GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	Reference Number: PHW/STP05 Version Number: 2 Date of Next review: 07 June 2026

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 / Rhiannon Beaumont-Wood
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Accountable Executive Director/Director	Rhiannon Beaumont-Wood, Executive Director Quality, Nursing and Allied Healthcare Professionals.
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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.
2	10.03.23	07.06.23	05.07.23	Additional detail given around delegation of responsibility and procedures to ensure cold chain has been maintained. Approved by Rhiannon Beaumont-Wood

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 (IP&C) lies with the Chief Executive and organisational arrangements for management arrangements for IP&C are delegated to the Executive Director of Quality, Nursing and Allied Health Professionals. This is implemented through the advice and work of the Lead Nurse for Infection Prevention and Control.

Lead Nurse for Infection Prevention & Control

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

Peer vaccinators

With regards to vaccine storage & cold chain management, peer vaccinators should ensure that:

- They have undertaken the required training prior to the start of the staff flu vaccination programme, including the 'Immunisation elearning programme – vaccine storage' module if appropriate and the Peer Vaccinator Competency Checklist, which includes cold chain management.
- They can demonstrate knowledge and understanding of the rationale for maintaining the vaccine cold chain.
- They are familiar with local protocols for cold chain management and the action to be taken in case of cold chain failure and who to contact.
- They are aware of the contents of this procedure and how to access it.
- If peer vaccinators are on the rota for fridge checking, they must undergo the fridge checking training package and be signed off as competent.

Fridge checking staff

- Should be aware of the contents of this procedure and how to access it.
- Must have undergone the fridge checking training package and be signed off as competent by a Registered Nurse member of the QNAHPS team.
- Must understand the impact of fridge temperatures going out of range and the need to act if this occurs, and the action to be taken and who to contact.

Staff receiving vaccines

- Should be aware of the contents of this procedure and how to access it.
- Must have undergone the vaccine delivery training package and be signed off as competent by a Registered Nurse member of the QNAHPS team.

Storage of Vaccines at Public Health Wales Sites

Each site storing and/or administering vaccinations should have sufficient appropriately trained staff available to conduct and record fridge temperature checks at least once a day on all standard operational working days, excluding weekends and bank holidays. This is described in more detail below. These staff are not required to be a Registered Health Professional. They must complete the training package and be signed off as competent by a Registered Nurse within the QNAHPS team. In particular, all identified staff must know when and how to escalate concerns and any incidences of the temperature going out of the acceptable range of 2 to 8 ˚C A record of the identified staff should be kept at each site storing or 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.

Transportation and Vaccine Administrators

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.
- 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 or instructing any external provider secured via Service level agreements as required.

A named responsible person should be identified by the Lead Nurse for IP&C to be responsible for the receipt and management of vaccines on arrival to sites and must be signed off as competent against the Vaccine Deliveries Competency Checklist before the start of the flu campaign. They do not need to be a Registered Health Professional but must have undertaken the training package and be signed off as competent by a Registered Nurse within the QNAHPS team prior to undertaking the role. They must ensure the following-

- Vaccines are immediately stored in a fridge after delivery, maintaining the cold chain at all stages.
- There are no leakages, damage or discrepancies in the number of the delivered vaccines.
- 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 in the designated repository. All paper records will be destroyed in line with confidential waste guidance.
- 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, and should not be packed tightly into the space. 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 at least two maximum/minimum thermometers, with one independent of mains power. Digital thermometers or data loggers are the most reliable. Good practice is to use two data loggers in case of battery failure.

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.

People who are designated fridge temperature checkers must have completed the appropriate training and be signed off as competent against the Fridge Temperature Checking Competency Checklist. **People must not delegate the responsibility to anyone who has not undergone this training and assessment.**

See Appendix A for instructions on how to read and reset the thermometers of the fridges in PHW.

Do observe the 'Four Rs'

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

Note:

Some fridge thermometers show a 'load' temperature and an 'air' temperature'. The current, maximum and minimum temperatures for both should be monitored and recorded.

'Load' Temperature - The 'load' temperature refers to the actual temperature of the vaccine or medicinal product placed in the pharmacy fridge. The load temperature more accurately reflects the temperature of the medicinal product. It is sometimes referred to as the 'true' temperature.

'Air' Temperature - The 'air' temperature measures the temperature circulating around the medicinal products in the refrigerator. Air temperature can vary within the refrigerator and can change quickly when refrigerator doors are opened. Air temperature changes much more rapidly than the load but provide an early warning that the fridge may be becoming too warm for the vaccines inside.

Records of temperature monitoring

An example of a temperature monitoring template can be found in Appendix B. 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, trained responsible person on site. Thermometer should be reset after each reading.
- On a Monday this must be performed at the start of the working day and at the end of the day, to ensure any temperature excursions over the weekend are identified as soon as possible.
- On all other days, the fridge must be checked, as a minimum, at 16:00 each day.
    - This ensures that the vaccines will not be stored out of temperature range for longer than 24 hours, the general time up to which they can still be used.
    - This will ensure that the fridge temperature is checked as near to the weekend as possible, limiting the gap as far as possible before the next check on the Monday morning.

Every vaccine session

- Before opening the fridge, the minimum, maximum and current temperatures should be checked, to ensure that the ideal temperature range has not be breached in the hours before the vaccine session. If the thermometer shows any temperature out of range, the data logger should be reviewed and the process for vaccine incidents below followed.
- The placement of vaccines within the fridge should be checked to ensure no boxes are touching the back of the fridge.
- At the end of each session the fridge door should be checked to ensure it is closed properly and locked.

- If the fridge temperature has risen to above 8°C, the person replacing the vaccines must wait by the fridge until the temperature returns to between 2°C and 8°C.

Every Week:

- The Lead Nurse for IPC, or a delegated deputy, will review the temperature recording chart for the previous week and download the data logger data, to check for discrepancies.

Every Month:

- Complete the Cold Chain Quality Assurance Tool (Appendix C), to be completed by a Registered Health Professional (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 D 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 F offers a proforma to ensure all necessary information is collected and submitted.
- **If the fridge checker is not a Registered Health Professional, they must report the incident to the Lead Nurse for Infection Prevention and Control or other Registered Nursing member of QNAHPS,** via the staffwintervaccination@wales.nhs.uk email, and complete a Datix.
- The QNAHPS team member will take over the management of the incident, and will also inform the Executive Director for Quality, Nursing & Allied Health Professionals (QNAHPs) or deputy.
- Registered Health Professionals 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 E sets out these actions in a flowchart.

An investigation will be carried out by the Assistant Director of Quality, Nursing and Allied Health Professionals into the incident and 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 levels and a report considered at the Public Health Wales Vaccine Planning and Delivery group and Infection Prevention and Control group.

*'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 rise in temperature 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 the Executive Director of Quality, Nursing and Allied Health Professionals. Such reporting and assurance will be reported to the PHW Vaccine Planning and Delivery group, quarterly Infection, Prevention and Control group. In addition assurance reporting will be provided as appropriate to the Business Executive Team and Quality, Safety and Improvement Committee that arrangements are in place for the safe monitoring and delivery of staff vaccination. The latter will be reported by exception as appropriate and as part of quarterly and/or annual IP&C reporting arrangements.

Appendix A: How to read and reset the fridge thermometer(s)

20220203 How to reset the large CQ2 fr

Appendix B: Daily Temperature Log

Daily temperature log v4.docx

Appendix C: 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						

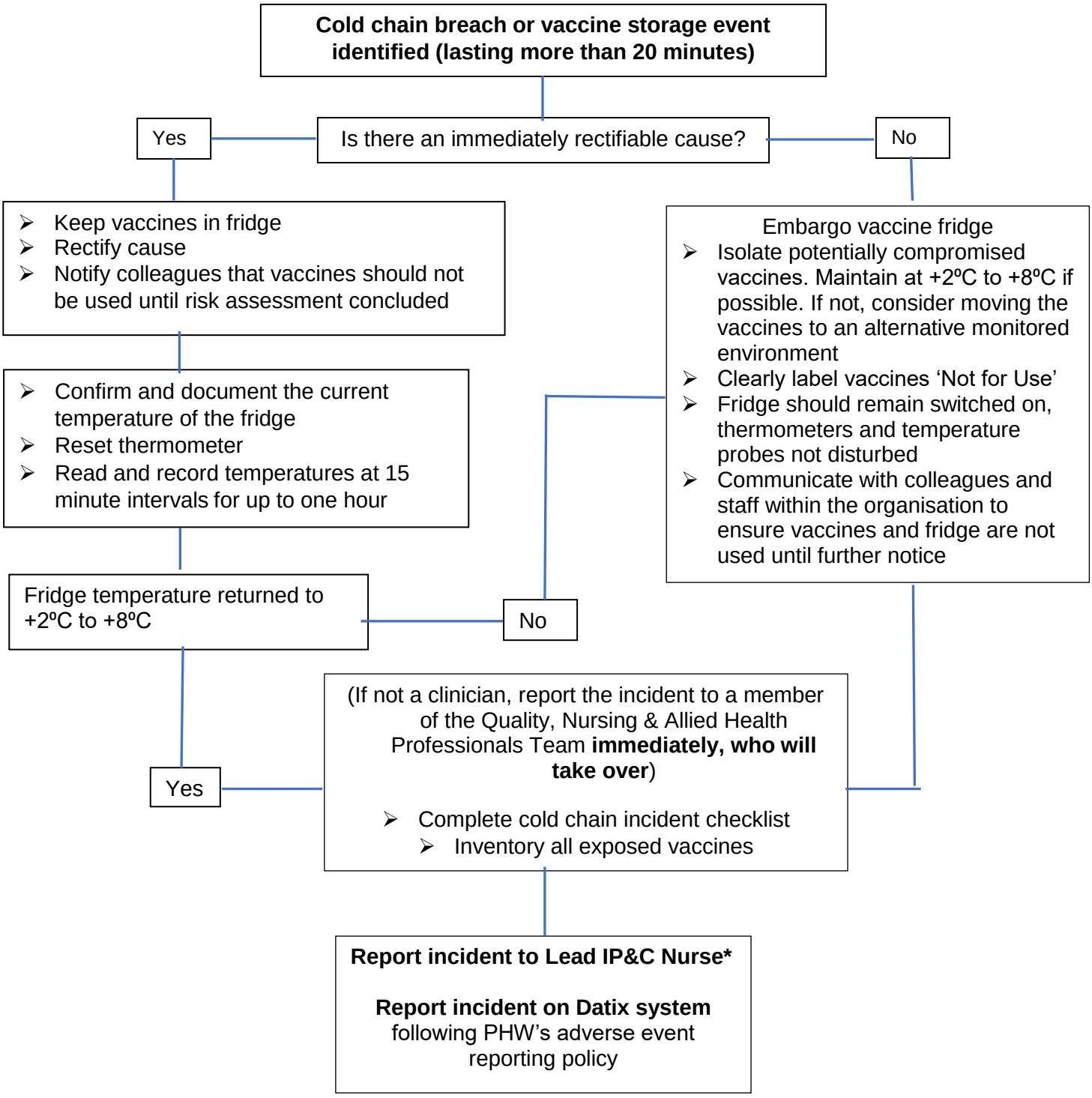
Criteria	Audit Result			Comments/ action to be taken	Target date (if non-compliance evident)	Completed
Storage and Stock Control	Yes	No	n/a			
Vaccines/Insulin are stored in the body of the fridge not in the fridge door.						
Items are stored away from the back and sides of the fridge and the freezer 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.						

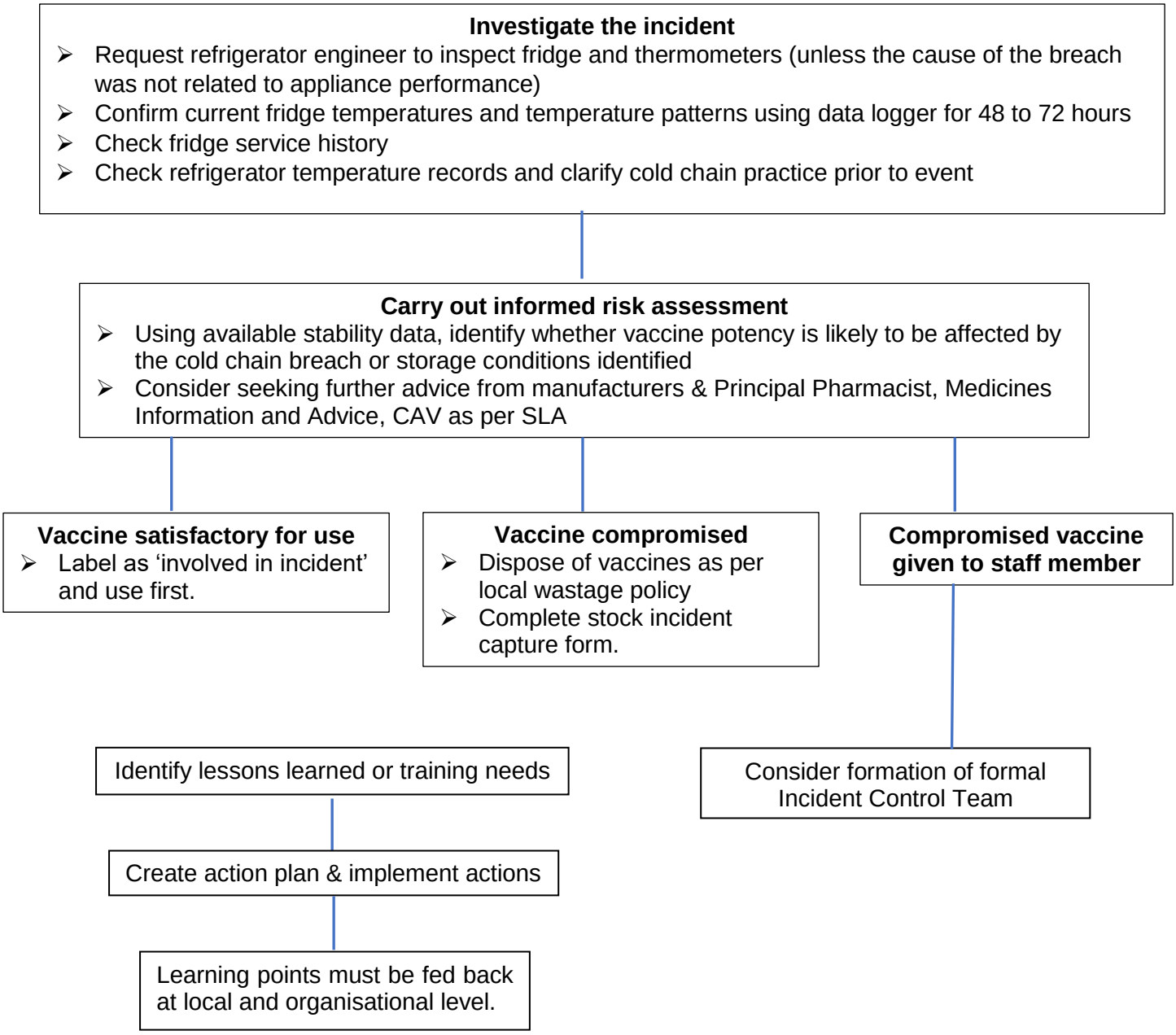
Audit date-_____ Site Audited-_____ Auditor-_____
Return to- Lead Nurse for IP&C

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



Appendix F: 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)	