Health Protection Scotland

NHS National Services Scotland

Guidance on Vaccine Storage and Handling

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1. Introduction

1.1 Aim and scope of the guideline

This guidance sets out a framework outlining the minimum standards that are required for 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 2010 and supplements the recommendations in Chapter 3 of Immunisation against Infectious Disease 2006 (the Green Book).

The guidance is aimed at all staff and healthcare professionals in Scotland who are involved with the planning or delivery of immunisation programmes in all care settings.

The key 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. These local policies are also intended to support general practices in fulfilling their contractual obligations under the NHS (General Medical Services Contracts) (Scotland) Regulations 2004 (SSI 115) or the NHS (Primary Medical Services Section 17C Agreements) (Scotland) Regulations 2004 (SSI 116) in relation to the storage and handling of vaccines.

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 temperature 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.

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 by distribution companies, storage in a refrigerator in a pharmacy, then onward transport to GP practices and other 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, including manufacturer's stability data, 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
- 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 and health care professionals involved with the transport, storage and administration of vaccines must understand the importance of the cold chain and ensure that it is maintained.

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 in place to ensure the correct storage and handling of vaccines in their area of responsibility. These procedures should include the information on the following:

- Ordering and receipt of vaccines
- Storage and stock rotation of vaccines
- Transportation of vaccines
- Monitoring refrigerator temperatures
- Action to take in the event of cold chain breach.

These procedures should be approved by the appropriate manager and should be reviewed on a regular basis.

In each site where vaccines are stored or used the manager/healthcare professional/independent contractor with the overall 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 when the main vaccine supervisor is unavailable. The designated vaccine supervisor or their deputy will be responsible for ensuring that:

- all vaccines are ordered and handled correctly
- refrigerator temperatures are appropriately monitored
- procedures are written, approved and reviewed as appropriate
- all staff involved with handling of vaccines are appropriately trained.

The designated vaccine supervisor or their deputy should undertake an audit of vaccine storage and handling recommendations on an annual basis. A specimen self audit checklist is attached as appendix 1.

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

3.2 Ordering of vaccines

In all areas where vaccines are used there should be a procedure detailing the process and responsibility for ordering and receipt of vaccines. 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-ordering or stock piling. 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 to GP practices and the NHS.

GP practices should normally have no more than two to four weeks supply of vaccines at any time. 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 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 regularly.

3.5 Transport of vaccines to outlying clinics and domiciliary visits

Vaccines requiring refrigeration should be transported to 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. Validated cool boxes should be used in accordance with the manufacturer's instructions to ensure the correct storage of vaccines. 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.

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

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. 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 manufacturers 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 and disposed of in accordance with local pharmaceutical waste policy arrangements.

4. Storage of Vaccines and the Vaccine Refrigerator

4.1 General requirements

Vaccines 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, designed to provide a stable, uniform and controlled temperature throughout the unit.

Vaccines should not be stored within a domestic refrigerator as this equipment not designed for the storage of vaccines, does not have accurate temperature controlling systems, can have significant temperature variation across the unit and the temperature varies significantly every time the door is opened.

To support decisions concerning procurement of pharmaceutical refrigerators a specification for a refrigerator suitable for storage of vaccines is laid out in appendix 2.

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.

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. 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.

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.

Vaccine stock should be arranged systematically so that any member of staff looking for a product can determine quickly whether that product is available in the refrigerator. It is good practice to post a list of products stored in the refrigerator with a shelf location (as appropriate) on the outside of the door. This will minimise the amount of time the refrigerator door is open.

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/fused spur 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 defrost and/or clean the refrigerator or 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 cut, refrigerator doors should be kept closed and the temperature monitored until either the supply is reinstated or alternative arrangements for storage can be made. 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.

4.5 Placement of refrigerator

Refrigerators should be placed in an area where the ambient room temperature is in accordance with the operating conditions recommended by the refrigerator manufacturer. 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 location and hence preformance 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 Defrosting and cleaning

If the vaccine refrigerator is not of the type that has an automatic defrosting cycle then it should be regularly defrosted in line with the refrigerator manufacturer's recommendations.

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 defrosting or cleaning has been carried out should be made.

Vaccines should be transferred to another pharmaceutical refrigerator with appropriate monitoring of temperatures or validated cool box, during the defrosting or cleaning.

Any spillage of vaccines should be dealt with in accordance with NHS board waste management policy.

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 temperature record for that refrigerator.

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 temperature record should also contain date at which the refrigerator was used for the first time.

5. Monitoring Vaccine Refrigerator Performance and Storage Conditions

5.1 The refrigerator thermometer

The vaccine refrigerator should be continually monitored to ensure the temperature remains within the specified range of +2°C to +8°C. This should be carried out using a calibrated maximum/minimum digital thermometer that will allow the recording of current temperature along with the highest and lowest temperatures over a period of time. Ideally the digital thermometer will be able to record temperatures to one decimal place.

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 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.

When a new vaccine refrigerator or a calibrated maximum/minimum digital thermometer is being procured the thermometer should be independent of mains power, so temperatures can be measured in the event of electricity loss.

All digital maximum/minimum thermometers should:

- be read from the outside of the refrigerator without opening the door
- have an accuracy of at least +/- 1°C
- be supplied with a calibration certificate if available
- have the calibration checked on an annual basis.

5.2 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 type of maximum/minimum thermometer used in the practice/clinic/unit.

In all areas where vaccines are stored there should be a procedure for daily recording of refrigerator temperatures. A specimen standard operating procedure for monitoring refrigerator performance is attached at appendix 3. A copy of this procedure should be kept beside the refrigerator and be readily available for reference.

The current, maximum and minimum temperatures should be monitored and recorded legibly at least once each working days. 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 4. 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. The use of whiteboards

as a method of logging results is not acceptable. 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 temperature at a similar time each day e.g. first thing in the morning before the refrigerator door is opened for the first time. 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.

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

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, cleaned or defrosted. 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 defrosting 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.

The individual checking the temperature should sign the recording sheet.

The main vaccine supervisor can delegate the monitoring of refrigerator temperatures to other staff, but should ensure that staff undertaking this task understand all aspects of the process. This can be facilitated by using the 'four Rs':

Read: daily reading of the thermometer's maximum, minimum and current temperatures at least once 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.

5.3 Retention of temperature records

Retention of records under the NHS Code of Practice (Scotland) is governed by Scottish Government Records Management: NHS Code of Practice (Scotland) version 2.1, January 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.

5.4 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 checks suggest the thermometer is faulty, 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 informed
- 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
- defrosting
- unplugging of refrigerator from power socket or other loss of power
- malfunction or failure of the refrigerator or thermometer
- frosting up of probe.

If there are any concerns about the storage of the vaccine and subsequent viability, the suspect stock should be quarantined but kept within a suitable pharmaceutical refrigerator. 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 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 check list 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 have been 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, batch numbers, expiry dates, quantity.
- Discuss with the designated contact in the NHS board to request assessment of 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 to be delivered problem.
- Document all action.

Appendix 1: Vaccine Storage and Handling Specimen Self Audit Tool

The purpose of this audit tool is to provide a checklist to allow the designated vaccine supervisor or their deputy to undertake a self audit of the arrangements for the storage and handing of vaccines in any areas where vaccines are stored in order to identify areas where improvement is necessary.

A separate form should be used for each refrigerator used to store vaccines.

Any areas of concern should be discussed with the manager in charge of the practice/clinic or department.

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	
Date of audit	

Location of refrigerator	
Refrigerator Identification Number	
Manufacturer/Model/Serial Number	
Approximate age (years)	

Section 1 People

There is evidence that:	**Yes**	**No**	**Comment**
there is a designated person in charge of monitoring the storage and handling of vaccines			
there is a named deputy for the designated person			
all staff involved with the handling of vaccines have been trained appropriately in maintenance of the cold chain			
all staff involved with recording of daily temperatures are familiar with the operation of max/min thermometers			

Section 2 Equipment

General requirements of vaccine refrigerator	Yes	No	Comment
There is evidence that:			
a pharmaceutical refrigerator is used to store vaccines			
the refrigerator is locked when not in use or within a room that is locked when not occupied			
the refrigerator is only used for storage of vaccines and medicines			
no more than two thirds of the internal volume is used to store vaccines			
there are no vaccines stored in the door of the refrigerator			
there are no vaccines stored in enclosed plastic trays at bottom of refrigerator			
the stock is arranged systematically within the refrigerator so that any member of staff looking for a product can determine quickly whether that product is available in the refrigerator.			
the refrigerator is hard wired or all plugs are clearly marked 'refrigerator: do not switch off			
the refrigerator is situated away from heat sources			
the refrigerator is situated away from direct sunlight			
the refrigerators is in an area where the ambient room temperature is in accordance with the operating conditions recommended by the refrigerator manufacturer			
there is adequate ventilation space around the refrigerator			
the refrigerator has an auto defrost function or for refrigerators which do not have an auto defrost that the refrigerator is defrosted in accordance with manufacturer's advice			
the refrigerator is cleaned regularly			

The refrigerator thermometer	Yes	No	Comment
There is evidence that:			
the thermometer is digital			
the thermometer can record current, maximum and minimum temperature			
the thermometer is integrated into the fridge with a digital display			
the thermometer is independent of mains power (i.e. has battery back up)			
in case of independent Max/Min digital thermometer the probe is placed in middle of the refrigerator			
the calibration is checked on an annual basis			

Daily temperature recording	Yes	No	Comment
There is evidence that:			
a separate record is used for each refrigerator			
the current, maximum and minimum temperature has been recorded at least daily on working days			
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			
the designated person has reviewed the temperature records on a monthly basis			
any readings outwith the recommended range have resulted in action to resolve the issue			
information about activity such as defrosting etc that may affect temperature is recorded			
temperature records are retained in accordance with guidance			

Section 3 Procedures

There is evidence that:	Yes	No	Comment
all staff have access to NHS board guidance/policy for handling/ storage of vaccines			
there are procedures for ordering vaccines			
there are procedures for receipt of vaccines			
there are procedures for rotation of vaccine stock and checking expiry dates			
there are procedures for daily temperature recording			
there are procedures for action to be taken following recording of temperatures out with recommended range			
there are contingency plans in place in the event of equipment failure			

Appendix 2: 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)
- Transparent door
- Internal illumination
- Wall mounting brackets (for small vaccine refrigerators)
- More sophisticated continuous temperature recording devices

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.

Appendix 3: 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	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 log book is required for each appliance).
2) At least once each day, preferably at the start of the day, 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.– 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 daily temperatures have been recorded, the maximum/minimum thermometer should be reset following the manufacturer's instructions.

Appendix 4: Specimen Temperature Recording 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 temp (+2°C to +8°C)**	**Minimum temp (+2°C to +8°C)**	**Maximum temp (+2°C to +8°C)**	**Note factors which may affect refrigerator performance**	**Max/min. thermometer memory cleared and checked (initial)**	**Signature**
		5.1°C	3.4°C	7.2°C	Tidying stock	AN	A Nurse
1st							
2nd							
3rd							
4th							
5th							
6th							
7th							
8th							
9th							
10th							
11th							
12th							
13th							
14th							
15th							
16th							
17th							
18th							
19th							
20th							
21st							
22nd							
23rd							
24th							
25th							
26th							
27th							
28th							
29th							
30th							
31st							

RECORDINGS FOR MONTH REVIEWED: **Date:** **Signature:**