NHS National Services Scotland

Guidance on vaccine storage and handling.

Version 3.

Health Protection Scotland

Acknowledgement

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What has changed since the last version?

The major changes from Version 2.0 (September 2013) include;

Section 3.5	Transport of vaccines to schools, outlying clinics, and domiciliary visits has been updated to reflect the importance of maintaining the cold chain during school immunisation sessions
Section 4.2	Type of refrigerator – new information regarding the increased risk of fridge failures has been added
Section 5.1	Monitoring refrigerator temperatures (daily temperature recording) – a recommendation for twice daily monitoring and recording of vaccine refrigerators had been added
Section 5.2	The refrigerator thermometer – changes to the responsibilities of the vaccine supervisor monthly checks to include analysing temperature records for temperature trends/drifts, confirming expiry date checks and thermometer reset carried out and documented

1. Introduction

1.1 Aim and Scope of the guideline

This guidance sets out a framework outlining the minimum standards that are required for effective storage and handling of vaccines thereby minimising the risk of compromising the effectiveness of vaccines given to patients. This document updates the guidance on vaccine storage and handling issued by Health Protection Scotland in (2013) and supplements the recommendations in Chapter 3 of Immunisation against Infectious Disease 2006 (the Green Book). https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3.

The guidance is aimed at all staff involved with the planning or delivery of immunisation programmes in all settings. The purpose of this guidance is to support NHS boards by providing a framework within which NHS boards are expected to align their local policies regarding vaccine storage and handling.

1.2 Background Information

The success of any immunisation programme depends upon the use of effective vaccines. All vaccines should be stored, transported and administered in accordance with the manufacturer's instructions. Vaccines will lose their effectiveness over time and any storage out with the manufacturer's recommended range will speed up this loss. Loss of effectiveness is cumulative and irreversible.

Inappropriate vaccine storage can be serious, has the potential to present a public health problem and constitutes a risk to patient safety. Vaccines that are not stored and transported in accordance with manufacturer's instructions may result in the failure of the vaccine to protect and in extreme circumstances may require individuals to be revaccinated. Vaccines are expensive and can be in short supply. Inappropriate storage can result in vaccine wastage which causes a financial loss for the NHS and can increase pressure on vaccine supplies.

The Promoting Effective Immunisation Practice e-learning programme, a collaboration between Health Protection Scotland and NHS Education for Scotland (NES) is an educational resource on immunisation for health professionals in Scotland. The programme has a module on storage and handling of vaccines. More information on this programme is available at http://knhswww1.the-knowledge-business.com/KNHSIMM/ImmunisationProgrammeGuide.pdf.

2. The Cold Chain – what it is and why it is important

The cold chain is the name given to the system of transportation and storage of vaccines whilst maintaining the recommended temperature range between +2°C to +8°C. It is essential to maintain an unbroken cold chain from the point of vaccine manufacture, through transportation to distribution companies, storage in a refrigerator in a pharmacy, transport to clinical settings where vaccines are stored in a refrigerator until they are used. Heat speeds up the decline in potency of most vaccines. Freezing of vaccines can cause loss of vaccine effectiveness, increased reactogenicity and hairline cracks in the container, the latter leading to contamination of the contents. Effectiveness cannot be guaranteed for vaccines unless they have been transported and stored at the correct temperature.

Cold chain maintenance has three main components: equipment used for transport and storage, appropriately trained personnel and robust procedures. All three elements must combine to ensure that vaccine effectiveness is maintained by ensuring the vaccine is transported and stored at the recommended temperature up to the point that the vaccine is administered.

All vaccines are covered by the terms of the vaccine manufacturer's marketing authorisation (product licence). These will include the manufacturer's recommended storage requirements. Unless specific advice states otherwise, vaccines that have not been transported or stored according to the terms of the marketing authorisation are no longer covered by that authorisation and the liability for use is then transferred from the manufacturer to the prescriber/health care practitioner.

The maintenance of the cold chain is therefore important to;

- Give assurance/confidence in potency of vaccine
- Ensure maximum effectiveness/clinical benefit from immunisation
- Minimise risk to vaccine effectiveness from extremes of temperature
- Ensure compliance with manufacturer's marketing authorisation
- Minimise financial loss and pressure on vaccine supplies from vaccine wastage

3. Key Principles of Vaccine Storage and Handling

3.1 Introduction

All staff involved with the transport, storage and administration of vaccines must understand the importance of maintenance of the cold chain. In each site where vaccines are stored or used, the manager with the overall responsibility for vaccine storage and handling should ensure there are written standard operating procedures (SOPs) in place. These SOPs should include information on the following aspects of vaccine storage and handling;

- Ordering
- Receipt
- Storage
- Stock rotation
- Transportation
- Monitoring refrigerator temperatures
- Action to take in the event of cold chain breach

These SOPs should be reviewed and approved at least every two years by the appropriate manager. (see specimen SOP – Appendix 1)

In each site where vaccines are stored or used, the person with the responsibility for vaccine storage and handling should designate one member of staff to be the main vaccine supervisor and another member of staff should be identified as a deputy. The designated vaccine supervisor or their deputy will be responsible for ensuring:

- All vaccines are ordered, received into stock and handled correctly
- Refrigerator temperatures are appropriately monitored
- Any cold chain breaches result in action to resolve the issue, and are documented and reported
- All staff involved with handling of vaccines have access to SOPs and are appropriately trained

In all sites where vaccines are stored there should be an annual audit. A specimen audit checklist for use by NHS board staff or practice staff is attached as Appendix 2.

3.2 Ordering of vaccines

In all areas where vaccines are used there should be a SOP detailing the process for ordering vaccines. This should specify who is responsible for placing orders. Nationally procured vaccines should be ordered from NHS board vaccine holding centres using the standard order form used within the NHS board.

Vaccine stocks should be monitored by the designated vaccine supervisor or their deputy to avoid over or under ordering. Care should be taken when ordering vaccines, especially as certain vaccines are packaged in multiple quantities. Incorrect ordering can result in wastage and unnecessary costs.

In front line clinical settings there should normally be no more than two to four weeks supply of vaccines at any time. This will be sufficient for routine provision. Best practice is to order small quantities on a regular, scheduled basis. Ordering should be done in sufficient time to ensure that there is always an adequate supply for clinics. Excess stock may:

- increase the risk of vaccination with out-of-date vaccines
- increase wastage and the cost of disposal
- increase the likelihood of problems associated with over-packed refrigerators i.e. poor air flow, temperature elevation, potential freezing and poor stock rotation
- delay the introduction of new vaccines until local supplies have been used
- increase the cost of replacement of stocks if the refrigerator fails
- increase the pressure on the performance of refrigerators in periods of high demand, e.g. during the influenza vaccination season

3.3 Receipt of vaccines

All deliveries of vaccines must be handed to the designated recipient and not left unattended. On receipt, deliveries of vaccines should be dealt with immediately. They should be examined for leakage or other damage. The vaccines received should be checked against the order/delivery note and a signature provided to confirm receipt. All deliveries should be checked carefully at time of receipt as vaccines cannot be returned later. Vaccines requiring refrigeration should be placed in the refrigerator immediately after checking and signing to accept delivery and should not be left at room temperature.

3.4 Rotation of stock

Vaccine stocks should be placed within the refrigerator so that stock with the shortest expiry is used first. This may not always be the most recently delivered vaccine. Expiry dates should be checked on a monthly basis and this process must be documented in the vaccine refrigerator temperature log book.

3.5 Transportation of vaccines to schools, outlying clinics, and domiciliary visits

Vaccines requiring refrigeration should be transported to schools and outlying clinics in a vehicle which has been validated and is monitored throughout the journey or in cool boxes that have been validated to maintain the temperature within the recommended range of +2°C to +8°C for the period of transport. If vaccines are being stored in schools prior to their use they should be stored in a pharmaceutical refrigerator with temperatures being monitored as described in section 5.1.

All staff involved with transport and storage of vaccines in schools and outlying clinics should be appropriately trained to ensure cool boxes are used appropriately. Validated cool boxes should be used in accordance with the manufacturer's instructions to ensure the correct storage of vaccines at all times. With time and use, cool boxes may no longer be able to maintain this temperature range for extended periods and so good practice is to consider periodic revalidation of cool boxes. Domestic cool boxes should not be used.

Where the purchase of validated cool boxes for the purpose of transport of vaccines is under consideration then advice should always be sought from the appropriate person in the NHS board.

Validated cool boxes suitable for transport of vaccines are available from a number of suppliers. Suppliers should be able to provide details of the validation process and results.

When transporting vaccines only the amount of vaccine necessary for each session should be removed from the refrigerator. These should be placed quickly into a validated cool box and opening must be kept to a minimum. Cool boxes must be sealed appropriately during transportation and at school vaccination sessions. Consideration could be given to use of tamper evident seals during transportation and also to the use of additional temperature monitoring devices to provide evidence of cold chain maintenance.

If there are any unused vaccines left over at the end of a vaccination session, provided they have been stored in a validated cool box, used in accordance with the manufacturer's instructions, the vaccines can be returned to the vaccine refrigerator. It is good practice to label returned vaccines and use them at the earliest opportunity.

3.6 Disposal of expired stock

Any out of date stock should be appropriately quarantined, disposed of and recorded in accordance with local pharmaceutical waste policy arrangements.

4. Storage of vaccines and the vaccine refrigerator

4.1 General requirements

Vaccines requiring refrigeration should be stored in their original packaging in a pharmaceutical refrigerator at a temperature between +2°C to +8°C and protected from light. Storage in the original packaging allows easy product identification, easy checking of batch numbers and expiry dates and the packaging offers some protection against temperature fluctuation.

Ideally the principle of 'strive for 5' should be adopted, as a temperature of +5°C gives a greater leeway for protection against fluctuations in temperature.

Food, drink and clinical specimens should not be stored in refrigerators used for vaccines or medicines.

There should be sufficient refrigerator capacity to store the maximum vaccine storage needs (including seasonal influenza vaccine).

No equipment or power supply is infallible and in all areas where vaccines are stored there should be contingency plans in the event of equipment failure. Such plans should consider the need for and location of back up facilities and detail the actions required by individuals and their responsibilities.

Vaccines are Prescription Only Medicines and should be stored under locked conditions. Refrigerators should either be lockable or within a room that is locked when not occupied by a member of staff. When the refrigerator is not in use the key should be removed and held by the appropriate person as detailed in local procedures.

4.2 Type of refrigerator

Vaccines should be stored within a pharmaceutical refrigerator that is specifically designed for the purpose of storing vaccines or medicines. These are designed to provide a stable, uniform and controlled temperature throughout the unit. Vaccines should not be stored in a domestic refrigerator.

To support decisions about procurement of pharmaceutical refrigerators a specification for a refrigerator suitable for storage of vaccines is detailed in Appendix 4.

Refrigerators suitable for storage of vaccines are available from a number of suppliers. Where the purchase of a refrigerator for the purpose of storage of vaccines is under consideration then advice should be sought from the appropriate person in the NHS board.

With age the risk of a refrigerator failing increases with an increased resultant loss of vaccines. Audit data from several NHS boards suggests that the majority of cold chain incidents due to refrigerator failure occurred in refrigerators over 5 years old. Consideration should be given to a programme of replacement of older refrigerators before problems occur.

4.3 Organisation of the refrigerator

Vaccines should be spaced evenly throughout the refrigerator to allow cool air to circulate around the vaccine packages. No more than two thirds of the internal volume for the refrigerator should be filled.

Vaccines should not touch the back or sides of the refrigerator to ensure adequate circulation of cool air. Manufacturers of refrigerators will usually provide guidance regarding the clearance required. If there is any doubt it is reasonable to leave an air gap of 4cm between vaccines and the internal sides of the refrigerator.

Pharmaceutical refrigerators do not have storage compartments/shelves in the refrigerator door and refrigerators with these should not be used to store vaccines. Vaccines should not be stored in any integral enclosed plastic trays at the bottom of the refrigerator that may be found in some older style vaccine/pharmacy refrigerators. These prevent the circulation of cool air and may lead to warming of vaccines.

Vaccines should be organised within the refrigerator so that they can be found quickly and to minimise the length of time that the door is open. It is considered good practice to display a map on the door of the refrigerator listing the contents and their shelf location.

4.4 Power Supply

Accidental disconnection from power source is a common reason for breaches of the cold chain. Where possible the mains supply to the refrigerator should be directly wired ('spurred') in to the electrical supply. Where this is not possible, arrangements should be put in place to ensure the plug is never pulled out, and the switch is never turned off (These arrangements could include difficult access to the socket e.g. behind the refrigerator or physical cover).

Any switches that are used to connect refrigerators to the power supply should be clearly identified 'Refrigerator – Do Not Switch Off'

Vaccine refrigerators should not be switched off other than to clean and/or defrost the refrigerator, in the event of an electrical emergency or if the refrigerator is being worked on by an engineer. In these cases, the vaccine stock should be transferred to another appropriate pharmaceutical refrigerator or validated cool box. Vaccine refrigerators may be switched off temporarily (less than 5 minutes) in order to replace a faulty light bulb without the stock being moved but this should be noted on the refrigerator temperature record.

In the event of a power outage refrigerator doors should be kept closed and the temperature monitored until either the supply is reinstated or alternative arrangements for storage can be made. It is important to document the time the power outage began and ended, if it is known and to record the maximum temperature reached throughout. A contingency plan should be in place for such eventualities. Each incident should be reported to the appropriate person in accordance with local NHS board arrangements for guidance. Contact the local NHS board for guidance if there is a planned time-limited power outage.

4.5 Placement of refrigerator

Refrigerators should not be situated in direct sun light, near a radiator or other heat source. There should be adequate ventilation space around the refrigerator to allow free circulation of air to cool the compressor motor. Where possible refrigerators should not be placed against an external wall as in some circumstances these may be subject to hot and cold temperatures with changes in weather.

4.6 Installation of a new refrigerator/movement of an existing refrigerator

When a new refrigerator has been installed or where a refrigerator has been moved it should be placed into the area where it will be used, ensuring that it is level, and left for 24 hours before switching it on, as tilting refrigerators can affect the placement of the coolant within the compressor.

Where a refrigerator is switched on for the first time or after a prolonged period of time where it has been switched off the refrigerator should be left to run for a period of time before it is used to store vaccines. There is no exact requirement stated by refrigerator manufacturers but good practice suggests that the refrigerator is run for 48 hours with twice daily checks of current, maximum and minimum temperature to ensure the unit is functioning correctly before it is used to store vaccines.

When a refrigerator has been switched off for a short period to undertake defrosting or as a result of a brief interruption in power supply, the refrigerator temperature should be allowed to stabilise within the recommended range (+2°C to +8°C) after it has been switched on before being used to store vaccines.

4.7 Cleaning the refrigerator

Refrigerators should be kept clean. Where routine cleaning is required domestic detergent and water should be used. All cleaning solutions should be thoroughly rinsed off and care exercised to avoid damage to the unit. A record of when cleaning has been carried out should be made in the vaccine refrigerator temperature log book. Vaccines should be transferred to another pharmaceutical refrigerator with appropriate monitoring of temperatures or validated cool box, during cleaning. Any spillage of vaccines should be dealt with in accordance with NHS board waste management policy.

The vast majority of pharmaceutical refrigerators now have automatic defrost functionality, however, where refrigerators do not have this function they should continue to be defrosted in accordance with manufacturer's instructions.

4.8 Maintenance

All refrigerators should be maintained in line with manufacturer's advice. Portable Appliance Testing (PAT) should be undertaken in accordance with local arrangements.

The refrigerator door seals should be checked regularly to ensure a good seal is maintained.

4.9 Identification of the refrigerator

Each refrigerator used to store vaccines should be clearly identified, on the refrigerator, by a unique number or code (e.g. asset number) and this should be recorded in the vaccine refrigerator temperature log book.

It is not sufficient, for example, to identify it as 'Small refrigerator – Doctors' Room' as the use of the room may change or the refrigerator may be moved.

For all new refrigerators the vaccine refrigerator temperature log book should also contain the date at which the refrigerator was used for the first time.

5. Monitoring vaccine refrigerator performance and storage conditions

5.1 Monitoring refrigerator temperatures (daily temperature recording)

The designated vaccine supervisor or their deputy is responsible for ensuring all staff dealing with the storage of the vaccines and daily temperature recording are competent in reading and resetting the maximum/minimum thermometer.

In all areas where vaccines are stored there should be an SOP for monitoring/recording of refrigerator temperatures. Recording twice daily at the start and end of daily work sessions is recommended, however, the Green Book states that once daily recording as a minimum is acceptable. See specimen SOP for monitoring refrigerator performance attached at Appendix 1.

The current, maximum and minimum temperatures should be recorded legibly and monitored twice a day. After each recording the thermometer memory should be reset. A standard temperature monitoring record should be used. A specimen temperature monitoring record is attached at Appendix 2. Temperature records relating to a particular refrigerator should be kept close to that refrigerator (but not inside) for ease of reference and should be clearly identified as relating to that appliance. A separate temperature record should be kept for each refrigerator. Electronic records are acceptable provided they capture all of the recommended information and are stored on a system that has appropriate back up.

It is good practice to record the temperatures at a similar time each day e.g. first thing in the morning before the refrigerator door is opened for the first time and just before leaving the site at the end of the work session. This will allow review of trends in results recorded, help highlight any changes in temperatures recorded and deviation in refrigerator performance. Any trend of increasing or decreasing temperatures within the recommended range should be investigated before problems occur. The individual checking the temperature should sign the recording sheet.

It is also good practice to record any activity which may affect the temperatures recorded e.g. tidying, re-stocking, cleaning, at the time it takes place

5.2 Monitoring refrigerator temperatures (monthly check)

The vaccine supervisor is responsible for carrying out the following checks at the end of each month;

- reviewing the temperature records to identify trends and investigate problems before they occur
- confirm from the temperature records that there is evidence that the thermometer is being reset
- confirm that a review of expiry dates has been carried out

5.3 The refrigerator thermometer

The refrigerator should be fitted with a thermometer capable of continuous monitoring to ensure that the temperature remains within the specified range of +2°C to +8°C.

For new vaccine refrigerators a calibrated digital thermometer will be provided in the form of an integral probe connected to a digital display. Where a calibration certificate is supplied by refrigerator manufacturers it should be retained as evidence of calibration.

For older refrigerators, without an integral thermometer connected to a digital display, a calibrated, independent maximum / minimum digital thermometer capable of recording temperatures to one decimal place should be used. If using this type of device, the probe should be positioned in the middle of the refrigerator among the vaccines. The probe should not rest on, or be near, the refrigerator light and should not be near the door or the refrigerator back plate.

Analog devices are not acceptable. The integral or independent refrigerator maximum / minimum thermometer should:

- be able to be read from the outside of the refrigerator without opening the door
- record to one decimal place
- have an accuracy of at least +/- 1°C
- be supplied with a calibration certificate if available
- have its accuracy checked at least on an annual basis
- ideally be independent of mains power, so that temperatures can be measured in the event of electricity loss. (NB it is important to ensure that batteries are inserted and replaced in accordance with manufacturers or NHS board recommended timescales)

5.4 Resetting the thermometer

The designated vaccine supervisor must ensure that staff know how to reset the thermometer. The maximum/minimum thermometer should be re-set by clearing the thermometer memory after each reading. To ensure the reset has been carried out correctly, the maximum, minimum and current temperatures should be checked again and if the thermometer has been correctly reset these should all show the same (current) temperature.

It is good practice to reset the thermometer at the end of a clinic if the refrigerator door has been opened on several occasions or if the refrigerator has been re-stocked or cleaned. Resetting should be carried out once the current temperature reading has returned to within the recommended range.

If temperatures are noted to be outwith the recommended range then this should be recorded along with action taken to resolve the issue. For example, if cleaning the refrigerator has taken place or the door has been left open for a period of time e.g. to re-stock the refrigerator, this should be recorded in the comments column.

Monitoring the refrigerator temperatures should be facilitated by using the ‘four Rs’

Read: reading of the thermometer’s maximum, minimum and current temperatures twice daily on all working days

Record: recording temperatures in a standard fashion and on a standard form, including signing each entry on the recording sheet.

Reset: resetting the thermometer after each reading. The thermometer should also be reset when temperatures have stabilised after periods of high activity.

React: the person making the recording should take action if the temperature falls outside +2°C to +8°C and document this action.

5.5 Retention of temperature records

Retention of records under the Records Management: NHS Code of Practice (Scotland) (2012). Under pharmacy records: quality assurance it is recommended that refrigerator temperature records should be retained for the life of any vaccine stored therein with a minimum of a one year retention period.

As shelf lives specified by vaccine manufacturers can be up to four years or longer, retaining records for five years will generally enable the full storage history of vaccines to be accounted for.

5.6 Checking the performance of the refrigerator/thermometer

Calibrated electronic temperature logging devices suitable for checking the performance of the refrigerator (temperature mapping) and refrigerator thermometer are available from a number of suppliers. Where the purchase or use of temperature logging devices is under consideration then advice should be sought from the appropriate person in the NHS board.

6. Action to be taken following recording of temperatures found to be outwith the recommended range

If temperatures outwith the recommended range (+2°C to +8°C) are identified the following actions should be taken:

- Consideration as to whether this has implications for the cold chain storage of current and recently administered vaccine stock
- The appropriate contact in the NHS board needs to be consulted to ensure that a risk assessment of the impact of temperatures on the affected vaccines is undertaken
- The servicing of the refrigerator should be a priority

A procedure should be available to describe the actions that should be taken in the event of the temperature going outside the recommended range (+2°C to +8°C). The designated vaccine supervisor or their deputy should be informed and a note of any action taken or comments on temperatures outside the +2°C to +8°C range should be clearly made on the temperature recording log. It is important to review action taken to ensure an appropriate outcome.

Reasons for readings being out of recommended range may include:

- door being left open
- re-stocking
- unplugging of refrigerator from power socket or other loss of power
- malfunction or failure of the refrigerator or thermometer

If there are any concerns about the storage of the vaccine and subsequent viability, the suspect stock should be quarantined and kept within a suitable pharmaceutical refrigerator but must not be destroyed until further investigation and risk assessment has been completed by NHS board staff. Advice should be sought from the designated contact in the NHS board. A system of notifying local staff with responsibility for vaccines should be in place. An incident/record form should be completed using NHS board standard operating procedures for incident reporting. Where incidents occur within a general practice setting, independent contractors and their staff should be encouraged to use NHS board procedures for incident reporting. This will provide details of the incident and action taken to reduce the risk of recurrence.

The following checklist provides a framework for the essential steps that should be taken in the event that the recorded maximum and/or minimum temperature is outwith the recommended range of +2°C to +8°C.

- The person noting the temperature should inform the designated vaccine supervisor or their deputy and/or the appropriate manager
- The cause should be immediately investigated and where possible the problem should be rectified
- Assess the period of time the products are exposed to temperature out with recommended range
- Place affected stock into quarantine but keep stock in refrigerator – transfer to another refrigerator if possible

- Record details of products that are affected; vaccine name, brand, batch numbers, expiry dates, quantity
- Discuss with the designated contact in the NHS board to request a risk assessment be carried out and obtain advice regarding whether stock can be used
- Assess implications for stock and arrange for further supplies to meet immediate clinical need
- Ensure action taken to prevent/reduce risk of recurrence of problem
- Document all actions

Health Protection Scotland has produced Vaccine Incident Guidance: actions to take in response to vaccine errors as a starting point from which to consider the appropriate response to vaccine incidents and to provide consistent advice to vaccinators when incorrectly handled vaccines have been administered to patients. This guidance is available at: http://www.hps.scot.nhs.uk/immvax/resourcedetail.aspx?id=1056

Appendix 1: Specimen standard operating procedure for monitoring refrigerator performance and recording temperatures

Practice/clinic/unit name:		
Designated Vaccine Supervisor:		
Deputy:		
SOP Number:		
SOP Title	Temperature recording and checking procedure	
Page(s)		
Written by	Signature	
Approved by	Signature	
Date approved		
Review date		

Appliance Details

Appliance identification	Appliance location	Use and limits	Fitness for purpose review
		Vaccine storage at +2°C to +8°C	Twice daily on all working days

Standard limits
Refrigerator temperature +2°C to +8°C

Procedure

1. At the start of each month, a new record sheet should be used for each appliance (A vaccine refrigerator temperature log book is required for each appliance).
2. Twice daily preferably at the start and end of the working session, the maximum / minimum thermometer is read and the maximum temperature, minimum temperature and current temperature are recorded along with the date and time.
3. Each entry should be checked to ensure that all three are within the +2°C to +8°C range.
4. Note any cleaning, re-stocking activities which may have been undertaken and which may have a potential to effect refrigerator performance.
5. If all readings are within the range, then the person recording signs the entry and no further action is needed.
6. If any part of the entry is out of range, then the person recording should try to identify any reason that could explain the discrepancy and they should bring it to the attention of the designated vaccine supervisor and/or manager of the practice/clinic/department.
7. If there is any doubt about whether the contents may have been compromised due to inappropriate storage conditions, quarantine the stock but continue to keep it under the correct refrigeration conditions. Check as soon as possible with an appropriate person, e.g. Supplying pharmacy on telephone .....
8. Record any reason for the discrepancy, any advice given and the expert source consulted.
9. Record any action taken and sign the log sheet.
10. On each occasion, after the temperatures have been recorded, the maximum/minimum thermometer should be reset following the manufacturer's instructions.

11. The designated vaccine supervisor should review the temperature records on a monthly basis ensuring that:
    - the temperatures are within the recommended range
    - there is evidence that thermometer has been reset on each occasion
    - expiry date checks have been carried out
    - the above processes are documented appropriately

Appendix 2: Vaccine storage and handling specimen audit checklist

The purpose of this audit checklist is to provide a tool to assess the arrangements for the storage and handling of vaccines in any areas/sites where vaccines are stored in order to identify areas where improvement is necessary.

A separate audit checklist should be used for each of the refrigerators used to store vaccines.

Any areas of concern should be discussed with the manager in charge of the area/site.

Where any issues are identified these should be discussed where required with the appropriate person in the NHS board and remedial action undertaken.

Audit undertaken by	Name:
	Designation:
	Name:
	Designation:
Site being audited	
Date of audit	
Location of refrigerator	
Refrigerator Identification Number	
Manufacturer/Model	
Approximate age (years)	

Section 1 People

Who is the designated person in charge of monitoring the storage and handling of vaccines	Name:	
	Designation:	
Who is the named deputy for the designated person	Name:	
	Designation:	

Section 2 Procedures/Training

There is a Vaccine Storage and Handling Protocol in place that provides evidence that:	Yes	No	Comment
All staff have access to information regarding NHS board guidance/policy for handling/storage of vaccines			
All staff involved with the handling of vaccines have been trained appropriately in maintenance and monitoring of the cold chain			

There is a Vaccine Storage and Handling Protocol in place that provides evidence that:	Yes	No	Comment
There are Standard Operating Procedures for:			
• ordering vaccines			
• receipt of vaccines			
• rotation of vaccine stock and checking expiry dates			
• daily temperature monitoring/recording			
• review of temperature records on a monthly basis			
• transportation of vaccines whilst maintaining the cold chain			
• action, documentation and reporting of incidents following recording of temperatures out with recommended range			
There are contingency plans in place in the event of equipment failure			
There is evidence that all staff involved with the handling of vaccines have read and understand the procedures			
Procedures are reviewed at least annually			

Section 3a Equipment – The vaccine refrigerator

There is evidence that the pharmaceutical refrigerator used to store vaccines:	Yes	No	Comment
Is locked when not in use and the key is removed or within a room that is locked when not occupied			
Is only used for storage of vaccines and medicines			
Is filled to no more than two thirds of the internal volume			
Has no vaccines stored in enclosed plastic trays at bottom of refrigerator			
Has vaccines organised in a way that allows quick access and minimises the time that the refrigerator door is open.			
Is directly wired (spurred) or all plugs are clearly marked ‘refrigerator: do not switch off or are physically covered			
Is situated away from heat sources and direct sunlight			
Has adequate ventilation space around the refrigerator			
Has an auto defrost function			
Is cleaned regularly			

Section 3b Equipment – The refrigerator thermometer

There is evidence that:	Yes	No	Comment
The thermometer is integrated into the refrigerator with a digital temperature display to one decimal place			
The thermometer is capable of recording the current, maximum and minimum temperatures			
A digital thermometer capable of recording temperatures to one decimal place is being used and continues to record data during power /mechanical failure of the refrigerator			
In case of independent Max/Min digital thermometer the probe is placed in middle of the refrigerator			
Other devices are used to record temperatures during power/ mechanical failure of the refrigerator			☐ SD Card ☐ Other ☐ Data Logger
The calibration of the thermometer or temperature monitoring devices is checked at least on an annual basis			

Section 4 – Temperature monitoring / recording

There is evidence that:	Yes	No	Comment
A separate record is used for each refrigerator			
The current, maximum and minimum temperature has been recorded at least daily on working days (twice daily recording considered best practice)			
The temperature record is kept close to the refrigerator			
There is evidence that the thermometer is reset after each reading			
The daily temperature records are signed by the person taking the reading			
Information about activity such as restocking/cleaning the refrigerator etc that may affect temperature is recorded			

There is evidence that:	Yes	No	Comment
There is evidence that the vaccine supervisor has signed to indicate that they have; • reviewed the temperature records on a monthly basis, and the temperatures are within range • there is evidence that thermometer has been reset on each occasion • expiry date checks have been carried out • the above processes are documented appropriately			
Any readings outwith the recommended range have resulted in documented action to resolve the issue			
Temperature records are retained in accordance with guidance			

Appendix 3: Specimen Temperature Record

Practice /ward	Refrigerator location
Month / Year	Appliance number

The temperature should be maintained between +2°C and +8°C
If temperature outwith this range report immediately to designated vaccine supervisor

Date	Time	Current temperature (+2°C to +8°C)	Minimum temperature (+2°C to +8°C)	Maximum temperature (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max/min. thermometer memory cleared and checked (initial)	Signature
Example row		5.1°C	3.2°C	7.3°C	Tidying stock	AN	A Nurse
1st							
1st							
2nd							
2nd							
3rd							
3rd							
4th							
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17th							

Date	Time	Current temperature (+2°C to +8°C)	Minimum temperature (+2°C to +8°C)	Maximum temperature (+2°C to +8°C)	Note factors which may affect refrigerator performance	Max/min. thermometer memory cleared and checked (initial)	Signature
Example row		5.1°C	3.2°C	7.3°C	Tidying stock	AN	A Nurse
17th							
18th							
18th							
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31st							
31st							

The designated vaccine supervisor should review the temperature records on a monthly basis ensuring that;

- the temperatures are within range
- there is evidence that thermometer has been reset on each occasion
- expiry date checks have been carried out
- the processes are documented appropriately

Recordings for the month reviewed by:
Date:
Signature:

Appendix 4: specification for a vaccine refrigerator

The following is a specification of the features that should be considered when procuring a new vaccine (medicines) refrigerator:

A number of suppliers will supply a pharmaceutical refrigerator for storage of vaccines/ medicines which should meet the following criteria.

The following criteria are viewed as essential:

- Maintains internal air temperature between +2°C and +8°C – adjustable default/range/ alarm set points – clear instructions on adjustment of refrigerator set/alarm points should be provided
- Forced air cooling i.e. fan assisted
- CFC and HCFC free refrigeration system and insulation
- Audio/visual local alarm signal on temperature deviation, ideally with remote alarm terminals providing mains failure alarm signal
- Digital temperature display with MAX/MIN memory for continuous monitoring
- Have a thermometer with an accuracy of at least +/- 1°C
- The thermometer is independent of mains power such that measurement of temperature is possible in the event of mains power loss
- Be supplied with a calibration certificate
- Lockable solid door for security
- Wire shelves/baskets or shelves capable of allowing air ventilation
- Fully automatic defrosting

The following features may also be considered:

- Designed for efficient and effective operation in high ambient temperatures
- Adjustable feet for levelling and rear roller for easy positioning (lockable)
- Glass door
- Internal illumination
- Wall mounting brackets (for small vaccine refrigerators)
- Continuous temperature recording devices with autodialler/text function

General points such as power requirements, heat output, fan/refrigerator noise, size, weight, ease of cleaning should also be considered as with purchase of any equipment.