NSW GOVERNMENT Health Population Health

The cold chain and other amazing things!

If we don't protect our vaccines they won't protect our community!

Prepared by Chris Staples

March 2022


PASHA BULKER

Vaccine storage

Why are we concerned about vaccine storage management?

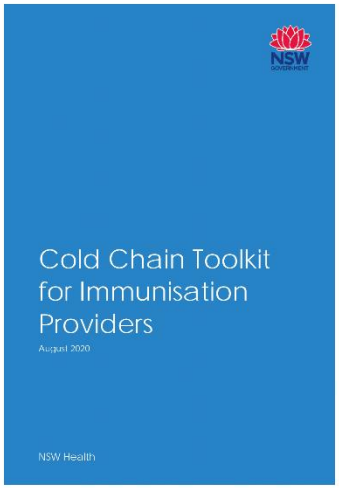
- Ensure people receive an effective product
- Vaccines are expensive & often in short supply
- Professional accountability – we don't want to re-vaccinate patients

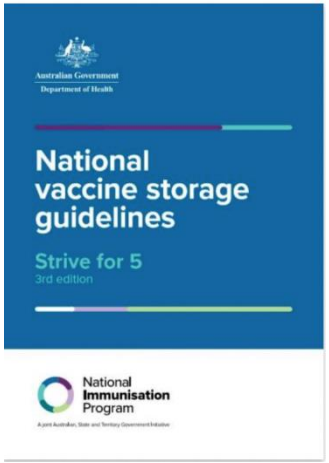
What is the cold chain?

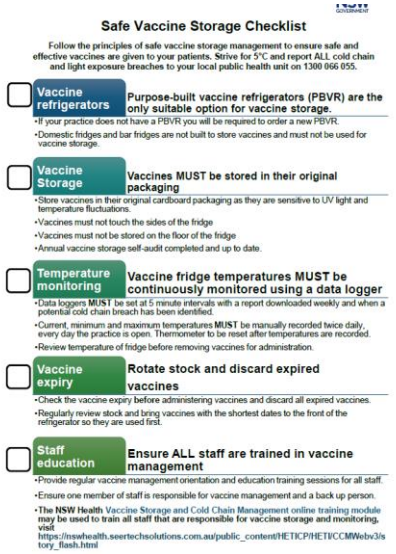
Vaccines must be stored and transported within the recommended temperature range of +2°C to +8°C at all times.

Where to we go for help?

https://www.health.nsw.gov.au/immunisation/pages/default.aspx






Safe Vaccine Storage Checklist

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

Vaccine refrigerators — Purpose-built vaccine refrigerators (PBVR) are the only suitable option for vaccine storage.
- If your practice does not have a PBVR you will be required to order a new PBVR.
- Domestic fridges and bar fridges are not built to store vaccines and must not be used for vaccine storage.

Vaccine Storage — Vaccines MUST be stored in their original packaging
- Store vaccines in their original cardboard packaging as they are sensitive to UV light and temperature fluctuations.
- Vaccines must not touch the sides of the fridge
- Vaccines must not be stored on the floor of the fridge
- Annual vaccine storage self-audit completed and up to date.

Temperature monitoring — Vaccine fridge temperatures MUST be continuously monitored using a data logger
- Data loggers MUST be set at 5 minute intervals with a report downloaded weekly and when a potential cold chain breach has been identified.
- Current, minimum and maximum temperatures MUST be manually recorded twice daily, every day the practice is open. Thermometer to be reset after temperatures are recorded.
- Review temperature of fridge before removing vaccines for administration.

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

Staff education — Ensure ALL staff are trained in vaccine management
- Provide regular vaccine management orientation and education training sessions for all staff.
- Ensure one member of staff is responsible for vaccine management and a back up person.
- The NSW Health Vaccine Storage and Cold Chain Management online training module may be used to train all staff that are responsible for vaccine storage and monitoring, visit https://nswhealth.seertechsolutions.com.au/public_content/HETICP/HETI/CCMWebv3/story_flash.html

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Our wonderful website, make it a favourite!

https://www.hnehealth.nsw.gov.au

Immunisation

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Why do we keep talking about vaccine storage?

Usually we get it right!

However, sometimes we get it wrong!

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How do we manage vaccine storage

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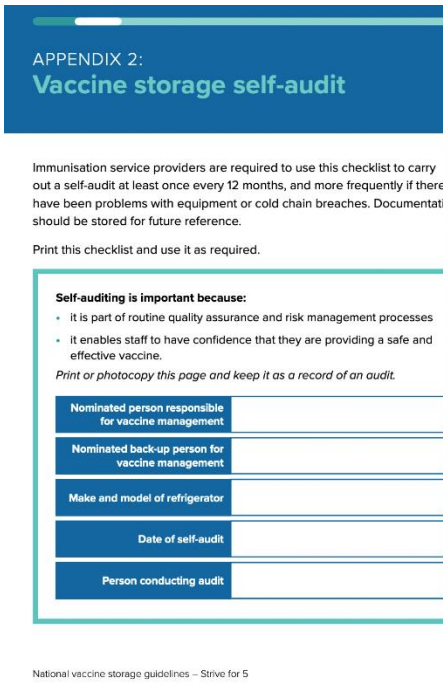
Another PPE

- ❑ People
- ❑ Processes
- ❑ Equipment

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. Documentati 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	

National vaccine storage guidelines – Strive for 5

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?

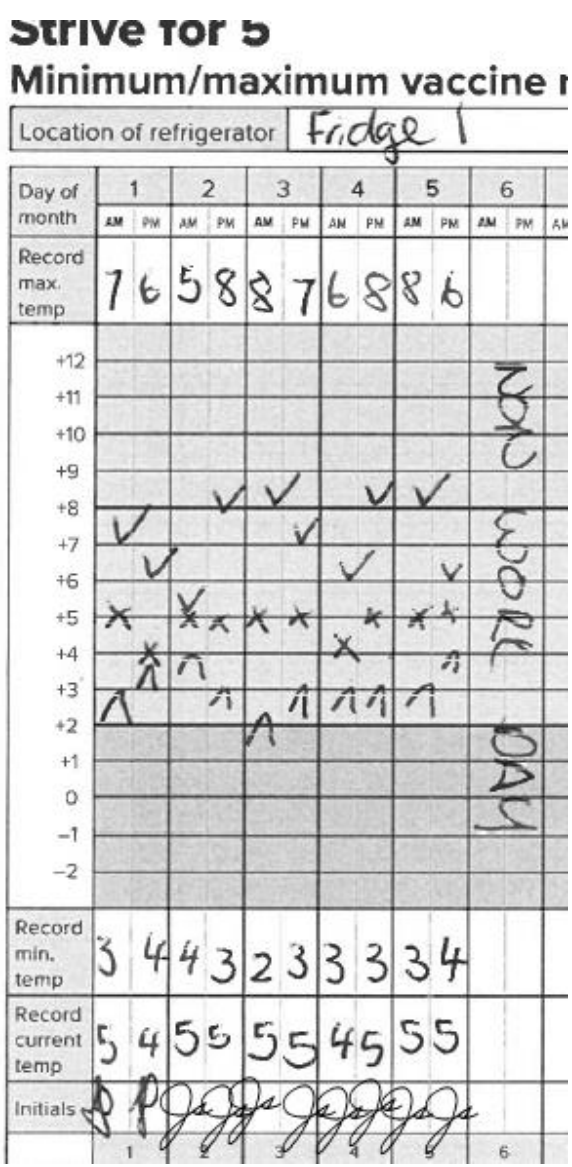
QARS Quality Audit Reporting System

https://www.health.gov.au/sites/default/files/national-vaccine-storage-guidelines-strive-for-5-appendix-2-vaccine-storage-self-audit_0.pdf

Monitoring equipment

Data logger:

- 5 minute recording intervals, run continuously
- Downloaded and CHECK data weekly
- Don't keep this information and location a secret, save it to a shared drive that all staff can access in you absence
- serviced/calibrate/check accuracy every 12 mths.



Min Max thermometer:

- You **must have** a battery operated min/max for each vaccine fridge and alternate cold storage. (eskies)
- **This is in addition to the built in min/max thermometer on your fridge**
- Current, minimum and maximum temperatures must be recorded and plotted twice daily
- battery must be changed when low or every 12 months

What else do you need?

Stickers

On your fridge, power point and meter box – get them from the Commonwealth website

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

In this collection

- Collection description
- Guidelines
- Posters
- Stickers
- Appendices

Regular maintenance

- Refrigerater
- Logger
- Min/max thermometer

This includes checking the accuracy of all equipment every 12 months

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 preformed on the Min/Max thermometer.

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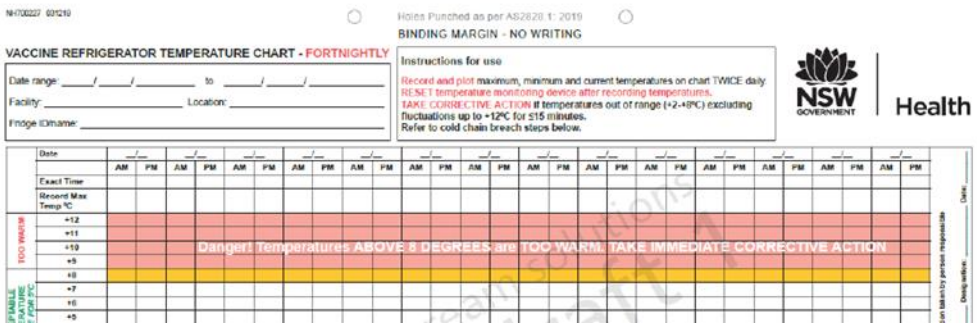
NSW Health requires HNELHD facilities requirements

You need to **plot and record** the minimum, maximum and current temperatures on this chart, it is good practice for all immunisation providers to use this standard temperature graph.

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)



Downloads

Strive for 5 — Vaccine Fridge Temperature Chart Poster

Download PDF - 114 KB , 2 pages
Download Word - 26 KB , 1 page

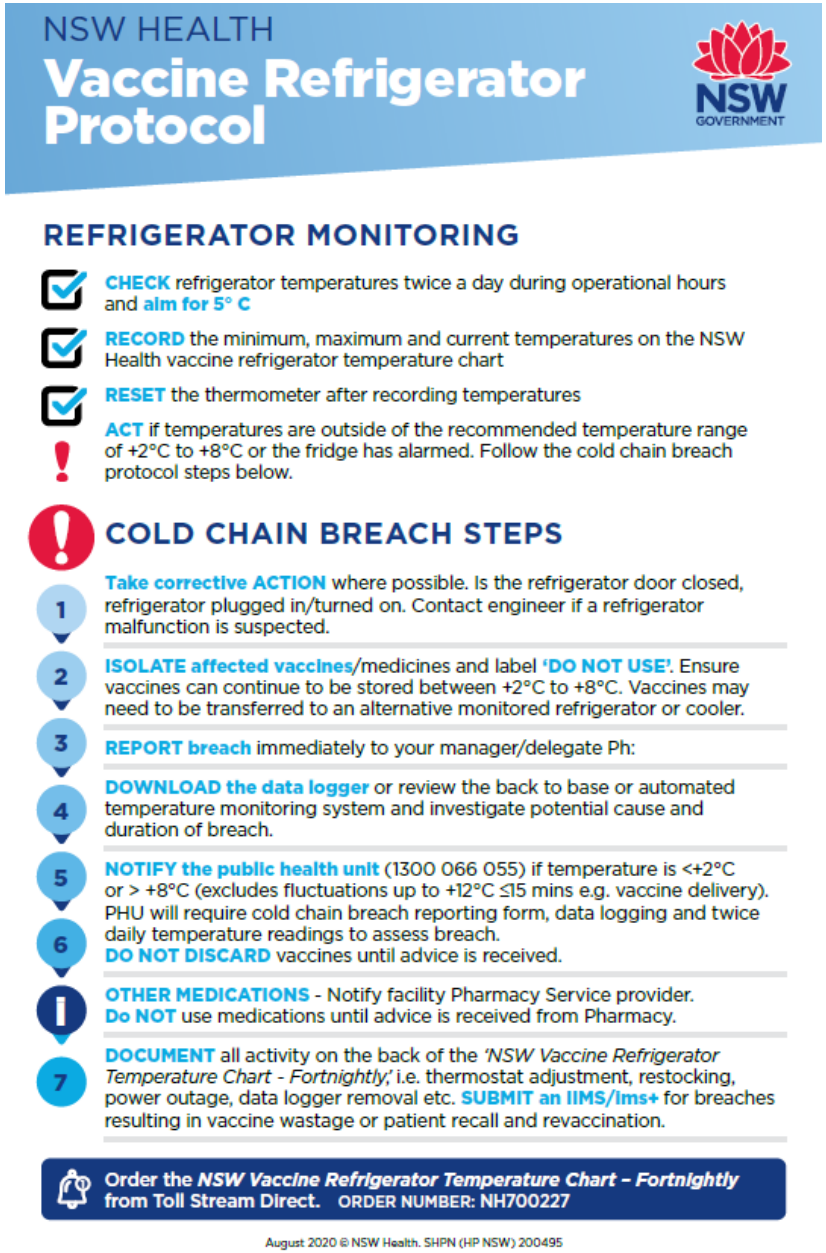
Order this resource

Order ID: IT0179

You can order this resource by contacting National Mailing and Marketing:

- Email - health@nationalmailing.com.au
- Phone - 02 6269 1080

Reporting a cold chain breach



NSW HEALTH

Vaccine Refrigerator Protocol

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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 (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

Vaccine storage records need to be stored as a clinical record on a common drive in an appropriately named folder; eg. vaccine refrigerator temperature loggings.
These include scanned manually recorded temperature graphs, vaccine delivery charts as well as computer loggings, maintenance reports etc

VACCINE FRIDGE COMPUTERISED TEMPERATURE LOGGINGS

Deciding if vaccines can be kept in the event of a cold chain breach requires careful consideration of temperature and 'time out of zone' data. This is made easier if we can look at the logger file, not a picture (pdf) of the graph. We have the software to open your files.
To send your logger file:

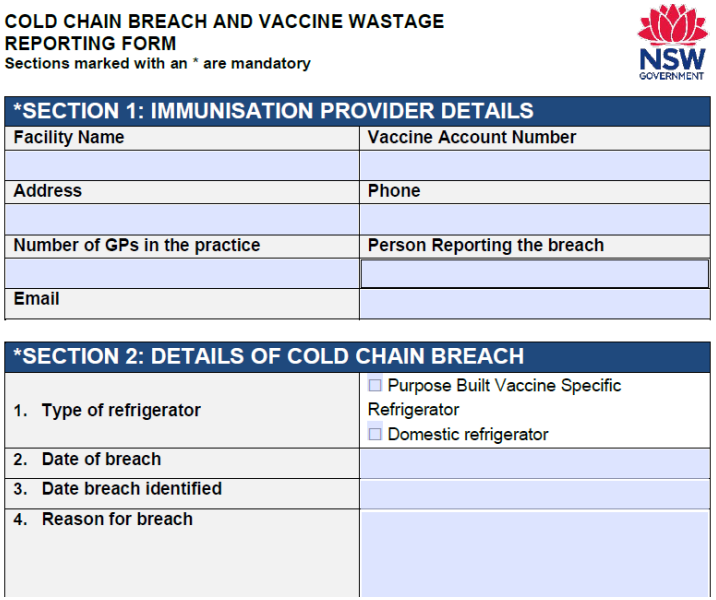
1. Go to the location on your computer where the file is stored
2. Right click on the file and select the option to SEND. This should attach the file to an email
3. Send it to hnelhd-phimmunisation@health.nsw.gov.au
4. Ensure you have a signature block on your email.

How to complete the cold breach and wastage report form

Go to HNELHD website

https://www.hnehealth.nsw.gov.au/our_services2/population-health/immunisation

- Fill this form in online so it can be emailed back to the team
- Complete section 1and 2 carefully and include reason for the breach. Note if this is their first excursion or breach



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

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*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	☐ Purpose Built Vaccine Specific Refrigerator ☐ Domestic refrigerator
2. Date of breach	
3. Date breach identified	
4. Reason for breach	

continue

Only complete section 3 if it was a fridge malfunction or the reason from breach is unknown

- Section 4 vaccine details take your time and note the explanation at the top.
- Total number of doses exposed to first breach
- In brackets – (total number of doses exposed to second breach)

***SECTION 4: VACCINE DETAILS**

Count and enter the exact number of doses of each vaccine
cold chain breach.
Vaccines exposed to a second breach shoul
Total number of doses exposed to first breach (total numb

Vaccine	*Doses	PHU advice	Vaccin
MMRII	5 (5)	Retain 5 (Discard 5)	Infanri

Vaccine	*Doses	PHU advice	Vaccir
Act-HIB	5 (9)	Select	MMR II
Adacel	7	Select	Neis-V
Afluria Quad		Select	*Nimer (Provide bat expiry date
Bexsero		Select	Pneum
Boostrix	12 (10)	Select	Preven
Engerix B (adult)		Select	Priorix
Engerix B (paed)	5	Select	Priorix
Fluad Quad	15 (12)	Select	Proqua
Fluarix Tetra		Select	Quadra

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Reporting form continued

- Attach the required documents listed on the last page

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

Under the final section 'Public Health Unit Only', the PHU staff will add information on what vaccines can be retained and labelled and which vaccines need to be discards and other actions required.

This section is the PHU report to NSW Health.

Public Health Unit Use Only

PHU Contact person:

Reason for cold chain breach:

- ☐ Refrigerator malfunction
- ☐ Power outage
  - ☐ planned
  - ☐ unplanned
- ☐ Storm
- ☐ Human error
- ☐ Unknown/other
- ■ Flood
- ☐ Fire

Action(s) taken:

Vaccines quarantined: ☐ Yes ☐ No

Fridge service requested: ☐ Yes ☐ No
Service report received: ☐ Yes ☐ No

HETI module recommended: ☐ Yes ☐ No
Certificates received: ☐ Yes ☐ No

Stop placed on vaccine account: ☐ Yes - Date: ☐ No

Comments:

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Take home to do list – rotate your stock

- Ensure you have battery operated min/max thermometers
  - Batteries changed every 6-12 months
- Ensure your fridge is serviced every 12 months
- Ensure your data logger is set for 5 minute recording, battery is replaced and serviced as per manufacture instructions or every 12 months and is set to run continuously
- Ensure no vaccines a stored on the floor of your fridge and always in their original packaging
- Ensure you and another staff know how to down load your data logger AND how to attach this file to an email
- COMPLETE YOUR ANNUAL STRIVE FOR 5 SELF AUDIT or QARS (HNE facilities)
- Consider purchasing extra PBVF now if you need additional storage. This will need to be logger for 72 hours before vaccines can be stored in it

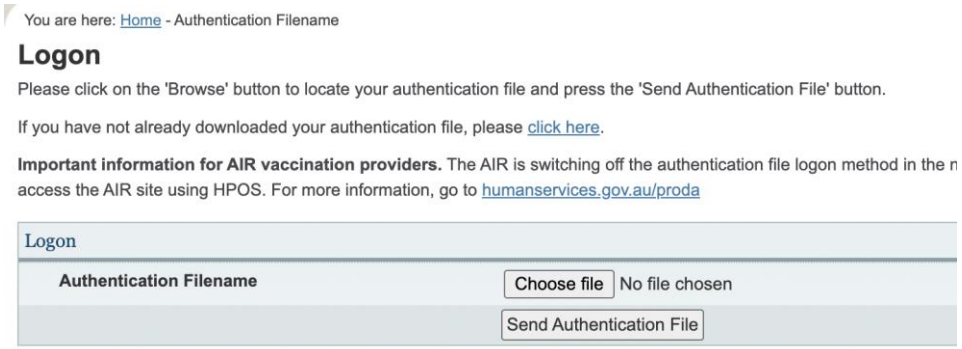
PRODA (provider Digital Access)

PRODA (Provider Digital Access)

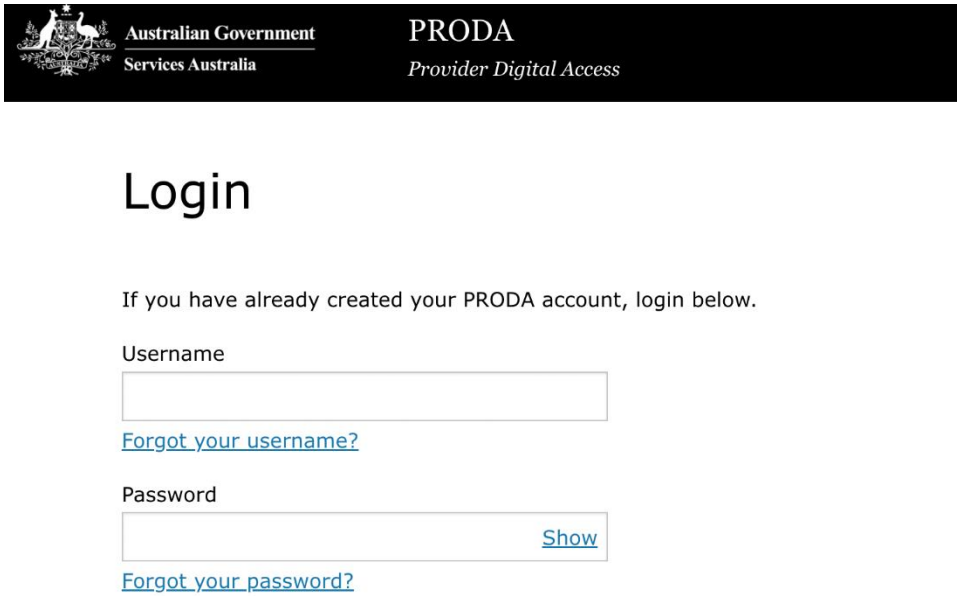
PRODA is an online identity verification and authentication system. It lets you securely access government online services

Why? – because we have no idea who had access through the old authentication file method, and there was no record of who was doing what.

old



new



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AIR ACT 2015 & AMENDMENT

OVERSEAS RECORDS responsibility of provider the patient presents to

I've been everywhere

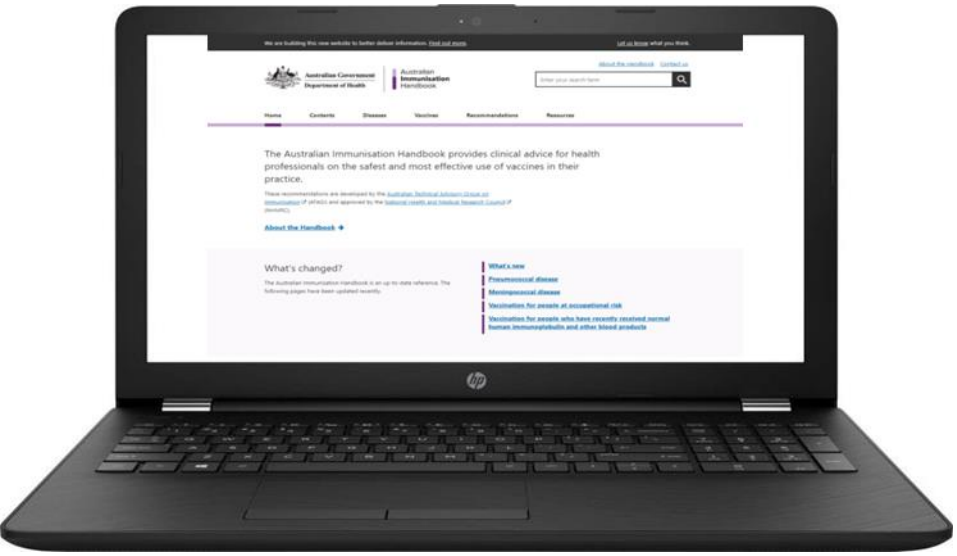
The digital handbook

Download on the App Store or Play Store

The new app is now available for free download on Apple's App Store and Google's Play Store

Visit the website

https://immunisationhandbook.health.gov.au



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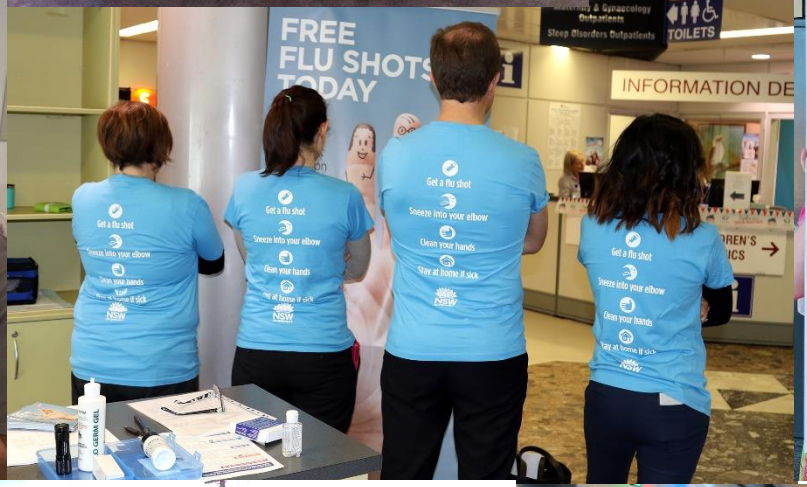

FREE
FLU SHOTS
TODAY
TOILETS
INFORMATION DE
Get a flu shot
Sneeze into your elbow
Clean your hands
Stay at home if sick


VACCINE
HEROES
23-24
AUGUST
2019
HNECC PHU PHN
NEWCASTLE


"MY CHILD HAS
BEEN VACCINATED
AGAINST
MENINGOCOCC
DISEASE"


DUALIS

Excuse me while I indulge myself

Haematopoietic stem cell transplant recipients

Protective immunity to vaccine-preventable diseases is partially or completely lost after an allogeneic or autologous haematopoietic stem cell transplant (HSCT).

Haematopoietic stem cells can be sourced from either the intended recipient (autologous) or a donor (allogeneic). Haematopoietic stem cells can be taken from peripheral blood, bone marrow or umbilical cord blood.

People become immunocompromised after HSCT for many reasons. Chronic GVHD is associated with functional hyposplenism and, therefore, increased susceptibility to infections with encapsulated organisms, especially *Streptococcus pneumoniae*. People with chronic GVHD who remain on immunosuppressive medicine are also recommended to receive antibiotic prophylaxis.[24]

Published guidelines do not support separate vaccination schedules for autologous or allogeneic HSCT recipients because of limited data. The same vaccination schedule is recommended for both groups, regardless of the donor source (peripheral blood, bone marrow or umbilical cord) or preparative chemotherapy (ablative or reduced intensity).[26,27] However, recommendations for receiving **live vaccines** may vary according to the person's level of immunocompromise after HSCT.

Inactivated vaccines in HSCT recipients

HSCT recipients usually have a poor immune response to inactivated vaccines during the first 6 months after HSCT.

Resources for the immunocompromised

The Australian Immunisation Handbook

Melbourne Vaccination Education Centre
Post chemotherapy and haematopoietic stem cell transplant (HSCT) immunisation guideline for children < 2 years post cancer treatment, July 2021 - https://mvec.mcri.edu.au/wp-content/uploads/2014/06/Post-chemotherapy-and-haematopoietic-stem-cell-transplant_July-2021.pdf

NCIRS Factsheets, Meningococcal vaccines
https://www.ncirs.org.au/meningococcal-b-vaccination-a-guide-for-healthcare-providers - Indicates that Bexsero is free for HSCT patients

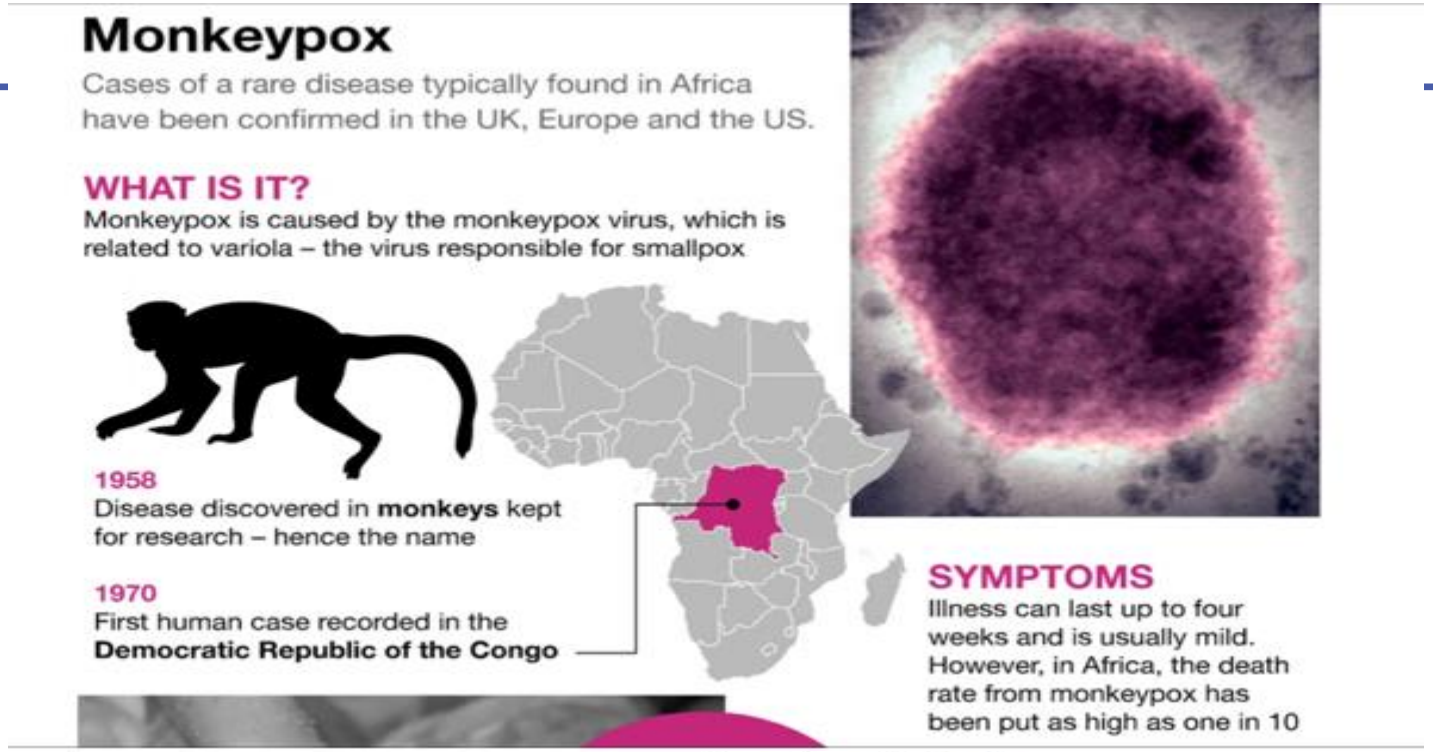
The schedule is shown in Table. Recommendations for revaccination after haematopoietic stem cell transplant in children and adults.

IMMUNISATION COALITION

PneumoSmart

Spleen Australia

https://spleen.org.au/



Secondary attack rate

Only 16 peer-reviewed articles reported secondary attack rates (SARs). Details are presented in S3 Table. A review of these articles did not establish any evolution in SAR over time. More than half of the articles (9/16) reported an SAR of 0% [8,23,30,42,49–52,57], and this spanned the decades from the 1970s through 2010–2019. Similarly, over those same five decades, the SAR ranged from 0.3–10.2% in 6/16 articles [5,14,20,22,54,56]. In the remaining article, a median SAR of 50% was reported in an outbreak among 16 households [25].

Countries/Clade	Case Fatality Rate	95% CI[1]
All countries[2]	78/892 = 8.7%	7.0%– 10.8%
Central African clade[3]	68/640 = 10.6%	8.4%– 13.3%
West African clade[4]	9/247 = 3.6%	1.7%– 6.8%
West African clade, African countries only	9/195 = 4.6%	2.1%– 8.6%

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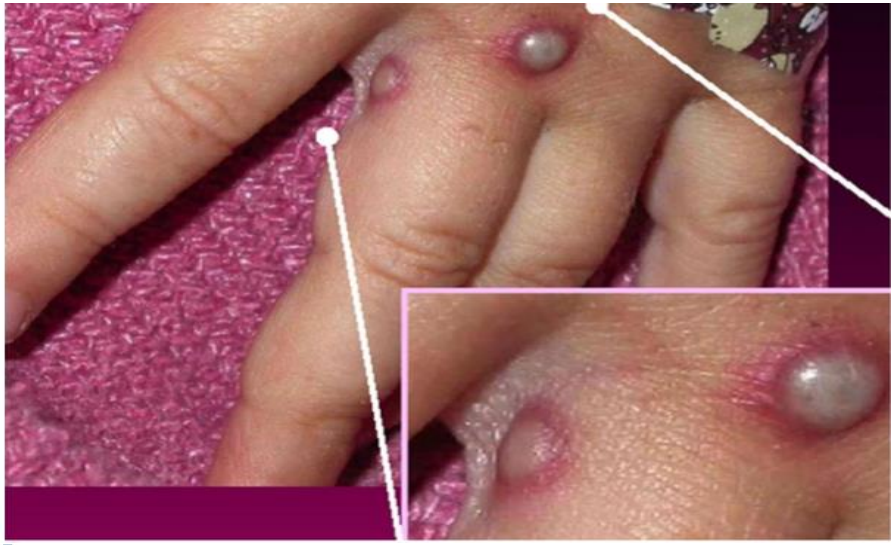
Monkeypox



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