GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	Reference Number: PHW 17 Version Number: 1 Date of Next review: 17 November 2025

Vaccines (Handling and Storage) Cold Chain Management Procedure

Introduction and Aim

The aim of this procedure is to ensure that vaccines are stored in accordance to temperature recommendations thus remaining potent at point of delivery and complying with licensing requirements. Staff providing such vaccination services must be aware of the professional responsibilities and standards in the management of handling and storage of vaccines in line with national guidance.

Linked Policies, Procedures and Written Control Documents

All corporate policies and procedures are available on the Public Health Wales website

- UK Health Security Agency (2013) Immunisation against infectious disease, Storage, distribution and disposal of vaccines: the green book, chapter 3.
  Storage, distribution and disposal of vaccines: the green book, chapter 3 - GOV.UK (www.gov.uk)
- Advisory Document on Ordering, Storage and Handling of Vaccines. All Wales VPDP. 7th revision vaccine handling and storage advice Sept 17.pdf (wales.nhs.uk)
- Vaccine Incident Guidance Responding to errors in vaccine storage, handling and administration Vaccine Incident Guidance (publishing.service.gov.uk)
- The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 (legislation.gov.uk)

Scope

This procedure will apply to:

- all premises in which internal Public Health Wales vaccination programmes to staff are delivered.
- all staff employed by Public Health Wales who are working to deliver and support an internal vaccination programme.

Equality and Health Impact Assessment	An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.
Approved by	Leadership Team
Approval Date	17 November 2022

Review Date	17 November 2025
Date of Publication:	24 November 2022
Accountable Executive Director/Director	Rhiannon Beaumont-Wood, Executive Director Quality, Nursing and Allied Healthcare Professionals.
Author	Jennie Leleux, Lead Nurse Infection Prevention and Control, Quality Nursing and Allied Healthcare Professionals.

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
1	24.08.22	17.11.22	24.11.22	Updated content. Clarified roles of vaccinators, Lead Nurse for IP&C and Health & Safety. Addition of flowcharts and checklist for cold chain breaches.

1. Introduction

Immunisation is a highly effective way of protecting individuals and communities from infectious disease. To remain potent, vaccines must be stored within the manufacturers' recommended storage temperatures usually at 2 to 8°C. Failure to store vaccines correctly can reduce vaccine effectiveness and cause vaccine failure in addition to being wasteful and costly to the NHS.

2. Roles and responsibilities

Ultimate responsibility for Infection Prevention and Control lies with the Chief Executive and delegated to the Executive Director of Quality, Nursing and Allied Health Professionals. This is supported through the work of the Lead Nurse for Infection Prevention and Control.

The Lead Nurse for Infection Prevention and Control (IP&C) will be responsible for the ordering of vaccine stock supported by the staff uptake data presented and discussed at PHW Vaccine Delivery meetings.

Each site delivering vaccinations should have a delegated responsible person conducting and recording temperature checks at least once a day on all standard operational working days, excluding weekends and bank holidays, as discussed with the Estates and Health and Safety Division. The delegated responsible person will be identified by agreement by Head of Estates and Health and Safety and the Lead Nurse for Infection Prevention and Control and is not required to be a registrant. A deputy responsible person should also be agreed in the case of absence of the delegated responsible person. A record of these delegated staff should be kept at each site delivering internal vaccinations alongside the stock records and temperature monitoring records.

The Lead Nurse for IP&C will carry out the monthly Quality Assurance checks to provide assurance that the fridge monitoring and cleaning is being performed correctly; and in conjunction with the Estates and Health and Safety Division, will be responsible for ensuring all vaccine fridges and portable fridges comply with the minimum standards for yearly servicing.

All staff within Public Health Wales (PHW) involved in vaccine transportation or administration are required to comply with the procedure detailed within this document.

3. Procedure/Process/Protocol Objectives

To provide vaccinators with standards and information regarding:

- The requirement for a delegated responsible person and deputy to be responsible for receipt and care of vaccines. (Named staff can delegate the monitoring of refrigerator to a deputy, but should ensure that staff undertaking this task understand all aspects of the process)

- The management and maintenance of the cold chain including storage of vaccine and monitoring requirements.
- Audit requirements.
- Incident reporting and what action to take if the cold chain is broken.
- Local contacts / links for advice / support.

4. Handling and Storage of Vaccines

4.1 Ordering and delivery

The Lead Nurse for Infection Prevention and Control will assume responsibility for ordering of vaccine to PHW sites.

A delegated responsible person should be identified by the Lead Nurse for IP&C to be responsible for the receipt and care of vaccines on arrival to sites, ensuring the following-

- Vaccine is immediately stored in a fridge after delivery, maintaining the cold chain at all stages.
- There are no leakages, damage or discrepancies in the delivered vaccine.
- Stock is properly rotated – shortest expiry date used first.
- A stock information folder keeping track of orders, expiry dates and running total of vaccines will be kept by each fridge.
    - At the end of the flu vaccination campaign the Lead Nurse for IP&C will ensure that this information is scanned and uploaded to SharePoint. All paper records will be destroyed.
- Ordering is done in sufficient time to ensure that there is an adequate supply for clinics; this will involve liaison with the Lead Nurse for IP&C.

4.2 Management of the Cold Chain

4.2.1 Vaccine fridges

All premises within PHW which deliver the internal seasonal influenza immunisation programme to staff should have a validated vaccine fridge (domestic fridges are not suitable for storing vaccines)

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A validated fridge must be-

- Suitable for the storage of vaccines between +2°C and +8°C, where a mid-range of +5°C is good practice.
- Locked or kept in a locked room.
- Used only to store vaccines and medicines i.e. food or specimens must not be stored alongside vaccines.
- Large enough to hold the stock and allow sufficient space around the vaccine packages for air to circulate. Vaccines should be kept away from the side and

back walls of the refrigerator. It is preferable that vaccine fridges should be wired into switch-less sockets to avoid them being turned off accidentally, or a notice placed on the socket to mitigate accidental interruption of power.
- Vaccines stored in validated fridges must be kept in their original packaging.

4.2.2 Thermometers/Temperature monitoring

All fridges should ideally have two maximum/minimum thermometers, with one independent of mains power. Digital thermometers or data loggers are the most reliable.

The thermometer or data logger should be placed towards the back of the fridge and at the level of the middle shelf.

The temperature of all refrigerators in which vaccines are stored within PHW premises must be recorded on **all standard operational working days** when in use.

Do observe the four Rs

- Read: daily reading of the thermometer's maximum, minimum and current temperatures at the same time every day during the working week
- Record: recording temperatures in a standard fashion and on a standard template, including signing each entry on the recording sheet
- Reset: resetting the thermometer after each reading. The thermometers should also be reset when temperatures have stabilized after periods of high activity
- React: the person making the recording should take immediate action (see Section 4.5) if the temperature falls outside +2°C to +8°C and document this action immediately.

Records of temperature monitoring

An example of a temperature monitoring template can be found in Appendix A. This should be kept in the folder by the fridge and uploaded to SharePoint at the end of the flu campaign.

Records will be retained for five years.

4.2.3 Cold Chain Monitoring / Documentation Requirements

Every day (during standard operational working hours):
- Fridge temperature monitored and logged by delegated responsible person on site. Thermometer should be reset after each reading.

Every vaccine session
- At the end of each session the fridge door should be checked to ensure it is closed properly and locked.

Every Week:

- Fridge contents should be checked at least once by a registrant to ensure stock rotation/ dates and supply.

Every Month:

- Complete the Cold Chain Quality Assurance Tool (Appendix B), to be completed by a registrant (involved in vaccine delivery).

Every Year:

- Annual Fridge Service / Thermometer Calibration.

4.3 Validated vaccine carriers

Validated carriers must be used to transport vaccines between sites and during clinic sessions, if away from the main vaccination fridge. They must be used according to manufacturer's instructions.

When in use:

- Temperatures of carriers should be monitored when in use, using validated max/min thermometers.
- Temperatures should be recorded when packed and upon arrival at site.
- Keep vaccines in their original packaging.
- Take only enough vaccine for a particular session and minimise exposure of the vaccines to room temperatures.
- If there are any unused vaccines left over at the end of a vaccination session, providing there is evidence from the temperature monitoring that the cold chain has been maintained, the vaccines can be returned to the vaccine refrigerator.
- Mark vaccines with date and time returned before returning to the fridge. Returned vaccines should be used at the earliest opportunity.
- If the cold chain cannot be guaranteed, a risk assessment should be done, see below, and then use at the earliest opportunity if appropriate.

4.4 Stock Management

Stock management is an important part of ensuring cold chain compliance. Do:

- Keep all vaccines in their original packaging during the storage.
- Make checks at least once a week to: Rotate stock so that those with the shortest expiry date are moved to the front of the refrigerator and used first. Remove any expired vaccines (there should be none) and discard in appropriate waste stream (yellow-lidded sharps bin) and record this.
- Mark clearly any vaccine returned to the fridge with the date and time of its return and place it at the front of the fridge so it is used first at the next session – this should only be done with vaccines that have remained in the cold chain.

Do not:

- Stock pile vaccine (no more than four weeks' stock).
- Store vaccines in the fridge door, the bottom drawer or adjacent to the freezer plate on the fridge.

4.5 What to do if the cold chain is broken

When a breach in the cold chain is suspected or potential problems with the storage of vaccines are identified, immediate corrective action should be taken. Appendix C sets out the actions in a flowchart. This includes submitting a Datix incident report.

If the breach in the cold chain appears to be less than 20 minutes duration, record the temperature and reason on recording sheet, and reset the thermometer. Check again at 20 mins. If no longer outside of minimum or maximum range, continue to use as normal.*

In the event of a cold chain breach lasting longer than 20 minutes or concerns regarding the storage of vaccines do not dispose of any vaccines or storage equipment until the process below has been following and the outcome known:

- Isolate potentially compromised vaccines clearly labelling 'not for use'. These vaccines should be maintained between +2°C to +8°C or moved to an alternative monitored environment that is able to maintain the recommended +2°C to +8°C temperature range.
- Ensure the vaccine fridge involved remains switched on at the main electrical supply and that thermometers and temperatures probes are undisturbed and all staff are aware the fridge should not be accessed.
- **Submit a Datix report** - the Vaccine Storage Incident Checklist in Appendix E offers a proforma to ensure all necessary information is collected and submitted.
- **If the fridge checker is not a registrant, they must report the incident to the Quality, Nursing & Allied Health Professionals (QNAHPs) team immediately** via the staffwintervaccination@wales.nhs.uk email, and complete a Datix.
- Registrants should notify the QHAHPS team but continue with the actions described in the flowchart.
- Inventory all exposed vaccines stored in the fridge, recording the quantity, batch number and expiry date as well as duration of the exposure to higher temperatures and maximum temperature reached (A fridge temperature log is helpful here) and where they were stored in the fridge.

Submit a Datix report and also report the incident to the Lead Nurse for IP&C, who will liaise with the Principal Pharmacist, Medicines Information and Advice, at Cardiff & Vale University Health Board, the Manufacturer of the Vaccines & the Vaccine Preventable Disease Programme Team as appropriate. Appendix D sets out these actions in a flowchart.

An investigation into the incident should identify contributing factors leading to the event and learning points, and an action plan should be created and put in place, to ensure similar incidents do not occur in the future. Learning points must be fed back at local and organisational level.

*'One off' fluctuations in fridge temperatures rising above +8°C but lasting less than 20 minutes, such as may occur when stock taking or restocking, are not likely to have breached the vaccine cold chain and as such do not require further action. The cause of the 'excursion' should be documented on the temperature recording chart, the maximum-minimum thermometer reset, and vaccines continued to be used to their expiry date.

Refer to Vaccine Incident Guidance (Vaccine incident guidance: responding to vaccine errors - GOV.UK (www.gov.uk)) for further guidance.

5. Incident reporting

Incidents must be reported via web system DATIX.

6. Monitoring compliance

Compliance will be monitored via the audit tools attached in the appendices to this document. The lead nurse for IP&C will review these audits to ensure compliance and provide assurance to Chief Executive and delegated to the Executive Director of Quality, Nursing and Allied Health Professionals. Such assurance will be reported in the PHW Vaccine Delivery meetings.

Appendix A: Daily Temperature Log

Fridge location: ……

Fridge identifier: ……

Month and Year: ……

Date	Time	Current temperature	Minimum temperature	Maximum temperature	Checked by (Signature)	Thermo-meter reset (tick)	Comments

Monthly review by:……. (name/signature)

Date:…….

Appendix B: Cold Chain Compliance Assurance Tool

Criteria	Audit Result			Comments/ action to be taken	Target date (if non-compliance evident)	Completion date
Equipment and Facilities	Yes	No	n/a			
Fridge is a pharmaceutical fridge (domestic fridges are not suitable for storage of vaccines or insulin)						
The fridge is situated away from direct heat source.						
Fridge plug is protected e.g. encased to prevent tampering, security marked "Do Not Switch Off" or is hardwired ('spurred').						
Fridge is cleaned and defrosted if necessary regularly (at least every 6 months).						
Only pharmaceutical items are stored in the fridge e.g. no food, drink or medical samples are stored in the fridge.						
Thermometer is able to give Max/Min/Current readings						

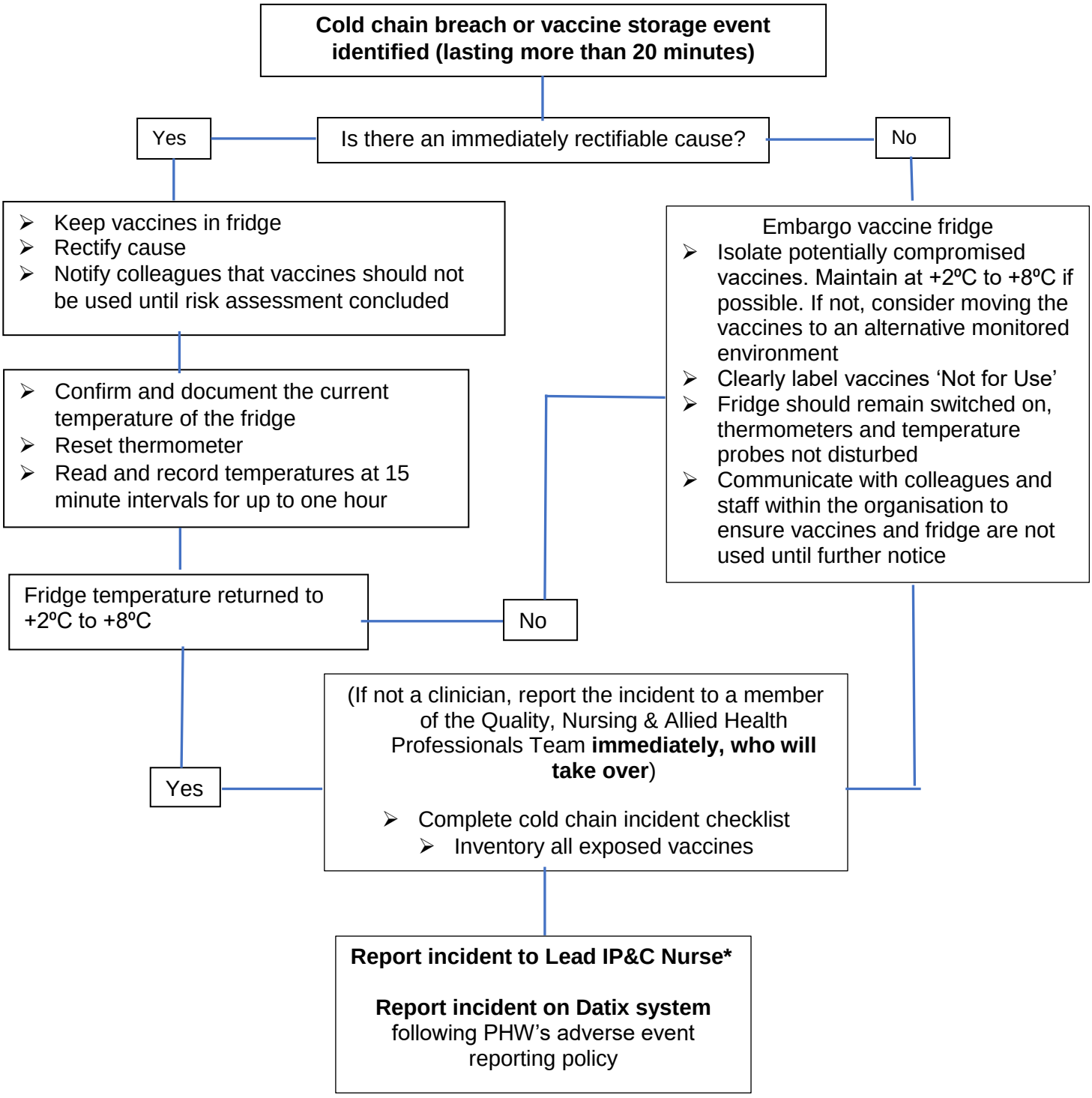
Criteria	Audit Result			Comments/ action to be taken	Target date (if non-compliance evident)	Completed
Storage and Stock Control	Yes	No	n/a			
Vaccines/Insulin are stored in the body of the fridge not in the fridge door.						
Items are stored away from the back and sides of the fridge and the freezer compartment if it has one.						
No more than 66% of the internal volume of fridge is filled.						
Vaccines are not being stored in the bottom drawer of the floor of fridge.						
Expiry dates are checked regularly at least once a month and records are kept of this activity.						
Stock rotation is carried out to ensure shortest expiry dates are used first.						
Cold chain deliveries are refrigerated immediately on receipt.						
Named person and deputy responsible for receipt of the cold chain lines.				Names....		

Criteria	Audit Result			Comments/ action to be taken	Target date (if non-compliance evident)	Completed
Temperature Monitoring	Yes	No	n/a			
Named person and deputy responsible for monitoring the fridge.				Names....		
Procedures in place for *at least* daily recording of temperatures.						
All staff involved in temperature monitoring are aware of responsibilities and SOP for Cold chain storage						
Recording form or equivalent is used.						
Minimum, Maximum and Actual temperature is checked and recorded.						
Reset button is used for every documented measurement.						
Procedures in place for action to be taken in the event of abnormal temperatures. (See SOP for Cold chain storage)						

Criteria	Audit Result			Comments/ action to be taken	Target date (if non-compliance evident)	completed
Contingency Arrangements	Yes	No	n/a			
Procedures in place for suitable monitored alternative storage to maintain cold chain when required.						

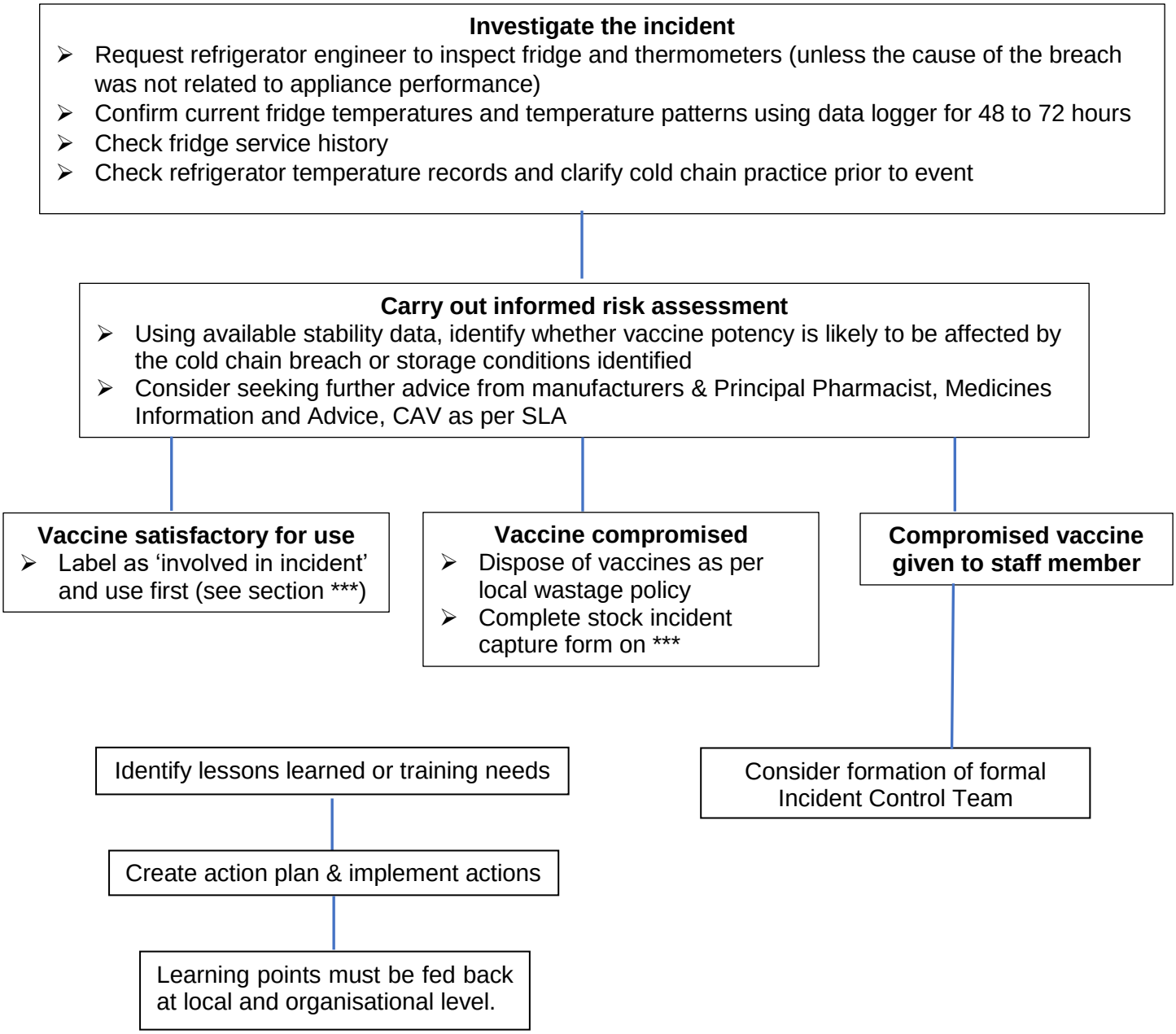
Audit date-_____ Site Audited-_____ Auditor-_____
Return to- Lead Nurse for IP&C

Appendix C: Responding to a cold chain breach or compromised storage event



*If Lead IP&C Nurse is unavailable, details of alternate contact will be listed in Out of Office messaging in emails or available from QNAHP Administrators.

Appendix D: Actions for Lead Nurse for IP&C on notification of a cold chain breach



Appendix E: Vaccine storage incident checklist

Question	Answer
Date and time of incident form completion	
Fridge location or identifier	
Date or time cold chain breach occurred	
Date or time cold chain breach identified	
What were the temperature readings when the breach was noticed?	Min…… Max…… Current……..
Date and time of last guaranteed storage between +2ºC to +8ºC	
Total duration of temperature excursion (hours or minutes). If multiple excursions have occurred, list dates and total excursion times.	
Do you have the fridge temperature record sheets or data logger sheets for the period in which the incident occurred?	
What alerted you to the cold chain breach or storage event?	
Is there an alarm fitted on the fridge and if so: • what parameters are set • after how long outside of +2ºC to +8ºC range does the alarm sound?	
Type of fridge (domestic or medicine)	Make…… Model…….. Serial number…….. Age……..
What date was the fridge last serviced?	
Has an engineer checked the fridge since the incident? What did their report say?	
Prior to this incident, was the fridge working with no issues?	
How often are fridge temperatures recorded?	
Who records the fridge temperature?	
What type of thermometer is in use? (for example, integral to fridge, battery operated independent thermometer, data logger)	
If there is a temperature probe in the fridge, what is its position in the fridge?	
When was the thermometer last reset?	
When was the thermometer last calibrated?	
Has continuous temperature monitoring with a data logger for 48 hours been performed since incident	

was identified?	
Result of 48 hours continuous temperature monitoring with a data logger	
Is there any explanation for the temperature excursions? (for example, restocking the fridge, busy clinic, power failure)	
Are there any obvious signs of freezing (for example, frosting on sides or back of the fridge, wet or damaged vaccine boxes)?	
Are any vaccines placed against the sides or back of the fridge or been pushed up against the cooling plate or cold air inlet?	
Have any of the vaccines involved in this incident previously been exposed to temperatures outside 2°C to 8°C? (involved in previous cold chain incident)	
What is the current vaccine stock in the fridge (name or type of vaccine, expiry date, quantity and location in fridge)?	
How often are vaccines ordered and what is the stock turnover time?	
Has anybody been vaccinated with vaccines involved in the incident? If so, how many people?	
Have the vaccine manufacturers been contacted directly about the incident and for stability data?	
Have any of the vaccines already been destroyed since the incident was identified?	
Has the cause of the breach been rectified and/or steps taken to prevent the problem recurring?	
Additional information or comments	
Form completed by: (name and signature)	