# NSW Health Vaccine Storage Cold Chain Audit

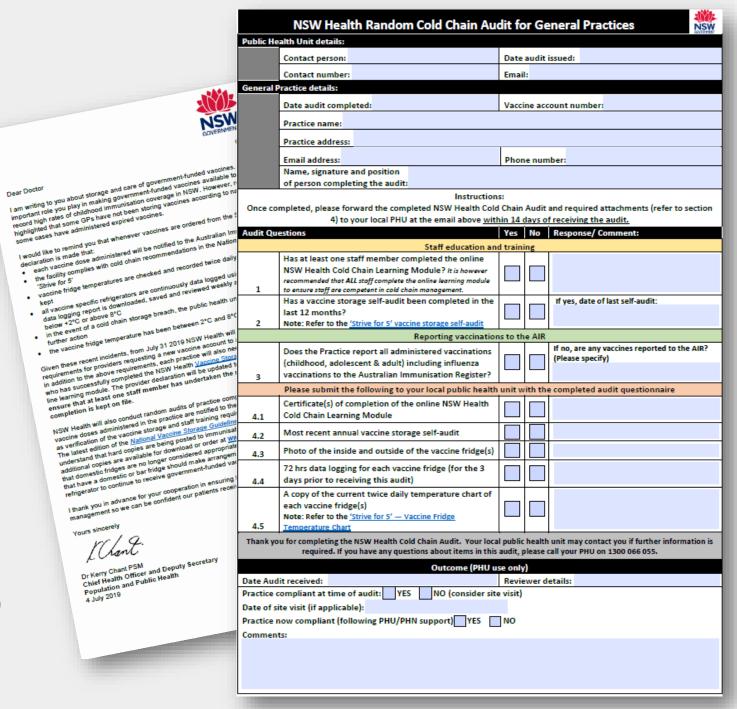


- NSW Health Audit Requirements
- Cold Chain Self-Audit
- 'Slush Test'
- Data Logging 101
- Min/Max Temperature Chart
- Esky/Cooler Use
- ➤ Cold Chain Breach Reporting 101
- Light Exposure
- Expired Vaccines



# NSW Health Audit Requirements

- Staff Education & Training
  - NSW Health Cold Chain Learning Module
  - Self-audit in last 12 months
- Reporting vaccinations to the AIR
- > Submission of:
  - Cold Chain Module certificates
  - Self-audit document
  - Fridge photos
  - 72hrs of data logging (individual readings)
  - Twice daily temperature chart



# **NSW Health Cold Chain Learning Module**

- www.immunisation.nsw.gov.au/immunisation
- One staff member at each practice MUST have completed this training
  - ALL staff should complete the training







# **Annual Vaccine Storage Self-Audit**

- Use Appendix 2 from the 'National Vaccine Storage Guidelines - Strive for 5'
- Must be done annually
- > Ensure every section is completed i.e. don't leave boxes unticked / uncrossed
- Vaccine fridges MUST be serviced annually

#### 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

#### **APPENDIX 2:** Vaccine storage self-audit

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

Print this checklist and use it as required.

#### Self-auditing is important because:

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

Print or photocopy this page and	keep it as a record of an audit.
Nominated person responsible for vaccine management	
Nominated back-up person for vaccine management	
Make and model of refrigerator	
Date of self-audit	
Person conducting audit	

# **Monitoring Equipment**

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					

This refers to your portable, battery operated min/max thermometers you should have for:

- your coolers and/or
- as a back up for your fridge in a power failure if your fridge does not have battery back up
- can be handy to have as a back up check for your fridge

Yes, your data logger does need servicing, a battery change, calibration, accuracy checking... different requirements for different data loggers

# **Thermometer Accuracy Check**

- 1. Fill a polystyrene or plastic cup with cold water.
- 2. Place the cup in the refrigerator freezer until a fine layer of ice forms on the top and small sections of ice form within the fluid (this may take up to  $2\frac{1}{2}$  hours). The presence of ice is an indication that the temperature of the water has reached 0°C.
- 3. Place the temperature probe into the middle of the container (be careful not to let the probe touch the container).
- 4. Observe the temperature on the display screen after 2 minutes.
- 5. Document the date of the accuracy check.

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')'

12/11/2020

Reached +0.2°C at 2 minutes







The thermometer must be accurate to ±1°C or better. If the temperature reading is more than 1°C above or below 0°C at 2 minutes, replace the battery (and record the date the battery was changed) and test again. If the temperature reading is still not within range, replace the thermometer.

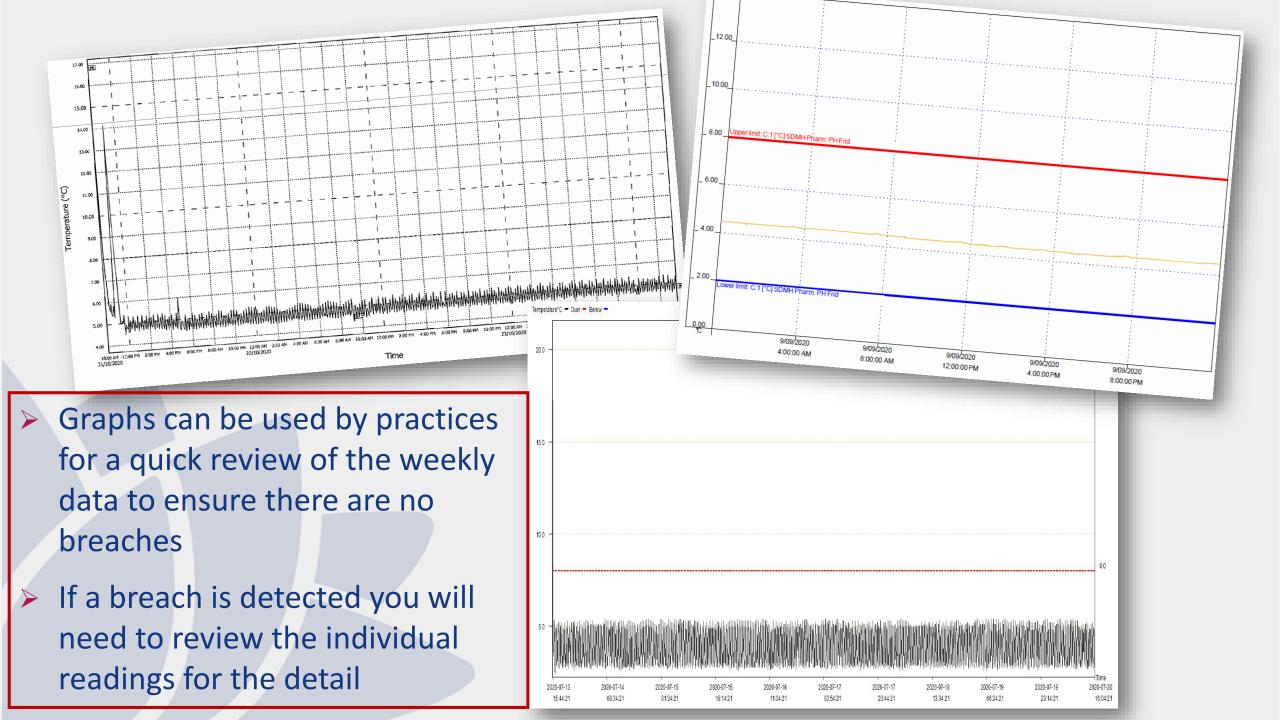
## Must be performed:

- Annually
- After every battery change
- In the event of cold chain problems or on direction from PHU



# **Data Logging 101**

- Place your data logger in the middle of the middle shelf or where you store most of your vaccines
- Down load data weekly
  - Monday morning or after any day/s of closure PRIOR to seeing patients
  - Reset data logger so it is only recording 7 days at a time
- Set temperature recording interval at 5 minutes
- Know how to access both graphs AND individual readings
- Service/recalibrate/check accuracy/change battery annually
- Ensure ALL staff know how to access the data or have a step by step written protocol that anyone can follow



1:23:59 AM 2:43:59 AM 4:03:59 AM 5:23:59 AM 6:43:59 AM 9:23:59 AM 10:43:59 AM 12:03:59 PM 2:43:59 PM 4:03:59 PM 5:23:59 PM 6:43:59 PM 6:43:59 PM 8:03:59 PM 10:43:59 PM	5.41°C 5.47°C 5.63°C 5.67°C 5.47°C 5.23°C 5.49°C 5.41°C 5.67°C 5.33°C 5.79°C 5.24°C 5.55°C 5.55°C	5.31°C 5.75°C 5.25°C 5.63°C 5.45°C 5.56°C 5.56°C 5.27°C 5.25°C 5.77°C 5.29°C 5.46°C 5.63°C 5.63°C	5.75°C 5.25°C 5.49°C 5.49°C 5.65°C 5.65°C 5.25°C 5.35°C 5.39°C 5.39°C 5.77°C 5.55°C 5.55°C 5.55°C	5.39°C 5.49°C 5.61°C 5.71°C 5.52°C 5.52°C 5.57°C 5.41°C 5.61°C 5.61°C 5.81°C 5.81°C 5.81°C 5.56°C 5.56°C 5.58°C 5.27°C	5.33°C 5.71°C 5.23°C 5.62°C 5.524°C 5.55°C 5.28°C 5.24°C 5.77°C 5.29°C 5.49°C 5.63°C 5.63°C 5.63°C	5.79°C 5.25°C 5.58°C 5.47°C 5.61°C 5.63°C 5.70°C 5.70°C 5.35°C 5.35°C 5.35°C 5.35°C 5.59°C 5.59°C 5.59°C	5.37°C 5.52°C 5.59°C 5.69°C 5.55°C 5.23°C 5.59°C 5.41°C 5.43°C 5.52°C 5.33°C 5.79°C 5.56°C 5.56°C 5.56°C	5.47°C 5.37°C 5.69°C 5.65°C 5.45°C 5.23°C 5.55°C 5.59°C 5.79°C 5.79°C 5.25°C 5.50°C 5.65°C 5.65°C	5.81°C 5.23°C 5.59°C 5.47°C 5.59°C 5.65°C 5.24°C 5.27°C 5.65°C 5.33°C 5.33°C 5.33°C 5.33°C 5.50°C	5.68°C 5.31°C 5.53°C 5.59°C 5.57°C 5.57°C 5.37°C 5.45°C 5.45°C 5.37°C 5.79°C 5.25°C 5.56°C 5.55°C 5.52°C	3 4 5 6	27/10 27/10	10/2020  0/2020  0/2020  1  0/2020  1  /2020  1	5.63 5.43 5.22 5.55° 5.53° 5.37°C 5.73°C 71ime 12:00:00 12:02:00 2:04:00 2:06:00	206 30/05/2020 207 30/05/2020 208 30/05/2020 209 30/05/202 210 30/05/202 211 30/05/20	9.54:56 AM	17:10:00	
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- individual data readings must be saved each week along with the graph
- Provides detailed information about a breach or fridge operation review
- Important to know how to access this information from your data logger

						_			Time	Elap
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С	5.53°C	5.65°C	5.25°C	5.56°C	5.6	200	30/05/200	20	9,54.50 AN	١
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C	5.67°C 5.57°C	5.47°C 5.22°C	5.26°C 5.58°C	5.66°C 5.59°C	5.43	209	30/05/2	UZU	10:09:56 A	M
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# **Data Logging 101**

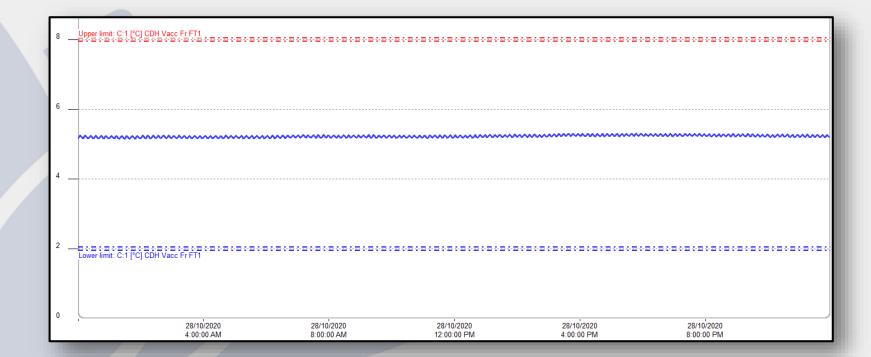
- ➤ If you notice there is a problem, address it IMMEDIATELY!!
- > DO NOT leave the logging to a non-clinical person without clinical review
  - If you are giving a vaccine, you **MUST** be **confident** that it has been stored correctly
  - This means, if someone else is downloading the data logging information, you should review it
- > DO NOT leave the logging to the least busy day of the week
- Weekly data log review/download is best done on a Monday morning prior to seeing patients AND after a day/s closure





# **Maintaining Fridge Temperature**

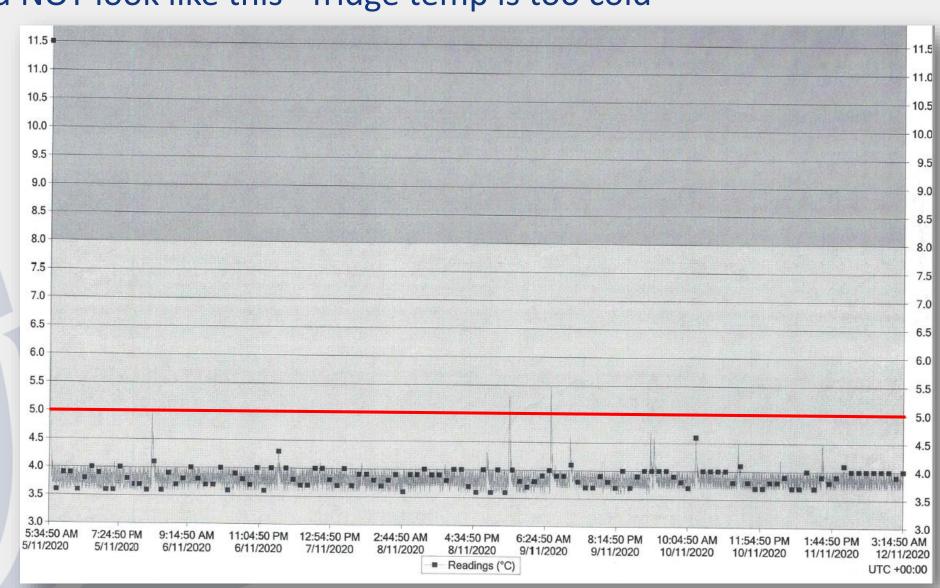
- ➤ There is a reason the National Vaccine Storage Guidelines have 'Strive for 5' in the title!!
- ➤ You need to aim to have your fridge average temperature sitting at or as close to 5°C
- What does this look like?



_		
Date	Time	C:1 [°C] CDH Vacc
28/10/2020		5.2
28/10/2020	9:02:00 AM	5.2
28/10/2020		5.2
28/10/2020		5.3
28/10/2020	9:08:00 AM	5.2
28/10/2020	9:10:00 AM	5.2
28/10/2020	9:12:00 AM	5.2
28/10/2020	9:14:00 AM	5.2
28/10/2020	9:16:00 AM	5.3
28/10/2020	9:18:00 AM	5.2
28/10/2020	9:20:00 AM	5.2
28/10/2020	9:22:00 AM	5.2
28/10/2020	9:24:00 AM	5.2
28/10/2020	9:26:00 AM	5.3
28/10/2020	9:28:00 AM	5.2
28/10/2020	9:30:00 AM	5.2
28/10/2020	9:32:00 AM	5.2
28/10/2020	9:34:00 AM	5.2
28/10/2020	9:36:00 AM	5.3
28/10/2020	9:38:00 AM	5.2
28/10/2020	9:40:00 AM	5.2
28/10/2020	9:42:00 AM	5.2
28/10/2020	9:44:00 AM	5.2
28/10/2020	9:46:00 AM	5.3
28/10/2020	9:48:00 AM	5.2
28/10/2020	9:50:00 AM	5.2
28/10/2020	9:52:00 AM	5.2
28/10/2020	9:54:00 AM	5.3
28/10/2020	9:56:00 AM	5.2
28/10/2020	9:58:00 AM	5.2
28/10/2020	10:00:00 AM	5.2
28/10/2020	10:02:00 AM	5.2
28/10/2020	10:04:00 AM	5.3
28/10/2020	10:06:00 AM	5.2
28/10/2020	10:08:00 AM	
28/10/2020	10:10:00 AM	5.2

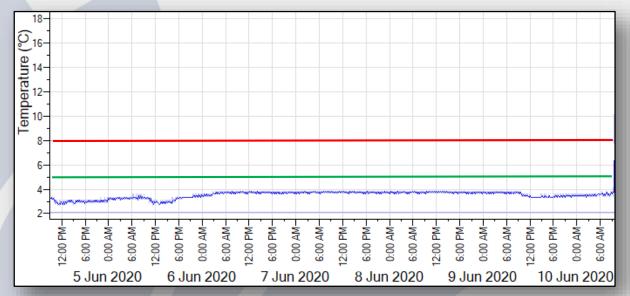
# **Maintaining Fridge Temperature**

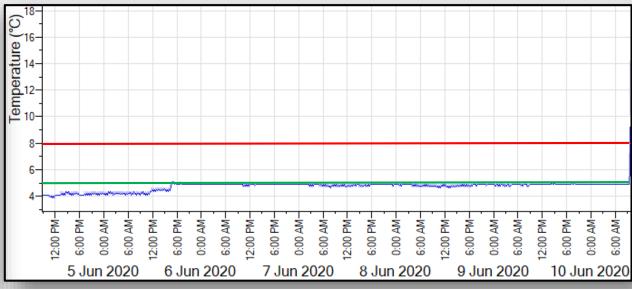
Should NOT look like this - fridge temp is too cold



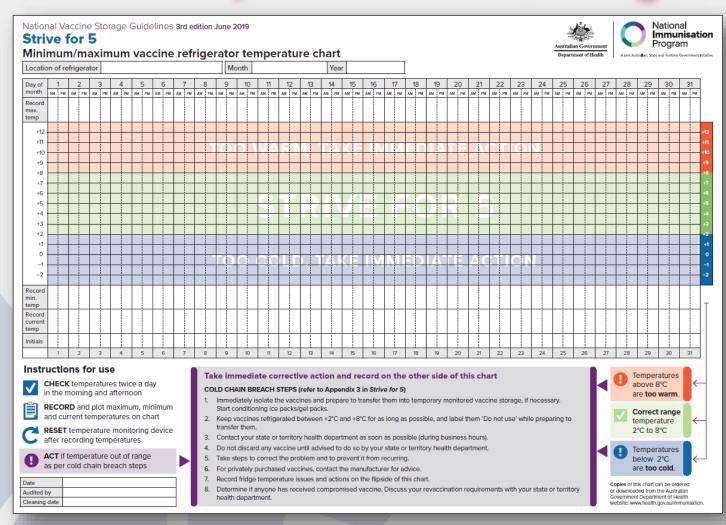
# **Know Your Fridge**

- Data log each shelf for a week
  - Each shelf may have a different temperature
  - Store vaccines that are less cold resistant on 'colder' shelves
  - Store vaccines that are more cold resistant on 'warmer' shelves
  - PHU can provide this information





# Min/Max Vaccine Fridge Temperature Chart



The 'Strive for 5' - Vaccine Fridge
Temperature Chart should be used to record
the current, minimum and maximum fridge
temperature twice daily.

NSW Health, 2020 'Cold Chain Toolkit for Immunisation Providers'

Date	Time	Max./min. temperatures	Problem	Action taken	Results	Initials
	-					
	-					
	-					
	-					
			-			
	_					
	-					
	+					
	-		-			

Order or download from the Australian Government Department of Health website:

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



# **Eskies/Coolers**



- Required under the Strive for 5 Guidelines
- Absolute LAST resort!!!
  - Difficult to maintain temperature
  - Not long term solution
  - Overnight???
  - Min/Max temperatures must be checked, recorded and reset every hour
- ➤ Thermostability data evidence that many vaccines are stable for a limited amount of time at temperatures >8°C to ≤25°C PHU to advise



### **BEST OPTION:**

Quarantine vaccines and keep fridge closed until PHU advice obtained



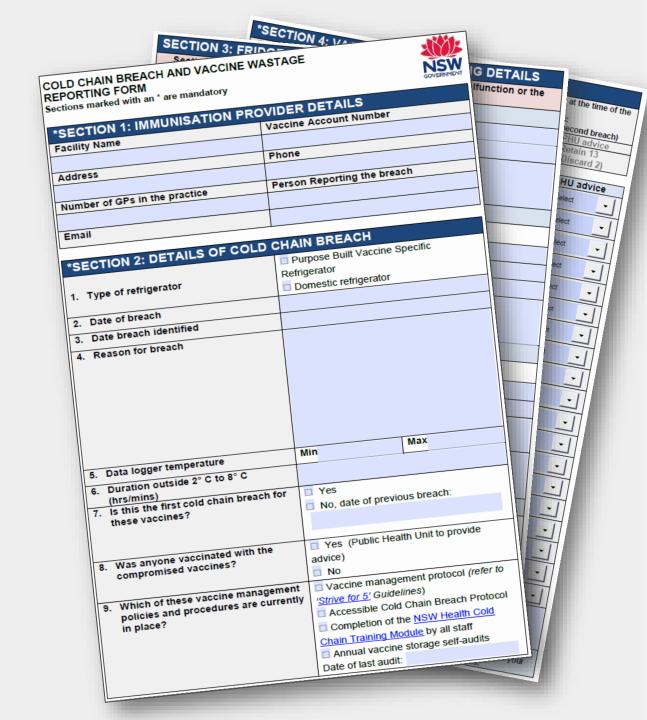
## **Cold Chain Breaches 101**

- Vaccines MUST NEVER be stored in a domestic refrigerator
- Please <u>DO NOT</u> try to save them by moving them in the event of a cold chain breach
- Leave them in your vaccine fridge with the door closed until you have received advice from the PHU
- Consider purchasing an Uninterrupted Power Supply to give your fridge power support in the event of a power failure



## **Cold Chain Breaches 101**

- Deal with the problem and quarantine the vaccines first
- Download the data logger information incl.: pre-breach, breach and post-breach individual recordings
- Complete the Cold Chain Breach & Vaccine Wastage Reporting Form in as much detail as possible
- Call the PHU to report



SECTION 3: FRIDGE AND COLD CHAIN MONITORING DETAILS							
	e has been a refrigerator malfunction or the 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	□ Inbuilt □ Portable						
Date of purchase							
Date of last battery change							
Date of last calibration/ service							
Further information (if applicable)							
3.3 Minimum/maximum thermometer d	etails						
Type of min/max thermometer	☐ Inbuilt ☐ 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	Yes						
vaccine storage?	□ No						
Type of alternative fridge used for	☐ Purpose Built Vaccine Specific Refrigerator						
back up vaccine storage	☐ Domestic refrigerator						
Further information (if applicable)							

Only complete this page if your fridge has malfunctioned or you do not know what caused the breach



#### \*SECTION 4: VACCINE DETAILS

Count and enter the <u>exact number</u> 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:

Total number of doses exposed to first breach (total number of doses exposed to second breach)

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 advic	e e	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 <b>▼</b>
Fluarix Tetra		Select	-	Quadracel		Select ▼
*Fluquadri (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 VaxII - adult		Select	•	Tripacel		Select ▼
Hep B VaxII - paed		Select	•	Vaqta Adult		Select ▼
Infanrix		Select	•	Vaqta Paed		Select ▼
Infanrix hexa		Select	•	Varilrix		Select ▼
Infanrix IPV		Select	·	Varivax		Select ▼
IPOL		Select	-	*Vaxigrip Tetra (Provide batch number and explry date below)		Select
		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.

- Please ensure you count actual vaccine doses rather than estimate based on how many boxes you have
- If it asks for batch number and expiry date please include this in the 'Additional advice' box
- Super helpful if you can complete this on your computer rather than printing out fillable PDF document



act 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:

Total number of doses exposed to first breach (total number of doses exposed to second breach) Vaccine PHU advice Vaccine \*Doses PHU advice Retain 5 Retain 13 MMRII 5 (5) Infanrix 13 (2) (Discard 5) (Discard 2)

Vaccine	*Doses	PHU advice	Vaccine	*Doses	PHU advice
Act-HIB	5	Retain and label	MMR II	((8))	Retain and label
Adacel	(5)	Discard	Neis-Vac C		
Afluria Quad	((111))	Discard	*Nimenrix (Provide balch number and expiry date below)	(3)	Discard
Bexsero	((1))	Retain and label	Pneumovax 23	(10) ((4))	Retain and label
Boostrix	((1))	Retain and label	Prevenar 13	(18) ((20))	Retain and label
Engerix B (adult)			Priorix	1	Retain and label
Engerix B (paed)			Priorix Tetra	(1)	Retain and label
Fluad Quad	((64))	Retain and label	Proquad	((2)) (((3)))	Retain and label
Fluarix Tetra			Quadracel	5	Retain and label
*Fluquadri (Provide batch number and expiry date below)			*Rabipur (Provide batch number and expiry date below)		
Gardasil 9	((3))	Retain and label	*MIRV (Rabies) (Provide batch number and explry date below)		
Havrix 1440			Rotarix	(5) ((2))	Retain and label
Hep B VaxII - adult			Tripacel		
Hep B VaxII - paed			Vaqta Adult		
Infanrix	(((2)))	Retain and label	Vaqta Paed		
Infanrix hexa	1 (2)	Retain and label	Varilrix		
Infanrix IPV	(5)	Retain and label	Varivax		
IPOL			*Vaxigrip Tetra (Provide batch number and expliny date below)		
			Zostavax	((18))	Retain and label

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

- If you have vaccines that have been through a previous breach/s you will need to indicate this as follows:
  - Number with no brackets = exposed to current breach
  - Number with 1 set of brackets i.e. (9) = exposed to current breach and 1 previous breach
  - Number with 2 sets of brackets i.e. ((9)) = exposed to current breach and 2 previous breaches
  - ... and so on ...
- Assessment is made using total time and highest or lowest temp across breaches



- > Place stickers on the vaccines we advise are able to be retained
  - Ensure you read the advice carefully!!
  - DO NOT obstruct expiry date or batch number with label
  - If the vaccines have been through multiple breaches, you will need to note the date of each breach on the label
- Labels are available to order free through the Better Health Centre email
  - NSLHD-BHC@health.nsw.gov.au



Place any vaccines to be discarded into the sharps container



# **Vaccine Storage**

- Vaccines are delicate biological substances that can be denatured by incorrect storage
- Vaccines MUST be stored in their original packaging
  - Protection from light (sunlight and UV)
  - Protection from temperature fluctuations from fridge door opening





# **Vaccine Storage**

Annual self audit question about fridge capacity...

# Review your vaccine storage capacity NOW

### **Equipment**

#### Vaccine 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?

- How did your fridge cope with the increased demand for influenza vaccine this year??
- ➤ What if you have to store NIP + influenza + COVID-19 vaccines in your fridge at the same time??
- > Do you need to purchase a larger fridge or an extra fridge??

# **Expired Vaccines**

- New formal reporting process
- Any time you find expired vaccines
- > As part of the ordering process



YES

Have you discarded any expired vaccines since your last order?

NO

## **NSW Vaccine Centre**



Home > Report Expired Stock - The Wollongong Hospital Pharmacy

#### Report Expired Stock - The Wollongong Hospital Pharmacy

Note: Report only expired stock on this page. Vaccines wasted due to a cold chain breach are not to be recorded on this page. All cold chain breaches must be reported to your local public health unit on 1300 066 055 using the Cold Chain Breach and Vaccine Wastage Reporting Form.

Vaccines may be used up to and including the expiry date unless otherwise stated in the manufacturer's product information. For example, a vaccine with expiry date 08/2020 can be used until the end of August 2020.

Vaccines that have already been reported at your location are listed at the bottom of this page. Please review this list to ensure that you do not report the same expired vaccines more than once.

Vaccine	Doses expired	Expiry date	
select a product	▼	•	<b>v</b>
select a product	▼	•	▼ ▼
select a product	▼	•	▼
select a product	▼	•	▼
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REPORT EXPIRED STOCK



# **Public Health Unit Immunisation Web Page**

- The Immunisation Team now has a dedicated web page that is kept up to date with all the latest information
- https://www.islhd.health .nsw.gov.au/servicesclinics/public-healthunit/immunisation-0
- Monthly newsletter, webinar links, links to all the good stuff on the internet ©

#### Immunisation-related information for:



Immunisation for the public



Immunisation for Health Professionals



Immunisation education



NSW School Vaccination Program



Aboriginal immunisation



News and Alerts

# Thank you for listening!!



## **Immunisation Team**

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