Cold Chain Management

Adapted from Immunisation Unit
Health Protection NSW
Cold Chain Education

Aims:

• Raise staff awareness of Cold Chain Management

• Prevent administration of ineffective vaccines and medications

• Prevent the need to revaccinate patients
Learning Outcomes

On completion of this session staff should be able to;

1. State the correct storage temperature for vaccines and medications

2. Identify the correct storage configuration for their vaccine and medication refrigerators

3. Identify, act upon and escalate any suspected Cold Chain breach

4. Perform temperature monitoring for their vaccine and medication refrigerator according to policy
What is the cold chain?

The ‘cold chain’ is the system of transporting and storing vaccines within the temperature range of +2°C and +8°C.

The cold chain begins from the time the vaccine is manufactured, continues through storage at the NSW State Vaccine Centre and ends when the vaccine is administered to the patient.

The cold chain is only as strong as the weakest link
What is a cold chain breach?

A breach occurs when the vaccines and medications are stored outside of +2°C and +8°C.

Outside this range the vaccine will die and medications will not work.
Why is Cold Chain management so important?

• Health professionals have a responsibility to ensure that clients receive effective health products (i.e. vaccines and medications that have not been adversely affected by heat or cold).

• Good vaccine management precludes the need to revaccinate clients who may, under circumstances of poor vaccine management, receive an ineffective vaccine.
What is the potential impact of a Cold Chain breach?

• Patient recall and revaccination
• Administration of ineffective medications
• Loss of faith in the organisation
• Litigation
• Staff hours spent on patient recall and management of incidents
• Reduction in supply of potent vaccines available for use
• Significant cost of replacement of inactive vaccines
Safe Vaccine Storage Management

- All vaccines and medications must be stored and managed according to National Vaccine Storage Guidelines *Strive for 5 2nd* Edition
- Vaccines should be stored in a purpose-built vaccine refrigerator
- Cold Chain Management is **EVERYONE’S** responsibility
- Monitor fridge temperatures twice daily, during department operating hours and record on the approved temperature chart
- All fridges must be continuously data logged with back to base monitoring
- Follow cold chain management policies and procedures
- Perform annual checks of all vaccine and medication storage equipment
Refrigerator Stock Configuration

• Not overstocked
• Air gaps around all walls
• Within temperature range (7.0°C)
• Data logger will be positioned in the middle of the refrigerator
• Wire baskets used to facilitate air flow
• No stock on bottom shelf. Note sticker
DO NOT PLACE STOCK ON THIS SHELF
Refrigerator Monitoring Equipment

ALL VACCINE AND MEDICATION REFRIGERATORS MUST HAVE A DATA LOGGER

- Each fridge must be continuously monitored using a data logger
- Each manager responsible for a fridge will receive the data logger report weekly
- Data logger report must be printed, reviewed for excursions outside +2°C to +8°C (known as a cold chain breach) and reported.
Refrigerator Monitoring Process

- Record minimum and maximum temperatures twice per day
- Reset the min/max thermometer after reading
- Record any events, such as deliveries, on the Temperature Monitoring Chart
- Follow cold chain breach protocol if temperature outside +2°C to +8°C
Vaccine refrigerator monitoring chart

| Date Range | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  | AM  | PM  |
|------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Date       |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Time       |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Exact Time |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| Record Max Temp °C |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| TOO WARM   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |
| TOO COLD   |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |     |

Danger! Temperatures ABOVE 8 DEGREES are TOO WARM. TAKE IMMEDIATE CORRECTIVE ACTION

Danger! Temperatures BELOW 2 DEGREES are TOO COLD. TAKE IMMEDIATE CORRECTIVE ACTION

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 vaccines, keep refrigerated between +2°C and +8°C (move stock to another fridge) and label "GUARANTEED 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. Contact the local public health unit (PHU) on 1300 066 056 for advice. Do not discard any vaccines until advice is provided by the PHU (next working day if out of hours)
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 ILMS (excludes breaches due to power outages)
# Vaccine Refrigerator Temperature Chart - Fortnightly

**Date range:** 05/07/2017 to 16/07/2017  
**Facility:** BANKSTOWN  
**Location:** WARD 2A  
**Fridge ID/Name:** WARD 2A FRIDGE

## 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° to +8°C) excluding fluctuations up to +12°C for ≤15 minutes.  
- Refer to cold chain breach steps below.

### Temperature Chart

<table>
<thead>
<tr>
<th>Date</th>
<th>AM</th>
<th>PM</th>
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</table>

**Record Max Temp °C**

<table>
<thead>
<tr>
<th>3.0</th>
<th>6.4</th>
<th>7.2</th>
<th>6.8</th>
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<th>6.0</th>
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<th>7.3</th>
<th>6.3</th>
<th>6.2</th>
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**Record Min Temp °C**

<table>
<thead>
<tr>
<th>3.0</th>
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<th>5.1</th>
<th>5.2</th>
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<th>5.3</th>
<th>5.1</th>
<th>5.4</th>
<th>5.3</th>
<th>5.6</th>
<th>4.7</th>
<th>4.9</th>
<th>4.9</th>
<th>5.2</th>
<th>5.6</th>
<th>4.9</th>
</tr>
</thead>
</table>

**Danger! Temperatures ABOVE 8 DEGREES are TOO WARM, TAKE IMMEDIATE CORRECTIVE ACTION**

**Too Cold**

<table>
<thead>
<tr>
<th>3.0</th>
<th>5.0</th>
<th>5.1</th>
<th>5.2</th>
<th>5.0</th>
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<th>5.3</th>
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<th>4.7</th>
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<th>4.9</th>
<th>5.2</th>
<th>5.6</th>
<th>4.9</th>
</tr>
</thead>
</table>

**Danger! Temperatures BELOW 2 DEGREES are TOO COLD, TAKE IMMEDIATE CORRECTIVE ACTION**

**Too Hot/Avoid**

<table>
<thead>
<tr>
<th>3.0</th>
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<th>5.1</th>
<th>5.2</th>
<th>5.0</th>
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<th>4.9</th>
<th>5.2</th>
<th>5.6</th>
<th>4.9</th>
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</thead>
</table>

**Acceptable Temperature Range for Vaccine**

<table>
<thead>
<tr>
<th>3.0</th>
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<th>5.2</th>
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<th>5.2</th>
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<th>4.9</th>
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</thead>
</table>

**Record Current Temp °C**

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<th>5.2</th>
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<th>4.9</th>
<th>5.2</th>
<th>5.6</th>
<th>4.9</th>
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</thead>
</table>

**Record Min Temp °C**

<table>
<thead>
<tr>
<th>3.0</th>
<th>5.0</th>
<th>5.1</th>
<th>5.2</th>
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<th>5.2</th>
<th>5.6</th>
<th>4.9</th>
</tr>
</thead>
</table>

**Temperature RESET**

<table>
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<tr>
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<th>5.1</th>
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<th>5.6</th>
<th>4.7</th>
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<th>4.9</th>
<th>5.2</th>
<th>5.6</th>
<th>4.9</th>
</tr>
</thead>
</table>

**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)

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Temperature Current/Min/Max</th>
<th>Actions taken</th>
<th>Name (please print)</th>
<th>Staff</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>15/7/17</td>
<td>MAX 7.8</td>
<td>Restocking fridge</td>
<td>Jane Smith</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## 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 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. Contact the local public health unit (PHU) on 1300 066 055 for advice. Do not discard any vaccines until advice is provided by the PHU (next working day if out of hours).
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 IIIMS (excludes breaches due to power outages).
### Vaccine Refrigerator Temperature Chart - Fortnightly

**Date range:** 23/07/2017 to 16/07/2017

**Facility:** BANKSTOWN  
**Location:** WARD 2A

**Fridge ID/name:** WARD 2A FREEZER

### 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°C to +8°C) excluding fluctuations up to +1°C for ≤15 minutes. Refer to cold chain breach steps below.

<table>
<thead>
<tr>
<th>Date</th>
<th>3/7</th>
<th>4/7</th>
<th>5/7</th>
<th>6/7</th>
<th>7/7</th>
<th>8/7</th>
<th>9/7</th>
<th>10/7</th>
<th>11/7</th>
<th>12/7</th>
<th>13/7</th>
<th>14/7</th>
<th>15/7</th>
<th>16/7</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Exact Time</strong></td>
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</tr>
<tr>
<td><strong>Record Max Temp °C</strong></td>
<td>-11</td>
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<td>-10</td>
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<tr>
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</tbody>
</table>

**Danger Temperatures:**

- Above 7 degrees are too warm. Take immediate corrective action.
- Below 2 degrees are too cold. Take immediate corrective action.

### Document actions taken when temperatures outside +2°C to +8°C (excludes fluctuations up to +1°C for ≤15 mins e.g. vaccine delivery)

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Temperature Current/Min/Max</th>
<th>Actions taken</th>
<th>(please print)</th>
<th>Staff Name</th>
<th>Signature</th>
</tr>
</thead>
</table>

**COLD CHAIN BREACH STEPS** (refer to Appendix 3 in ‘Store 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 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 as "OUT OF ORDER - DO NOT USE".
4. Determine breach temperature and duration. Download data logging(s).
5. Contact the local public health unit (PHU) on 1300 666 055 for advice. Do not discard any vaccines until advice is provided by the PHU (next working day if out of hours).
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 (excludes breaches due to power outages).
Hanwell Monitoring System

- Temperature transmitter probes are installed on every refrigerator and freezer where medication is stored.
- Temperature readings are taken every 2 minutes and transmitted to a central server.
- All alarm events (including who acknowledged them and any actions taken) are also recorded.
- The system will alarm whenever there is a temperature breach.
- The GREEN alarm status icon below will be seen when viewing via the web browser when all refrigerators are within limits.
Hanwell Monitoring System - Acknowledge

- A RED alarm status icon means that there is currently an ACTIVE alarm that has NOT been acknowledged.

- Alarms can be acknowledged via the Central Alarm Panel OR via SMS.

- For detailed instructions on how to ‘Acknowledge’ alarms, see SWSLHD policy ‘Cold Chain Management for Temperature Sensitive Medication and Vaccines’ SWSLHD_2017_XXX – Appendix 10.
The purpose of acknowledging the alarm is to inform other users that someone is aware of the alarm and has accepted responsibility for investigating the temperature breach.

It does NOT mean that the temperature breach has returned to normal.

A YELLOW alarm will be seen once the alarm has been acknowledged awaiting resetting of the alarm once the issue has been resolved.
Hanwell Monitoring System - Resetting

- It is the responsibility of the NUM or person In-Charge of the area where the alarm has been activated to acknowledge and reset the alarm.

- Resetting the alarm clears the alarm and returns the alarm monitoring to normal.

- Alarms must ONLY be reset if the event causing the alarm has been resolved and the refrigerator or freezer is within normal limits.

- If the alarm is reset while the refrigerator is still in ‘alarm condition’ it will re-alarm.
Hanwell Monitoring System - Resetting

To reset the alarm on the webpage choose

‘Reactivate Now’ under the Reactivation Method once the temperature has returned to normal limits
Hanwell Monitoring System – Trouble Shooting

• Restocking
  o avoid pushing the refrigerator into ‘Alarm’ mode
  o Frequent restocking of smaller amounts will have less impact on internal temperatures than a large restock.

• Physical obstruction
  o Door left open, air vents blocked
  o Power unplugged /switched off
  o Overcrowding

• Device issues
  o Refrigerator fan /compressor failure
Example data logging graph of a stable fridge
Example data logging graph of a high cold chain breach

If a breach occurs, follow SWLHD Cold Chain Breach Escalation process
Example data logging graph of a low cold chain breach

If a breach occurs, follow SWSLHD Cold Chain Breach Escalation process
Cold Chain Breach

In the event of a Cold Chain Breach i.e temperature outside the range of +2°C and +8°C the SWSLHD Cold Chain Breach Escalation pathway is activated immediately.
In the event there is alarm activation for any refrigerator unit in the facility, Switchboard staff are to immediately follow the escalation pathway.

1) **Business Hours** (Monday-Friday 0800-1630hr excluding public holidays):

   - Switchboard Operator immediately calls both:
   - 1. Ward Nursing Unit Manager
   - 2. Pharmacy Department

2) **After Hours** (all other times except business hours):

   - Switchboard Operator immediately calls both:
   - 1. After Hours Hospital Manager
   - 2. On Call Pharmacist

*Switchboard staff to contact the facility Operational Nurse Manager in business hours or Executive On-Call after hours with escalation.*
Refrigeration Alarm Escalation Pathway for Bowral & District Hospital

In the event there is alarm activation for any refrigerator unit in the facility, staff are to immediately follow the escalation pathway:

1) **Business Hours** (Monday-Friday 0800-1630hr excluding public holidays):
   - Operational Nurse Manager immediately calls both:
     - 1. Ward Nursing Unit Manager
     - 2. Pharmacy Department

2) **After Hours** (all other times except business hours):
   - After Hours Hospital Manager immediately calls both:
     - 1. Nurse in Charge of ward
     - 2. After hours support nurse

*Staff to contact the facility Operational Nurse Manager in business hours or Executive On-Call after hours with escalation issues. Written notification to be sent to pharmacy at all times.*
**Refrigeration Alarm Escalation Pathway for Primary and Community Health**

In the event that there is an alarm for ANY vaccine or medication refrigerator unit in any of the facilities, staff are to immediately follow the escalation pathway:

1) **Business hours (Monday to Friday 0800-1630 excluding public holidays)**

   - Operational Nurse Manager immediately calls both:
     - 1. Facility Nursing Unit Manager
     - 2. Pharmacy

2) **After Hours (all other times except business hours)**

   - Executive On-call acknowledges text, logs on to Hanwell website to assess risk and either:
     - 1. Actions immediately OR
     - 2. Actions next business day

*Staff are to contact the Operational Nurse Manager in business hours or Executive On Call in business hours or Executive On-Call after hours with escalation issues.*

*Written notification to be sent to Pharmacy at all times*
Cold Chain Breach Escalation Pathway

TEMPERATURE FOUND TO BE OUTSIDE THE RECOMMENDED RANGE OF +2°C AND +8°C. This excludes fluctuations of up to 12 degrees for less than 15 minutes (for example when restocking the fridge or rotating stock).

Ward Role:
- If temperature currently within range—quarantine stock inside fridge. **DO NOT DISCARD STOCK.**
- If temperature out of range—move quarantined stock to alternative medication fridge (another ward or to pharmacy).
- Place sign **“STOP! DO NOT USE THIS STOCK”** on the outside of the fridge door.
- Review transmitter probe information online.
- In business hours—Ward Manager or Team Leader to notify Pharmacy, providing transmitter probe information and vaccine refrigerator temperature chart recordings.
- Out of business hours—After Hours Manager to be notified, escalating to Pharmacist on Call if required.
- Source alternative stock within facility until further notice.
- Document the date and time breach identified and reported on the vaccine refrigerator temperature chart.
- Complete HIMS once impact on stored medications is determined by Pharmacy or Public Health Unit.

Pharmacy Role:
- Ensure stock is adequately quarantined and appropriately labelled.
- Review transmitter probe information and vaccine refrigerator temperature chart from affected fridge.
- Determine impact on the medication inside the fridge. Record the outcome and keep on file.
- Escalate to Operational Nurse Manager, further escalating to General Manager if stored medication is affected.
- Decommission and Recommission the transmitter probe if refrigerator is shut down for repairs.

IF VACCINES STORED IN THIS FRIDGE ... THEN
- Pharmacy to contact Public Health Unit (PHU) on 1300066055 in business hours
- Await advice on actions required due to breach.
- Record the outcome and keep record on file.

Public Health Unit Role:
- Review data and information supplied by facility to identify if a vaccine Cold Chain Breach has occurred.
- Advise Health Protection NSW who will formulate actions to be implemented as required.
- Liaise with facility to follow up actions as required.
Power outages

To salvage vaccines and medications:

1. Immediately quarantine the vaccines, keep the fridge door closed and attach a ‘Quarantine’ sign

2. Closely monitor fridge temperature via the data logger readings on the Hanwell website

3. If the temperatures gradually progress towards 8°C, follow the escalation plan
DO NOT USE THIS STOCK.

A cold chain breach is suspected, therefore all stock is quarantined until further notice from Pharmacy. Please contact Pharmacy/AHNHM if stock is required or for further information.
Common Issues resulting in Cold Chain breaches

• Overstocking
• Variety of refrigerators and data loggers
• Irregular servicing of vaccination and medication refrigerators
• Staff unsure of quarantine procedures
• Transporting from Pharmacy to the ward
Tips

• If in doubt… QUARANTINE! (you can source vaccines and medications from another department or pharmacy)
• Don’t put vaccines or medications in your pocket, even for a short time
• Don’t leave the refrigerator door open
• Angle the refrigerator up slightly at the front to facilitate auto-closing of the door
• Only remove vaccines for immediate use
• Check temperature before opening the door every time
• Check expiry dates and use oldest first
• Ensure valid medication order is present before removing vaccine
Summary

• Correct temperature range
• Monitoring and recording
• Storage considerations
• Escalation
• Quarantine
Local Vaccine / Medication Refrigerator Practical Demonstration

- Monitoring and recording temperature
- Stock configuration
- Signage
- Reset button
- Data Logger position
For more information…

• National Vaccine Storage Guidelines. Strive for 5 2nd Edition

• Cold Chain Management for Temperature Sensitive Medication and Vaccines SWSLHD_2017_XXX
Acknowledgement

- Barbara Wilson, Immunisation Coordinator, Albury Public Health Unit, for providing cold chain information and images