

Cold Chain Toolkit for Immunisation Providers

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1 Vaccine Storage and Cold Chain Toolkit for Immunisation Providers

This toolkit was developed to assist all immunisation providers, health care professionals and administration staff in the safe storage and management of vaccines. All immunisation providers must have access to the *National Vaccine Storage Guidelines, Strive for 5 (3rd edition) 2019*, either online or hard copy version. The Guidelines are referenced along with the NSW Health cold chain resources throughout this document.

1.1 National Vaccine Storage Guidelines, Strive for 5

The National Vaccine Storage
Guidelines, Strive for 5 (3rd edition)
2019 provide information for
immunisation providers for best
practice vaccine storage and cold
chain management. They are the gold
standard for safe vaccine storage in
Australia and should be referenced by
all immunisation providers storing
vaccines to ensure potent and
effective vaccines are administered to
patients.

The guidelines also includes a collection of resources that can be downloaded or ordered from the Department of Health available at https://www.health.gov.au/resources/collections/national-vaccine-storage-quidelines-resource-collection#stickers

1.2 How to use this toolkit

This toolkit should be used in conjunction with the <u>National Vaccine</u>

<u>Storage Guidelines, Strive for 5 (3rd edition) 2019</u>. Click on the 'Strive for 5' icon throughout the document to take you to the 'Strive for 5' guidelines for more detailed information about safely storing vaccines.

For more cold chain information visit the NSW Health cold chain webpage at

https://www.health.nsw.gov.au/immuni sation/Pages/cold-chainmanagement.aspx

2 Why is Vaccine Management Important?

Vaccines are sensitive biological substances that can become less effective or even destroyed if they are frozen or exposed to temperatures outside the recommended range of 2°C to 8°C, and/or exposed to direct sunlight or UV or fluorescent light. The loss of vaccine effectiveness is cumulative and cannot be reversed.

2.1 The Cold Chain



Refer to the National Vaccine Storage

Guidelines: Strive for 5 (section 2), safe vaccine storage.

The 'cold chain' is the system of transporting and storing vaccines within the safe temperature range of +2°C to +8°C to ensure the vaccines remain potent and effective.

If vaccines are stored outside of these temperatures, as may occur during a power outage or refrigerator malfunction, immunisation providers must contact their local public health unit for advice. Refer to Section 8.1:

Managing a Cold Chain Breach

2.2 Light exposure

Vaccines may lose potency if exposed to direct sunlight or ultraviolet (UV) light, including fluorescent light. If a vaccine loses potency it may become less effective in providing protection against vaccine preventable diseases and revaccination may be required.

To protect vaccines from light exposure they must be stored in the

purpose-built vaccine refrigerator inside their original cardboard packaging as per the storage recommendations of the product information. Vaccines must not be removed from the original cardboard packaging during storage.

The original cardboard packaging ensures vaccines are protected against:

- exposure to sunlight and ultraviolet (UV) light or fluorescent light
- temperature fluctuations
- possible breach of sterility
- tampering
- vaccine administration errors

DO NOT remove vaccines from their original cardboard packaging if your fridge is overcrowded.

Purpose built vaccine refrigerators must have capacity to store one months' supply of government funded and private vaccine stock (if required). Consider the volume of vaccines you store during peak times. You may require additional vaccine storage capacity to meet demand during the influenza season by hiring or purchasing an additional purpose-built refrigerator.

If vaccines have been stored outside of their original packaging Refer to Section 8.2: Managing a Light Exposure Breach.

2.3 Staff Education

Vaccine management is the responsibility of ALL staff ordering and handling vaccines. All staff should be trained to manage the cold chain including recording twice daily temperatures and reviewing the continuous refrigerator temperature readings from the data logger report or automated temperature monitoring system.

All practices receiving governmentfunded vaccines must have at least
one staff member who has
successfully completed the NSW
Health <u>Vaccine Storage and Cold</u>
<u>Chain Management</u> on-line learning
module to order vaccines. To prevent
cold chain incidents it is however
recommended that ALL staff complete
the online learning module.

A record of the certificate of completion of all staff that have completed the on-line learning module must be retained by the practice.

The NSW Health <u>Vaccine Storage</u> and <u>Cold Chain Management</u> on-line learning module is available at on NSW Health cold chain webpage:

 https://nswhealth.seertechsol utions.com.au/public_content /HETICP/HETI/CCMWebv3/sto ry_flash.html



3 Vaccine Storage



Refer to the National Vaccine Storage Guidelines: Strive for 5

(section 5), key recommendations for effective vaccine storage management.

Vaccines MUST be stored in a Purpose-built vaccine refrigerator (PBVR).

Vaccines are sensitive to UV light and must be stored in their original packaging to protect them from light and temperature fluctuations.

You may need to source an additional Purpose-built vaccine refrigerator for additional storage space to maintain adequate vaccine stock during the flu program or if you have more vaccines than your PBVR can hold. Check with the manufacturer about your fridge's vaccine storage capacity.

TIP: Vaccine fridge stickers are available to order via the Better Health Centre NSLHD-BHC@health.nsw.gov.au, please include the practice mailing address, contact number, quantity required, and product required i.e. NIP vaccine fridge labels.

It is best practice to:

- Store vaccines in open weaved baskets clearly labelled with the name(s) of the vaccine(s)
- Leave enough space between the vaccines and the walls of

the refrigerator to ensure adequate air flow

3.1 Vaccine Refrigerators



Refer to the National Vaccine Storage Guidelines: Strive for 5

(section 3, 6 and appendix 10) for information about purpose-built vaccine refrigerators.

Purpose-built vaccine refrigerators (PBVR) are specifically designed to store vaccines and temperature sensitive medications and must be used to store vaccines.

Domestic fridges and bar fridges are not built to store vaccines and MUST NOT be used for vaccine storage.

The refrigerator must have:

- an audible alarm to activate
 when the temperature reaches
 less than +2°C and greater than
 +8°C and is maintained until the
 alarm is manually deactivated
- a refrigerator plug electricity connection clearly labelled "DO NOT turn off power or disconnect this refrigerator" so that it is not unplugged accidentally. Stickers are available from the 'Strive for 5' resource collection on the Department of Health webpage.
- a lock on the refrigerator door, 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).

- have enough space between the wall and cabinet to ensure adequate air flow
- be placed in a secure room where only appropriate staff have access

3.2 Outreach and mobile immunisation clinics

For outreach and mobile immunisation clinics, vaccines should be packed into a cooler and monitored during transport and while contained within the cooler using the NSW Health Vaccine Cooler Temperature Chart available at

https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management

Purpose-built vaccine refrigerators do not have freezer compartments. An additional refrigerator with a freezer section will be required for storing ice packs and gel packs for use in an emergency or when packing a cooler for transport. **Refer to section 12: Power outages**.

Purchasing a new fridge?

- All new vaccine fridges must be stabilised and 72 hours of stable
- data logging submitted to the local public health unit before vaccine orders will be accepted by the NSW Vaccine Centre.

Moving address?

Following a change of address the fridge must be stabilised and 24 hours of stable data logging submitted to the local public health unit before vaccine orders will be accepted by the NSW Vaccine Centre.

4 Vaccine Temperature Monitoring Device

4.1 Temperature monitoring equipment



Strive for 5 Refer to the National **Vaccine Storage**

Guidelines: Strive for 5 (section 4), vaccine temperature monitoring devices.

To ensure vaccines are stored within the recommended temperature range, immunisation providers must, at a minimum have:

- A data logger or automated temperature monitoring system
- A minimum/maximum thermometer (inbuilt or portable) with an easy to read digital display to manually monitor the temperature of the refrigerator
- A supplementary portable minimum/maximum thermometer that is available for use in vaccine transportation or in the event of refrigerator failure.

4.1.1 Automated temperature monitoring systems

Automated temperature monitoring systems are also referred to as remote or wireless temperature monitoring systems are new in the market and can be used to continuously monitor refrigerator(s) temperatures in real time.

The wireless temperature-monitoring system provides real-time temperature readings, and email or text message

alerts when a temperature excursion outside the recommended +2°C to +8°C range occurs.

Unlike a data logger weekly download of the temperature readings is not required as they can be accessed at any time.

Practices with automated temperature monitoring systems must:

- Have a procedure in place to respond to alerts in a timely manner with clear roles and responsibilities and escalation procedures for accessing and reviewing temperatures and responding to alarms.
- Continue to perform twice daily manual temperature checks 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.
- Review the temperature readings at least weekly if there have been no alerts in the preceding week to ensure an alert has not been missed or actioned appropriately.
- Document any alerts and weekly review on the Strive for 5 - Vaccine Fridge Temperature Chart (Refer to Appendix 2).

4.2 Temperature Monitoring Requirements



Refer to the National Vaccine Storage Guidelines: Strive for 5 (section 5), monitoring and recording fridge temperatures.

Vaccines must be stored between +2°C and +8°C and in their original cardboard packaging, the optimal storage temperature for vaccines is +5°C. To ensure your purpose built vaccine refrigerator is running within the recommended temperature follow the temperature monitoring guide below.

How often	Action required
Before removing vaccines for administration	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)	 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	 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 <i>Strive for 5 - Vaccine Fridge Temperature Chart</i> (Refer to Appendix 2)
Annually	 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	 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

5 Vaccine Expiry

Immunisation providers must check the vaccine expiry date to ensure efficacious vaccines are administered to patients. The inadvertent administration of expired vaccines may require recall and revaccination of affected patients. To ensure expired vaccines are not administered to patients:

- Check all vaccine expiry dates when taking the vaccine out of the fridge and prior to administration.
- Regularly review vaccine stock and expiry dates including prior to ordering vaccines.
- When reviewing stock and receiving a vaccine delivery bring vaccines with the shortest dates to the front of the refrigerator so they are used first.

Contact your local public health unit on 1300 066 055 for advice if you inadvertently administer an expired government funded vaccine to a patient.

The public health unit will require the de-identified Patient(s) details including name (patient initials) and date of birth, vaccine name, dose number, batch number, expiry date and date of administration.

Contact the vaccine manufacturer for advice if expired private vaccines have been administered.

6 Ordering Vaccines

Vaccines can be ordered on the NSW Vaccine Centre vaccine online ordering system at https://nsw.tollhealthcare.com/

To apply for a vaccine account, contact your public health unit on 1300 066 055.

Aim for ONE routine vaccine order per practice per month, practices can place up to two orders if required.

Immunisation providers are responsible for:

- Ordering vaccines and maintaining appropriate levels of stock to meet practice immunisation program requirements while not exceeding the capacity of the refrigerator.
- Ensuring that stock is rotated when receiving new stock to prevent wastage of vaccines nearing expiry.

6.1 How to calculate monthly vaccine ordering requirements

There is a simple formula that can help you assess how much vaccine you order from month to month:

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

For example, if you had 40 doses of DTPa delivered one month ago and

only 35 were used, (that is, there are 5 left in the fridge):

Quantity to be ordered = 35 used

- 5 left over + 10% of used (3.5)

= 15 - 5 + 3.5

= 33.5 doses

You should therefore order 34 doses (or the nearest number if ordering multiple packs).

This formula is based on international best practice. The additional 10% is a buffer, which allows for unexpected variation in demand.

Additional points to consider:

- If special immunisation campaigns are underway, you may need to order additional supplies on top of the number given in the formula
- During the influenza vaccination season use the influenza vaccine ordering worksheet available in the influenza vaccination provider toolkit and NSW Health webpage at https://www.health.nsw.gov.au/immunisation/Pages/flu

TIP: Online ordering system alerts: Messages regarding changes to

alerts: Messages regarding changes to vaccine stock availability, particularly during the flu season, and any ordering restrictions will be regularly posted on the online vaccine ordering system. It is important to regularly check for new messages and keep your contact details up to date.

6.2 Authorised provider declaration

When placing a vaccine order, immunisation providers are required to electronically sign a declaration under the authorised providers AHPRA registration declaring that they:

- will notify any vaccine doses administered to the Australian Immunisation Register
- comply with cold chain requirements in the National Vaccine Storage Guidelines, Strive for 5 (current edition)
- monitor and record twice daily vaccine fridge temperatures
- continuously data log their vaccine fridge and download and review the data logging report weekly
- have maintained the vaccine cold chain since their last vaccine order and will report any cold chain breaches to their local PHU
- at least one staff member must have successfully completed the NSW Health Vaccine Storage and Cold Chain Management on-line learning module

It is the responsibility of the authorised practice provider to ensure that the signed declaration is true and the practice is compliant with mandatory vaccine storage and cold chain management requirements.

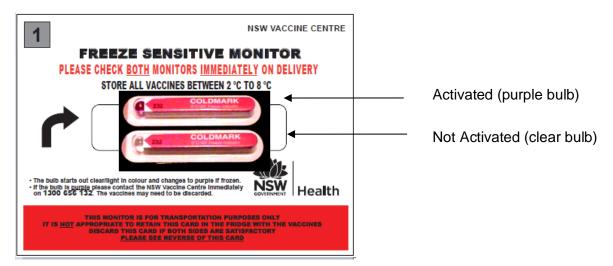
7 Vaccine Deliveries

When receiving a vaccine delivery, it is important to confirm that the cold chain has been maintained during transport and the integrity of the vaccines has not been compromised.

Before accepting the delivery and transferring the vaccines to a dedicated vaccine refrigerator, check the cold chain monitors and record the check on the back of the vaccine minimum/maximum temperature chart. There are two types of cold chain monitors the Coldmark monitor and heat indicator.

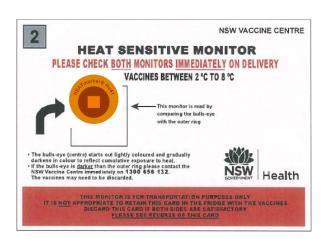
7.1 Freeze indicators

If the bulb on the Coldmark monitor is purple you must <u>not</u> use the vaccines as they will have been exposed to temperatures ≤0°C.



7.2 Heat indicators

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





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7.3 Vaccine delivery failures

A delivery failure occurs when a vaccine delivery:

- cannot be delivered due to a practice closing with no notice or
- the cold chain monitor(s) has activated at the time of delivery

In most cases, vaccines that are returned to the State Vaccine Centre are wasted as the cold chain cannot be maintained during transport for extended periods.

To prevent unnecessary vaccine wastage please contact the State Vaccine Centre on 1300 656 132 if your practice is closing unexpectedly.

7.4 Vaccine delivery issues

If the cold chain monitor(s) has activated contact the NSW Vaccine Centre immediately on 1300 656 132.

While awaiting advice, the vaccines **MUST** be:

- placed in the refrigerator
- isolated and
- labelled 'DO NOT USE'
- Record the breach on the back of the vaccine temperature chart

Note: For privately purchased vaccines, any concerns identified during transport should be directed to the manufacturer.

IMPORTANT: Notify the State Vaccine Centre if your practice is closing unexpectedly to ensure any vaccine orders awaiting delivery are placed on hold.

TIP: Moving address? Update your details on the online vaccine ordering system and submit 24 hours stable data logging to your local public health unit to continue to order vaccines.

Refer to The National Vaccine Storage Guidelines: Strive for 5 (Appendix 8), checklist for emergency storage of vaccines, to ensure your vaccines are transported within the recommended temperature range.

8 Managing and Reporting a Breach

8.1 Cold Chain breaches



Refer to Section 9 of The National Vaccine Storage Guidelines,

Strive for 5, for advice on how to pack a cooler.

A cold chain breach occurs when vaccine storage temperatures have been outside of the recommended range of +2°C to +8°C during storage or transport. This excludes excursions of >+8°C to up to +12°C for no longer than 15 minutes which may occur whilst restocking the refrigerator.

Immunisation providers must report all cold chain breaches to their local public health unit.

- Refer to the <u>NSW Cold Chain</u> <u>Breach Protocol</u> (Appendix 3)
- Isolate vaccines and place a 'DO NOT USE' sign on the fridge.
- 3. Continue to store vaccines between +2°C to +8°C. The vaccines may need to be transferred to an alternate purpose built vaccine refrigerator or cooler if available, see point 7 below.
- Do not discard any vaccines until directed by your local public health unit.
- Download and review the data logging report to assess the duration of the breach and temperature the refrigerator reached.
- 6. Report the cold chain breach by completing the Cold Chain Breach and Vaccine Wastage Reporting Form and contacting your local

public health unit on **1300 066 055** as soon as possible during business hours to report the breach for advice. If the breach occurs after hours, keep vaccines isolated and contact the public health unit on the next business day.

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

- 7. The Cold Chain Breach and Vaccine Wastage Reporting
 Form is available from https://www.health.nsw.gov.au/immunisation/Documents/ccbreporting-form.pdf
- 8. If transferring vaccines to a vaccine cooler (e.g. Esky), record temperatures on the Vaccine Cooler Temperature Chart available from https://www.health.nsw.gov.au/immunisation/Documents/cooler-temp-chart.pdf
 - For more information and to download the cold chain breach reporting form, vaccine cooler temperature chart and cold chain protocol visit the NSW Health webpage at: https://www.health.nsw.gov.au/immunisation/Pages/cold-chain-management

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9. Vaccines subject to cold chain breaches that are assessed by your local PHU as safe and effective to administer within their expiry date will need to be marked with the NSW Health Cold Chain Breach Label.

COLD CHAIN BREACH LABEL These vaccines have been exposed to a cold chain breach outside +2°C and +8°C and are OK to use within their expiry date. THEY MUST BE USED BEFORE ANY OTHER VACCINE STOCK DATE OF COLD CHAIN BREACH: / /

- Labels should be dated with the date of the breach and placed on the vaccine box. The label should not conceal the name of the vaccine or the expiry date.
- Any future cold chain breaches must be reported to your PHU as each breach is assessed on a case by case basis.
- Additional labels can be ordered from the Better Health Centre via email <u>NSLHD-BHC@health.nsw.gov.au.</u>
 Include the name, address and contact number of your practice and the quantity of cold chain labels required.

8.2 Light exposure breaches

If you become aware of vaccines which have been exposed to light during storage:

- Label the vaccines 'Do not use' and isolate them from other vaccines
- 2. Use the Cold Chain Breach and Vaccine Wastage Reporting Form to report all light exposure breaches to your local public health unit on 1300 066 055.
- 3. Include information about:
 - how long the vaccines have been stored outside of their original cardboard packaging and
 - if patients were vaccinated with potentially light affected vaccines.

The public health unit will provide revaccination advice if required.

TIP: If there is no suitable alternative monitored storage option, isolate the vaccines and leave them in the refrigerator with the door closed for the duration of the power outage and follow the NSW Cold Chain Breach Protocol (Appendix 2).

9 Managing a Power Outage



Refer to The National Vaccine Storage

Guidelines: Strive for 5 (Appendix 9), checklist for managing a power failure.

In the event of a power outage or refrigerator failure, ensure you have:

- a back-up plan available and staff are trained to manage power failures
- cooler, ice bricks and bubble wrap or an alternative purpose built vaccine refrigerator to store vaccines
- a portable minimum/maximum digital thermometer

In the event of a power failure:

- DO NOT transport vaccines to another unmonitored vaccine refrigerator or cooler. Alternative vaccine storage MUST have a minimum/maximum thermometer and/or data logger to monitor the temperature. Data loggers must have a visual display of minimum/maximum temperatures.
- DO NOT transfer vaccines to a domestic refrigerator (including bar fridges)

DO NOT put yourself or your staff in danger. If there is a power failure outside normal business hours, such as during a storm, the safety, health and wellbeing of staff should be the main priority.

10 Annual Vaccine Storage Self-Audits



Refer to The National Vaccine Storage Guidelines: Strive for 5

(section 5.9 and Appendix 2), vaccine storage self-audits.

A vaccine storage self-audit must be completed every 12 months and more frequently where there have been problems with:

- · equipment or
- cold chain breaches

The results of the audit must be reviewed by the person responsible for vaccine storage and cold chain management. If the audit identifies any concerns or questions arise, contact the local public health unit on 1300 066 055.

NSW Health will be conducting random audits of practice compliance.

This will include checking that all vaccine doses administered in the practice are notified to the Australian Immunisation Register, as well as verification of the vaccine storage and staff training requirements

Appendix 1: 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 to protect them from light

- •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

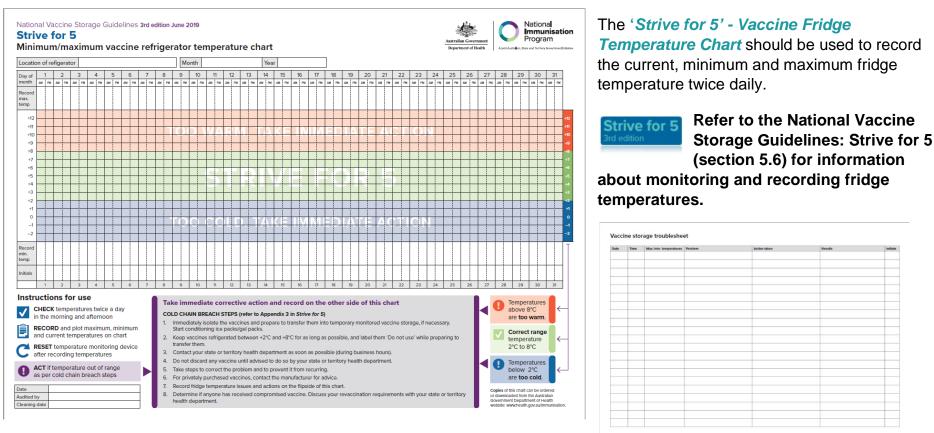
- •Check the vaccine expiry **before** administering vaccines and discard all expired vaccines.
- •Regularly review stock and bring vaccines with the shortest dates to the front of the refrigerator so they are used first.

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.
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Appendix 2: Strive for 5 — Vaccine Fridge Temperature Chart



The chart can be ordered or downloaded from the Australian Government Department of Health website:

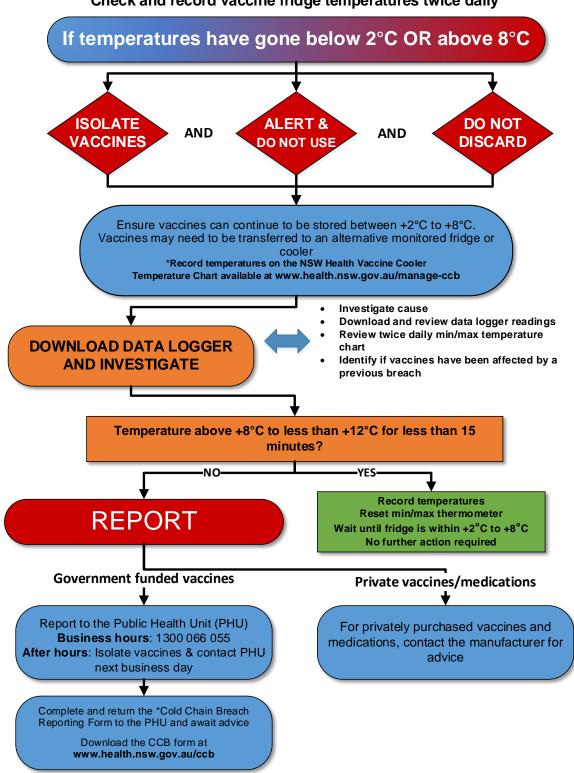
https://www.health.gov.au/resources/collections/national-vaccine-storage-guidelines-resource-collection

Appendix 3: NSW Cold Chain Breach Protocol



Managing a Cold Chain Breach

Check and record vaccine fridge temperatures twice daily



For more information visit www.health.nsw.gov.au/manage-ccb

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