigerator plug electricity connection must be clearly labelled ¹ “**DO NOT** turn off power or disconnect this refrigerator” so that it is not unplugged accidentally. Consideration should be given to hard-wiring the power board to prevent it from being accidentally disconnected.
- The refrigerator is to be plugged into an uninterruptible power supply (UPS). Where a UPS is not available, an emergency generator should be used during interruptions to the power supply.
- Where a refrigerator door does not close easily, consider using a lock on the refrigerator door or using a door closing device or leveraging the refrigerator to ensure the door closes freely and not left ajar after accessing the vaccines (front feet higher than back feet, check that this is acceptable with refrigerator manufacturer).
- The refrigerator must be placed with enough space between the wall and cabinet to ensure adequate air flow as specified by the refrigerator manufacturer (confirmed by asset/maintenance staff as appropriate).
- The refrigerator must be placed in a secure room where only appropriate staff have access. Alternatively, if a secure room is not available, the refrigerator door must be locked at all times with access only provided to the appropriate staff.

Domestic refrigerators **must not** be used for vaccine storage in NSW facilities.

3.2 Temperature Monitoring Equipment

3.2.1 Data Loggers

To investigate temperature excursions, all refrigerators that store vaccines must have a data logger in place (portable or in-built) or back to base data logging to continuously measure the refrigerator temperature. The data logger should be set to record temperatures at five minute intervals. Where a portable data logger is used, it should be secured to a shelf in the middle of the refrigerator to ensure consistent monitoring. Where a data logger has a probe, it should be placed inside a vaccine box to record the vaccine temperature rather than the ambient air. All facilities must have the appropriate equipment and software to download data logging/back to base monitoring reports.

Data logging reports must be downloaded, reviewed and saved weekly and/or when a potential cold chain breach has been identified during the manual twice daily temperature checks to ensure viable vaccines are administered to patients. All staff are to be trained on how to operate/manage the data logger and interpret its readings. Any actions taken in response to data logging must be documented and these records managed in accordance with the appropriate retention and disposal authorities for administrative records (*refer to section 11*).

¹ Refrigerator stickers and posters are available to download from the Australian Government website at: <https://beta.health.gov.au/resources/collections/national-vaccine-storage-resource-collection>

Twice daily minimum/maximum temperatures must also be visualised and manually recorded on the NSW Health Vaccine Refrigerator Temperature Chart ² (NH700227) in addition to ongoing data logging/back to base monitoring as this process ensures a timely alert to any cold chain breach. The temperature readings must be recorded from the inbuilt or portable minimum/maximum thermometer.

3.2.2 Minimum/maximum Thermometers

A portable minimum/maximum digital thermometer must be simultaneously used to monitor the temperature of the refrigerator when it does not have a battery back-up for the in-built temperature monitoring system (or generator power back-up) or is not plugged into a UPS. Minimum/maximum thermometers are also required to monitor coolers that are used as alternate storage, for example during a power outage or when transferring vaccines between wards. If using a cooler such as during a power outage, vaccine temperatures can be recorded on the '*Vaccine Cooler Temperature Chart*' (refer to Appendix 5).

3.2.3 Automated Temperature Monitoring Systems

Automated temperature monitoring systems are also referred to as remote or wireless temperature monitoring systems can be used to continuously monitor refrigerator(s) temperatures in real time. The systems use wireless monitoring to continuously transmit vaccine refrigerator temperature data to a web server. These systems allow users to access real-time temperature monitoring data from a connected device such as computer or phone and receive real-time alerts in the event of a sustained temperature excursion. Automated temperature monitoring systems can be used to monitor multiple fridges in large facilities and must be reviewed at least weekly if there have been no alerts in the preceding week.

Facilities with automated temperature monitoring systems must have a local procedure in place to respond to alerts. A local procedure is to include clear roles and responsibilities and escalation procedures for accessing and reviewing temperatures and responding to alarms. Robust governance structures are required to ensure any alerts to a suspected temperature excursion are responded to in a timely manner and the information is filtered to frontline staff accessing the purpose-built refrigerator. Any actions taken in response to alerts must be documented on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH700227) and these records managed in accordance with the appropriate retention and disposal authorities for administrative records (refer to section 11).

3.2.4 Disposable Cold Chain Monitors

Disposable cold chain monitors (CCMs) are used to detect heat and freeze breaches and accompany vaccines during transport from the NSW Vaccine Centre. When the vaccine order arrives from the NSW Vaccine Centre, the CCMs are to be checked and recorded on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH700227) or on a locally developed vaccine register.

² Order the NSW Health Vaccine Refrigerator Temperature Chart via the Stream Direct Catalogue as a POD print item (item number NH700227)

CCMs must be discarded following receipt of the vaccine delivery and must not be stored in the refrigerator and/or used to monitor vaccines after delivery. All breaches following vaccine delivery must be reported immediately to the NSW Vaccine Centre on **1300 656 132**. The vaccines must be quarantined in a functioning cold chain monitored purpose-built refrigerator and labelled '**DO NOT USE**' while awaiting for advice from the NSW Vaccine Centre.

4 REFRIGERATOR MONITORING

Visualise and manually record the refrigerator's current, minimum and maximum temperatures twice daily (refer to *Monitoring and recording refrigerator temperatures* in section 5.6 of 'Strive for 5') on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227; refer to Appendix 4). The temperature readings must be recorded from the inbuilt or portable minimum/maximum thermometer.

Twice daily manual temperature checks are required regardless of whether continuous data logging, back to base alarm systems or automated temperature monitoring systems are in use. This is to ensure frontline staff are familiar with the normal functioning of the refrigerator, can identify the early warning signs of potential refrigerator malfunction and ensure vaccines have not been subjected to a cold chain breach prior to administration.

Where a facility is not operational 24 hours/day for seven days/week, the refrigerator's current/minimum/maximum refrigerator temperature must be checked on the first operational day (since the last recording) and twice daily thereafter. The automated temperature monitoring system or data logging report is to also be downloaded and/or reviewed before any vaccines are removed for administration.

Reset the minimum/maximum thermometer after each reading, following any excursion outside +2°C to +8°C and on receipt of a new vaccine delivery. Ensure the refrigerator has returned to within +2°C to +8°C before resetting. If the refrigerator temperature reaches greater than 12°C for more than 15 minutes (refer to section 5 *Management of Cold Chain Breaches*).

Continuously measure the vaccine refrigerator temperature using a permanent data logger, back to base monitoring system or automated temperature monitoring system. The data logging/back to base monitoring report must be downloaded and reviewed by the NUM/MUM/delegate weekly and following any identified cold chain breach (excludes fluctuations up to 12°C for less than 15 minutes). Automated temperature monitoring system reports must be reviewed at least weekly if there have been no real-time alerts in the preceding week to prompt review of the temperature readings.

Each facility must have a local procedure for downloading and reviewing the data logging reports or monitoring and acknowledging alerts from the automated temperature monitoring system.

All staff responsible for cold chain management must have access to and know how to download and review the data logging reports (stored centrally in an appropriately named folder for each refrigerator and date), including back to base monitoring and automated temperature monitoring system reports as appropriate.

A back-up copy of the data logging graphs must be stored centrally in a file by the NUM/MUM/delegate. The NSW Health Vaccine Refrigerator Temperature Chart (NH700227) must be checked and signed off at the end of each fortnight before storing centrally.

Record any events for example, refrigerator restocking following a vaccine delivery, or refrigerator servicing, on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227). For cold chain breach management (*refer to Section 5 Management of Cold Chain Breaches*).

5 MANAGEMENT OF COLD CHAIN BREACHES

5.1 Cold Chain Breach Protocol

A 'cold chain breach' has occurred if a purpose-built refrigerator's temperature has been outside the recommended range of +2°C to +8°C. It excludes fluctuations up to +12°C, lasting no longer than 15 minutes, which may occur for example when stock taking or restocking a refrigerator. Such fluctuations must be recorded on the NSW Health Vaccine Refrigerator Temperature Chart (NH700227) to cross reference when reviewing the corresponding data logging report. All other cold chain breaches greater than +8°C that cannot be accounted for and any less than +2°C must be reported to the PHU for advice. Once a cold chain breach has been identified, the following procedures must be followed:

- Refrigerate and quarantine the potentially compromised vaccines (in a functioning purpose built and temperature monitored refrigerator) between +2°C to +8°C and label '**Do not use**'.
- Inform the NUM/MUM/delegate immediately.
- Download and review the data logging report.
- Complete the Cold Chain Breach and Vaccine Wastage Reporting Form (*refer to Appendix 2*)
- Contact the local PHU on **1300 066 055** as soon as possible during business hours. The PHU will require the cold chain breach reporting form, data logging and corresponding **twice** daily temperature readings to assess the breach.
- Vaccines must not be discarded until advice has been provided by the local PHU. PHUs will provide advice on vaccine disposal based on vaccine thermostability data available to Health Protection NSW.
- Report the type and exact number of vaccines wasted to the PHU as required. Expired vaccines must also be reported to the PHU using the Cold Chain Breach and Vaccine Wastage Reporting Form.
- Contact the relevant manufacturer for advice on privately purchased vaccines (vaccines not sourced from the NSW Vaccine Centre) as the PHU is unable to provide advice on private stock.
- Contact the facility pharmacist for advice on temperature sensitive medications.

5.2 Patient Recall and Revaccination

Cold chain breaches that have been identified after patients have been vaccinated with potentially compromised vaccine(s) require detailed information (*refer to Appendix 2 Cold Chain Breach and Vaccine Wastage Reporting Form and Appendix 3 Recall and Revaccination report*) to be forwarded by the ward/unit manager/delegate to the local PHU for advice on whether revaccination is required.

The PHU will assess each report on a case-by-case basis as not all cold chain breaches will result in patient recall and revaccination. A number of factors are considered by the PHU, including the type of vaccine and its thermostability, duration of breach and history of any previous breaches and the patient's vaccination history. The PHU will consult with Health Protection NSW to decide on the need for revaccination.

5.3 Incident Notification

Cold chain breaches that result in vaccine wastage or patient recall and revaccination of patients must be reported in the incident management system to facilitate investigation, resolution and minimise the risk of future incidents.

6 VACCINE MANAGEMENT AND STORAGE SELF AUDIT

Vaccine management and storage self-auditing is an essential component of routine quality assurance and risk management processes to ensure potent vaccines are administered. Facilities must ensure that:

- A base-line vaccine management self-audit is undertaken initially and at least annually in March thereafter (using the Quality Audit Reporting System-QARS). Audits may be required more frequently where there have been issues with equipment or cold chain breaches. All NUMs/MUMs/delegates must have access to QARS.
- Facility managers retain a record of the results and discuss them as a standing agenda item on the relevant District locally agreed committee to ensure locally identified issues are addressed and action is taken to improve compliance.
- The local public health unit (PHU) is contacted on **1300 066 055** for vaccine storage/management queries and/or issues identified during the audit.

7 MONITORING AND REPORTING

NSW public facilities are required to conduct vaccine management and storage self-audits annually in March using the 'Vaccine Management and Storage' questionnaire in the Quality Audit Reporting System (QARS). To enable consistent state wide reporting, the 'Vaccine Management and Storage' questionnaire in QARS must not be modified in any way.

Health Protection NSW will access and review District QARS reports via the Clinical Excellence Commission annually in April and access Districts compliance reports as required, to support response to cold chain incidents.

An annual statewide vaccine storage and cold chain management audit report will be submitted to the Chief Health Officer by June each year. It is the responsibility of each facility to review local audit results and address areas of low compliance.

8 EDUCATION

All NSW Health staff involved in vaccine transport, storage and administration must be trained in vaccine management to ensure the vaccines remain effective and potent.

All cleaning and maintenance staff must be educated on the importance of vaccine storage and cold chain management.

To facilitate staff education, cold chain management resources are available on the NSW Health website at: www.health.nsw.gov.au/immunisation and the vaccine online ordering system at: <https://nsw.tollhealthcare.com.au/>. The online My Health Learning 'Vaccine Storage and Cold Chain Management' module is available for all NSW Health staff.

Training should be undertaken by the following staff employed in NSW public facilities:

- managers (in clinical areas where vaccinations are administered)
- staff members and their delegate(s) that have been nominated as responsible for vaccine storage and cold chain management;
- pharmacy staff (where vaccines are stored in the pharmacy department);
- clinical governance/quality audit staff that are involved vaccine storage and cold chain management audits and policy development, and;
- staff that are involved in vaccine administration.
- The MyHealth learning module is also available on the NSW Health cold chain webpage for staff employed in private facilities.

Refer to *section 2.1 Cold Chain Management Principles* for more information on the roles and requirements for cold chain management.

9 VACCINE ORDERING

Review current stock to ensure the order does not overload or exceed refrigerator capacity.

Login to the web based online vaccine ordering system at <https://nsw.tollhealthcare.com.au> using the facility login or coordinate vaccine ordering via the facility pharmacy department. Contact the local PHU on 1300 066 055 for queries regarding vaccine ordering procedures.

Facilities must have a local procedure for detailing the login and password details for vaccine ordering. The details must be accessible only by staff responsible for ordering vaccines. Detailed vaccine ordering information is available at: www.health.nsw.gov.au/immunisation and the online vaccine ordering system is accessible at: <https://nsw.tollhealthcare.com.au/>.

10 VACCINE DELIVERIES

Each facility must have a written local procedure for receiving vaccines from the NSW Vaccine Centre and where vaccines are transported from a central pharmacy to an alternate refrigerator in a ward/unit within the facility or District (*refer to section 2.2*).

The CCMs must be checked immediately upon delivery from the NSW Vaccine Centre to identify any cold chain breach that has occurred during transport. The CCMs must be discarded following delivery and must not be stored in the refrigerator with the vaccines.

The vaccine delivery date, time, CCM status and staff initial, must be recorded on the reverse of the NSW Health Vaccine Refrigerator Temperature Chart (NH700227).

All vaccines must be refrigerated immediately following delivery, placing the oldest stock with the shortest expiry date to the front of the purpose-built refrigerator. Vaccines must not be removed from their original cardboard packaging to increase refrigerator capacity as they are sensitive to light including UV and fluorescent light.

Care must be taken so that that stock is not placed in such a way as to block or isolate a sensor that is located inside the refrigerator. Where this is a potential risk to block or isolate the sensor, add a label adjacent to the sensor to instruct staff not to place vaccines in front of it.

If a cold chain breach has been identified following a vaccine delivery from the NSW Vaccine Centre, the vaccines must be quarantined in a functioning refrigerator with a 'DO NOT USE' sign and the breach reported to the NSW Vaccine Centre on 1300 656 132 (**refer to section 3** Equipment; Disposable Cold Chain Monitors).

To prevent overstocking, the maximum amount of vaccine stock must be determined (as specified by the refrigerator manufacturer and confirmed by pharmacy as appropriate) for each refrigerator and vaccine stock maintained accordingly.

Minimise refrigerator door opening to prevent the temperature rising above +8°C. The use of a vaccine location map on the outside of a solid-door refrigerator may assist in quickly locating vaccines and keep door opening to a minimum. The use of labelled baskets may also reduce clutter and assist in the ordering and restocking process.

Any temperature excursions (excludes fluctuations up to +12°C, lasting no longer than 15 minutes, when stock taking or restocking) must be reported as per *section 5 Management of Cold Chain Breaches*.

11 RECORD MANAGEMENT

The retention periods of specific records are clearly defined in the NSW State Records Act (1998) General Disposal Authority. This is usually seven years, unless there are circumstances that require organisational compliance with mandatory or operating requirements.

- Retention periods for records such as data logging and vaccine refrigerator temperature charts are specified in the appropriate retention and disposal authorities for administrative records, specifically *Equipment and Stores (GA28): Maintenance 5.7.1*.

- Original source records may be copied and disposed of in accordance with the appropriate retention and disposal authorities for *Original or source records that have been copied (GA45)*.

12 REFERENCES

The Australian Government Department of Health (2019). National Vaccine Storage Guidelines Strive for 5 (3rd edition). Available from:
<https://beta.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5>

Australian Technical Advisory Group on Immunisation (ATAGI). The Australian immunisation handbook (online version). Canberra: Australian Government Department of Health, 2019 <https://immunisationhandbook.health.gov.au/fundamentals-of-immunisation>


13 APPENDIX LIST

1. Vaccine Refrigerator and Cold Chain Breach Protocol
2. Cold Chain Breach and Vaccine Wastage Reporting Form
3. Recall and Revaccination Report
4. NSW Health Vaccine Refrigerator Temperature Chart
5. Vaccine Cooler Temperature Chart


13.1 Vaccine Refrigerator and Cold Chain Breach Protocol

NSW HEALTH


Vaccine Refrigerator Protocol




REFRIGERATOR MONITORING




CHECK refrigerator temperatures twice a day during operational hours and aim for 5° C




RECORD the minimum, maximum and current temperatures on the NSW Health vaccine refrigerator temperature chart



RESET the thermometer after recording temperatures



ACT if temperatures are outside of the recommended temperature range of +2°C to +8°C or the fridge has alarmed. Follow the cold chain breach protocol steps below.



COLD CHAIN BREACH STEPS

1

Take **corrective ACTION** where possible. Is the refrigerator door closed, refrigerator plugged in/turned on. Contact engineer if a refrigerator malfunction is suspected.

2

ISOLATE affected vaccines/medicines and label '**DO NOT USE**'. Ensure vaccines can continue to be stored between +2°C to +8°C. Vaccines may need to be transferred to an alternative monitored refrigerator or cooler.

3

REPORT breach immediately to your manager/delegate Ph:

4


DOWNLOAD the data logger or review the back to base or automated temperature monitoring system and investigate potential cause and duration of breach.

5

NOTIFY the public health unit (1300 066 055) if temperature is <+2°C or > +8°C for >15 minutes (excludes fluctuations up to +12°C ≤15 mins e.g. vaccine delivery). PHU will require cold chain breach reporting form, data logging and twice daily temperature readings to assess breach.

6


DO NOT DISCARD vaccines until advice is received.



OTHER MEDICATIONS - Notify facility Pharmacy Service provider. **Do NOT** use medications until advice is received from Pharmacy.

7

DOCUMENT all activity on the back of the NSW Vaccine Refrigerator Temperature Chart - Fortnightly, i.e. thermostat adjustment, restocking, power outage, data logger removal etc. **SUBMIT an IIMS/ims+** for breaches resulting in vaccine wastage or patient recall and revaccination.



Order the **NSW Vaccine Refrigerator Temperature Chart - Fortnightly** from Toll Stream Direct. ORDER NUMBER: NH700227

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Vaccine Storage and Cold Chain Management

APPENDICES



13.2 Cold Chain Breach and Vaccine Wastage Reporting Form

The cold chain breach reporting form is available to download from www.health.nsw.gov.au/ccb

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	
5. Data logger temperature	Min <input type="text"/> Max <input type="text"/>
6. Duration outside 2° C to 8° C (hrs/mins)	
7. Is this the first cold chain breach for these vaccines?	<input type="checkbox"/> Yes <input type="checkbox"/> No, date of previous breach: <input type="text"/>
8. Was anyone vaccinated with the compromised vaccines?	<input type="checkbox"/> Yes (Public Health Unit to provide advice) <input type="checkbox"/> No
9. Which of these vaccine management policies and procedures are currently in place?	<input type="checkbox"/> Vaccine management protocol (refer to 'Strive for 5' Guidelines) <input type="checkbox"/> Accessible Cold Chain Breach Protocol <input type="checkbox"/> Completion of the NSW Health Cold Chain Training Module by all staff <input type="checkbox"/> Annual vaccine storage self-audits Date of last audit: <input type="text"/>

COLD CHAIN BREACH AND VACCINE WASTAGE REPORTING FORM

Sections marked with an * are mandatory



SECTION 3: FRIDGE AND COLD CHAIN MONITORING DETAILS

Section 3 must be completed if there has been a refrigerator malfunction or the cause of the cold chain breach is unknown	
3.1 Refrigerator details	
Date of refrigerator purchase	
Date of last refrigerator service	
Further information (if applicable)	
3.2 Data logger details	
Type of data logger	<input type="checkbox"/> Inbuilt <input type="checkbox"/> Portable
Date of purchase	
Date of last battery change	
Date of last calibration/ service	
Further information (if applicable)	
3.3 Minimum/maximum thermometer details	
Type of min/max thermometer	<input type="checkbox"/> Inbuilt <input type="checkbox"/> Battery operated
Date of purchase	
Date of last battery change	
Date of last accuracy check i.e. ice slurry	
Further information (if applicable)	
3.4 Alternative vaccine storage details	
Is there an alternative fridge for vaccine storage?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Type of alternative fridge used for back up vaccine storage	<input type="checkbox"/> Purpose Built Vaccine Specific Refrigerator <input type="checkbox"/> Domestic refrigerator
Further information (if applicable)	

COLD CHAIN BREACH AND VACCINE WASTAGE REPORTING FORM

Sections marked with an * are mandatory



*SECTION 4: VACCINE DETAILS

Count and enter the exact number of doses of each vaccine brand in the refrigerator at the time of the cold chain breach.

Vaccines exposed to a second breach should be recorded as follows:

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
MMRII	5 (5)	Retain 5 (Discard 5)	Infanrix	13 (2)	Retain 13 (Discard 2)

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
Act-HIB	Select	MMR II	Select		
Adacel	Select	Neis-Vac C	Select		
Afluria Quad	Select	*Nimenrix (Provide batch number and expiry date below)	Select		
Bexsero	Select	Pneumovax 23	Select		
Boostrix	Select	Prevenar 13	Select		
Engerix B (adult)	Select	Priorix	Select		
Engerix B (paed)	Select	Priorix Tetra	Select		
Fluad Quad	Select	Proquad	Select		
Fluarix Tetra	Select	Quadracel	Select		
*Fluquadril (Provide batch number and expiry date below)	Select	*Rabipur (Provide batch number and expiry date below)	Select		
Gardasil 9	Select	*MIRV (Rabies) (Provide batch number and expiry date below)	Select		
Havrix 1440	Select	Rotarix	Select		
Hep B Vaxil - adult	Select	Vaqta Adult	Select		
Hep B Vaxil - paed	Select	Vaqta Paed	Select		
Infanrix	Select	Varilix	Select		
Infanrix hexa	Select	Varivax	Select		
Infanrix IPV	Select	*Vaxigrip Tetra (Provide batch number and expiry date below)	Select		
IPOL	Select	Zostavax	Select		

*Additional advice e.g. batch # and expiry date

Vaccines that can be retained, should be clearly labelled using the NSW Health Cold Chain Breach Labels and used before any new stock. Any further cold chain breaches should be reported to your local public health unit as each breach is assessed on a case by case basis.

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

Public Health Unit Use Only

PHU Contact person:	
Reason for cold chain breach:	
<input type="checkbox"/> Refrigerator malfunction	<input type="checkbox"/> Unknown/other
<input type="checkbox"/> Power outage	<input type="checkbox"/> Flood
<input type="checkbox"/> planned	<input type="checkbox"/> unplanned
<input type="checkbox"/> Storm	<input type="checkbox"/> Fire
<input type="checkbox"/> Human error	
Action(s) taken:	
Vaccines quarantined: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Fridge service requested: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Service report received: <input type="checkbox"/> Yes <input type="checkbox"/> No	
HETI module recommended: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Certificates received: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Stop placed on vaccine account: <input type="checkbox"/> Yes - Date: <input type="text"/> <input type="checkbox"/> No	
Comments:	

This form should be completed and returned to your local public health unit in the event of a cold chain breach. Your local public health unit will provide advice on cold chain management and vaccine disposal (if required). Please email or fax this form to your local public health unit. You can contact your local public health unit on 1300 066 055.

13.3 Recall and Revaccination Report

The recall and revaccination report template is available from the public health unit.

REVACCINATION ADVICE

All fields must be completed



REVACCINATION ADVICE								
<i>*only first two letters of patients' first name and last name</i>								
*Name	DOB	Age	Vaccine given	Batch No.	Expiry	Vaccine Dose number	Date given	Revaccination advice (PHU use only)

Please fax this form to: xx xxxx xxxx or email to xxxxxxxx@health.nsw.gov.au

Vaccine Storage and Cold Chain Management

APPENDICES



13.4 NSW Health Vaccine Refrigerator Temperature Chart

Order the NSW Health Vaccine Refrigerator Temperature Chart via the Stream Direct Catalogue as a POD print item (item number NH700227)

NH700227 031219

Holes Punched as per AS2828.1: 2019

BINDING MARGIN - NO WRITING

VACCINE REFRIGERATOR TEMPERATURE CHART - FORTNIGHTLY

Date range: ____/____/____ to ____/____/____
 Facility: _____ Location: _____
 Fridge ID/name: _____

Instructions for use

Record and plot maximum, minimum and current temperatures on chart TWICE daily.
 RESET temperature monitoring device after recording temperatures.
 TAKE CORRECTIVE ACTION if temperatures out of range (+2-+8°C) excluding fluctuations up to +12°C for ≤15 minutes.
 Refer to cold chain breach steps below.



Health

	Date	1		2		3		4		5		6		7		8		9		10		11		12	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
TOO WARM	Exact Time																								
	Record Max Temp °C																								
ACCEPTABLE TEMPERATURE STRIVE FOR 5°C	+12																								
	+11																								
	+10																								
	+9																								
	+8																								
	+7																								
	+6																								
	+5																								
TOO COLD	+4																								
	+3																								
	+2																								
	+1																								
TOO COLD	0																								
	-1																								
	-2																								
	-3																								
	Record Current Temp °C																								
	Record Min Temp °C																								
Temperature RESET <input checked="" type="checkbox"/>																									
Staff Signature																									

Document actions taken when temperatures outside +2°C to +8°C (excludes fluctuations up to +12°C ≤15 mins e.g. vaccine delivery)

Date & Time	Temperature Current/Min/Max	Actions taken	Name (please print)	Staff Signature

COLD CHAIN BREACH STEPS (refer to Appendix 3 in 'Strive for 5')

1. Take corrective action where possible. Ensure fridge door is closed, fridge is plugged in/turned on. Contact engineer if broken
2. Immediately isolate the medicines/vaccines, keep refrigerated between +2°C and +8°C (move stock to another fridge) and label 'QUARANTINED STOCK - DO NOT USE'
3. Label affected fridge 'OUT OF ORDER - DO NOT USE'
4. Determine breach temperature and duration. Download data logging(s)
5. Where vaccines are involved in the breach contact the local public Health Unit (PHU) on 1300 066 055 for advice. Contact facility pharmacy department/on call pharmacist (for advice). Do not discard any medicines/vaccines until advice is provided.
6. Notify manager/delegate (next working day if out of hours)
7. Report fridge temperature issues and actions on this chart
8. Determine if anyone has received compromised vaccine. Discuss revaccination requirements with PHU as necessary
9. Report the incident on IIMS

Refer to the current edition of the National Vaccine Storage Guidelines 'Strive for 5' for detailed advice on vaccine cold chain management and storage

13.5 Vaccine Cooler Temperature Chart

The vaccine cooler temperature chart is available to download from www.health.nsw.gov.au/ccb

VACCINE COOLER TEMPERATURE CHART											
Facility name:						Vaccine Account Number:					
<p align="center">MAINTAIN TEMPERATURE RANGE: +2°C to +8°C and Strive for 5°C If the cooler temperature is outside +2°C to +8°C please contact your local public health unit on 1300 066 055 for further advice</p>											
If the ice packs HAVE been *conditioned and the cooler has been pre-chilled						If the ice packs have NOT been *conditioned and the cooler has NOT been pre-chilled					
Monitor and record the temperature every 15 minutes for the first hour, then hourly (provided temperatures are stable) using a battery operated minimum/maximum or data logger and reset the thermometer after each reading for accuracy						Monitor the cooler every 5 minutes for the first 30 mins then every 15 minutes for the second 30 mins then hourly (provided the temperatures are stable) using a battery operated minimum/maximum or data logger and reset the thermometer after each reading for accuracy					
DATE:											
TIME	COOLER 1			COOLER 2			COOLER 3			COMMENT/ACTION	SIGNATURE
	Current	Min	Max	Current	Min	Max	Current	Min	Max		
ANY COLD CHAIN BREACHES IDENTIFIED			Y / N	ANY ACTION REQUIRED			Y / N	DATE:		SIGNATURE:	

Vaccine Cooler Temperature Chart