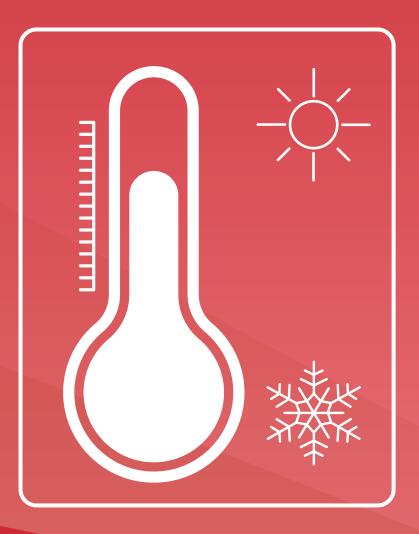
Vaccine Transport and Storage Policy - July 2017

AN INFORMATION POLICY FOR HEALTHCARE PROFESSIONALS

HEALTH PROTECTION





Contents

1. Introduct	tion	3
2. Indepen	dent contractors	3
3. Training	requirements	3
4. Ordering	g and monitoring of vaccine stock	3
5. Receipt a	and storage of vaccines	4
6. Vaccine i	refrigerators and maintenance	5
7. Tempera	ture monitoring	6
	t and storage of vaccines prior to administration in outlying schools	6
	t and storage of vaccines prior to administration in patients'	7
10. Use and	disposal of vaccines	7
	be taken following recording of temperatures found to be he recommended range	7
	re for dealing with an accidental and temporary disconnectio	
13. Audit red	quirements	8
Appendices		
Appendix 1	Suggested vaccine stock control log	9
Appendix 2	Suggested refrigerator temperture audit record sheet	11
Appendix 3	Cold chain audit tool and report	13
Appendix 4	Sample: Manufacturer's instructions for use of a vaccine porter	18
Appendix 5	Guidance - correct storage and monitoring of temperature sensitive drugs	19
References a	nd useful links	20

1. Introduction

This policy applies to all staff involved in all stages of the immunisation process.

Vaccines are both sensitive biological substances and Prescription Only Medicines (POM's).

Any vaccine stored outside the temperature range specified by the manufacturer is outside its licence. Manufacturer advice is required for potential 'off-label' use.

This policy aims to ensure that vaccines are stored and managed properly so that immunisation is carried out safely and efficiently.

Professionals responsible for vaccination will be able to use the policy to audit adherence to the standards in the document, thereby having confidence that they have reduced the risk of compromising the quality, efficiency and safety of the vaccine programme.

The main elements of this policy are:

- ordering and delivery
- restrictions on the use of centrally purchased vaccines
- storage
- maintenance of the cold chain
- auditing and monitoring of stock
- incident reporting

Every member of Department of Health and Social Care (DHSC) staff dealing with vaccines need to appropriately manage the cold chain. In addition, Managers need to regularly review the use, maintenance and management of equipment used for the transport and storage of vaccines.

2. Independent Contractors

All Independent Contractors are wholly responsible for the management of risks within their Practice. To support Independent Contractors in satisfying this duty the DHSC urges full compliance with the DHSC's governance policies and procedures.

3. Training requirements

Maintenance of the cold chain forms part of all immunisation training and updates. All staff dealing with vaccines should attend training annually.

Managers of General Practices or Pharmacies need to ensure that staff who receive vaccine deliveries and/or monitor refrigerator temperatures are adequately trained and understand the importance of not breaching the cold chain, but, more importantly, what to do if there is a breach.

4. Ordering and monitoring of vaccine stock

GP Practices should have no more than two to four weeks' supply (excluding influenza vaccine) of vaccines at any time. This will be sufficient for routine provision.

Excess stock may:

- increase the risk of vaccinations with date-expired vaccines
- increase wastage and cost of disposal by incineration
- increase the dangers of over-packed refrigerators, leading to poor air flow, 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 clinic refrigerators in periods of high demand; for example, during the seasonal influenza vaccination season (Refer to Figure 1)

A stock information system keeps track of orders, expiry dates and running total of vaccines (*Appendix 1*).

'Best practice' is to order small quantities on a regular, scheduled basis, and in sufficient time to ensure that there is an adequate supply for clinics.

Checks should be made at least once a week as stock needs to be properly rotated - shortest expiry date used first.

Remove any expired vaccines (there should be none) and discard in appropriate waste stream.

Mark clearly any vaccine returned to the refrigerator with the date and time of its return and place it at the front of the refrigerator so that it is used first at the next session - this should only be done with vaccines that have remained in the cold chain.

At least two named, people must be nominated for ordering, receipt and care of vaccines (suggest: one from the Nursing Team and one from Administration). All members of the Primary Care Team should be aware of the importance of good vaccine management.

Centrally purchased vaccines for routine immunisation programmes are ordered and delivered via Immform and should only be used for approved purposes. If centrally purchased stock is used for a purpose not authorised by the Department of Health and Social Care (DHSC), it should be replaced by privately purchasing the equivalent amount of stock. Failure to do this may constitute fraud or theft (Green Book updated 12 March 2013).

(DOH: Immunisation against Infectious Disease 2013)

5. Receipt and storage of vaccines

Vaccines must be unpacked immediately upon receipt - check that there are no leakages, damage or discrepancies in the delivered vaccines.

Vaccines should be placed in their original packaging in the main body of a designated vaccine refrigerator (not in drawers) at a suitable temperature, maintaining the cold chain at all stages.

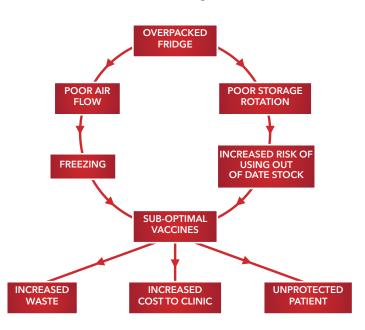
The date and time at which the vaccine was received should be entered onto a vaccine stock control log.

- Vaccines received which have been dispatched on the previous day should not be accepted unless delivered via validated refrigerated transport
- Air should be able to circulate around the boxes and between the shelves (refer to Figures 1 and 2)
- Vaccines must not be allowed to freeze

 freezing vaccines causes deterioration

 and can give rise to increased adverse reactions by:
 - irreversibly denaturing the proteins in the vaccines
 - reducing the efficacy of the vaccines
 - causing the emulsions in the vaccines to become unstable producing hairline cracks in the ampoule/vial/pre-filled syringe, potentially contaminating the contents. The glass spicules (small sharp pointed fragments) produced may also cause serious local adverse reactions
- When the refrigerator is being defrosted the vaccines should be transferred to another refrigerator or placed in a cool-box with suitable packaging

Risk of vaccine excess: Figure 1



6. Vaccine refrigerators and maintenance

A validated refrigerator must:

- be suitable for the storage of vaccines between +2°C and +8°C, a mid-range of +5°C is good practice
- be lockable, or stored in a room that is locked when not occupied by a member of staff
- be of the larder type (with no freezer compartment) large enough to hold the stock and allow sufficient space around the vaccine packages for air to circulate. It is recommended that the refrigerator is no more than 50% full to enable good air flow (Figure 2)
- have a maximum-minimum thermometer

 all refrigerators should ideally have

 two max/min thermometers, with one independent of mains power. If only one max/min thermometer is used, then a

- monthly check should be carried out to confirm that the calibration is accurate.
- Care should be taken to ensure that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the permitted range
- be dedicated to the use of vaccines food, drink and specimens must not be stored in the refrigerator
- be regularly maintained and records kept of this maintenance - managers should ensure that there is a maintenance contract that allows for at least yearly servicing and calibration of temperature gauges
- fridges should be cleaned as per manufacturers guidance.
- be wired into switchless sockets to avoid them being turned off accidentally - if this is not possible, a warning sign should be placed on the plug

Vaccine storage: Figure 2

- X No food or medical specimens
- X Do not place fridge in direct sunlight or near heat source
- X Do not remove vaccines from original boxes until ready to use
- X Do not store vaccines in fridge doors or in solid plastic trays/ containers within the fridge
- X Keep vaccines away from fridge walls and cold air vents



- ✓ Use a dedicated vaccine fridge
- ✓ Safeguard electricity supply
- ✓ No more than 50% full
- Place vaccines in clearly labelled plastic mesh baskets
- Group vaccines by type (Paediatric, Adult, Adolescent)
- ✓ Defrost/calibrate fridge regularly
- Ensure back up facilities are available in the event of fridge failing
- Be cleaned and defrosted regularly (if necessary) and records kept of these procedures
- Be situated away from a radiator or any other heat source that could affect their performance and should be appropriately ventilated
- ✓ Have the opening of its door kept to a minimum

7. Temperature monitoring

Named staff can delegate refrigerator monitoring 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, record, reset and react:

Read: daily reading of the thermometer's maximum, minimum and current temperatures at the same time every day during the working week.

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

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

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

Note: Unless there is manufacturer stability data supporting storage for vaccines outside of the +2°C to +8°C range, the DHSC advises that any vaccine that has not been stored as per its licensing conditions (contained in the Summary of Product Characteristics - SPC) is no longer a licensed product and should not be used.

8. Transport and storage of vaccines prior to administration in outlying clinics/schools

- A validated rigid-type medical grade cool-box and cool-packs should be used for transporting vaccines. Choose appropriate sizes of cool-box for the amount of vaccine needed
- Take only enough vaccines for a particular session and minimise exposure of the vaccines to room temperatures

- Cool-boxes should only be packed immediately prior to dispatch
- Vaccines must be kept in the original packaging, wrapped in bubble wrap (or similar insulation material) and placed into a cool-box with cool-packs as recommended by the manufacturer's instructions (Appendix 4)
- Open/Disturb box as little as possible to help maintain temperature
- If a refrigerator is not available at a vaccination site, the vaccines must be stored in the cool-box until used
- Everyone involved in the use of the transport boxes needs to be familiar with and adhere to the manufacturer's instructions
- Cool-boxes should be transported in the boots of healthcare workers' cars, not on car seats
- Mark vaccines removed for an external session before returning them to the refrigerator and then use them at the earliest opportunity

Transport and storage of vaccines prior to administration in patients' homes

This section is designed to provide for the safe administration of flu vaccines by the District Nursing Service. The only exception to the section about transport and storage of vaccines prior to administration in outlying clinics and schools is:

The manufacturer's Stability Data
Sheet for each seasonal flu vaccine is
to be obtained annually to support
the transport of vaccines outside of
the +2°C to +8°C range with the aim
of reducing vaccine wastage. If the
vaccine manufacturer will only give this

information following a breach of cold chain, as opposed to proactively, then the vaccine must be transported strictly as in Section 8.

Note: Heat speeds up the decline in potency in most vaccines, therefore reducing the shelf-life. In some cases the vaccines can be stored/transported above +8°C and used safely as long as the information in the Stability Data Sheet is applied appropriately.

10. Use and disposal of vaccines

- The minimum amount of vaccines necessary should be dispatched to the point of use
- The minimum amount of vaccines necessary on any one occasion should be removed from the refrigerator or coolbox - further visits to the refrigerator or cool-box may be necessary during the vaccination session
- Vaccines should be reconstituted in accordance with the manufacturer's instructions
- At the end of the session, opened ampoules, vials and pre-filled syringes should be placed in the appropriate sharps container for incineration
- At the end of the session, unused vaccines which have NOT been removed from the cool-box should be returned on the same day to the refrigerator and marked 'use first'. Such vaccines should not be recycled in this way a second time
- Unused vaccines which have date-expired should be disposed of as special waste. This means either returning them to the supplying pharmacy or manufacturer, or as special waste via Noble's Pharmacy, or as special waste via the Hospital's Porter Collection Service

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

Your local procedure should be available to describe the actions that should be taken in

the event of the temperature going outside the recommended range ($+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$). The designated member of staff for vaccine supervision or their on-duty deputy should be informed and a note of any action taken or comments on temperatures outside the $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ 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 drug manufacturer.

A system of notifying local staff with responsibility for vaccines should be in place.

An incident/record form should be completed using procedures for incident reporting.

Where incidents occur within a general practice setting, Independent Contractors and their staff should be encouraged to use 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 nominated vaccine staff member or their deputy and/or the appropriate Manager
- The cause should be immediately investigated and where possible the problem should be rectified
- Establish the exact period of temperature deviation (if a data logger system is used, download the recent fridge reading or use proper paper records of min/max temperatures)
- Place affected stock into quarantine but keep stock in refrigerator/cold chain
- Record details of products that are affected; vaccine name, batch numbers, expiry dates, quantity
- Discuss with the vaccine manufacturer to assess whether stock can be used
- Note, if the cold chain cannot be guaranteed for vaccines that have been administered to patients, it is likely that those patients will need to be recalled to receive repeat vaccinations
- Ensure action is taken to prevent/reduce risk of recurrence of the problem
- Inform the Health Protection Team, Public Health Directorate
- Document all action.

12. Procedure for dealing with an accidental and temporary disconnection of the electricity supply

- Note the current refrigerator temperature
- If inside the range +2°C to +8°C, reconnect the power supply - no further action is required
- If outside the range +2°C to +8°C, reconnect the power supply, taking note

- of the time at which you do this. Try to establish how long the vaccines may have been outside the range and check for any previous breaks in the cold chain
- Establish the number and type of vaccines in stock in the refrigerator and contact one of the people mentioned in Section 11 above for advice

13. Audit requirements

The following audits are required:

- **Every week:** Refrigerator contents should be checked at least once
- **Every month:** Vaccine stock should be audited and recorded
- Every three months: Audit records of stock and cold chain

An audit of the cold chain (Appendix 3) is to be submitted to the Health Protection Nurse, Public Health Directorate every 3 months. An anonymised report will be produced and distributed to Family Practitioners Services/GP Practices. The codes used will correspond with immunisation uptake reports issued by Family Practitioner Services.

The Public Health Directorate will undertake an annual external audit.

(Use a separate sheet for each vaccine brand)

Vaccine Name

	Initials and comments							
č	Stock balance							
Number	(to be marked use first')							
Number	or vaccines wasted							
Quantity	and to whom							
Quantity	in stock before delivery							
	Expiry Date							
Vaccine	Batch or Lot Number							
	Date and Time transferred to refrigerator							
Vaccine Check	(leakages, damage, discrepancies)							
Date	and Time Received							

Suggested vaccine stock control log

(Use a separate sheet for each vaccine brand)

Vaccine Name

	Initials and comments							
	Stock balance							
Number	(to be marked 'use first')							
Number	or vaccines wasted							
Quantity	ssued and to whom							
Quantity	in stock before delivery							
	Expiry Date							
Vaccine	Batch or Lot Number							
	Date and Time transferred to refrigerator							
Vaccine Check	(leakages, damage, discrepancies)							
Date	and Time Received							

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Cold chain audit tool and report

Inspe	Inspection Date: Auditor:										
Practi	Practice / Venue:										
No.	Questions		Answer								
1.	Does the Practice have a written procedure which be taken in the event of the vaccine being store		Yes No								
Comr	ments:										
2.	Does everyone in the Practice have access to th conversant with the content?	e Policy and are they	Yes No								
Comr	ments:										
3.	Confirm the name of two nominated people res	sponsible	Yes No								
	Name 1: Name 2:										
4.	Is there a designated deputy to cover for the resolvent of vaccines in times of absence?	sponsible safe storage	Yes No								
Comr	ments:										
5.	Are the procedures for the receipt, checking an of vaccines being followed?	d immediate refrigeration	Yes No								
Comr	ments:										
6.	Is there a file which is kept up-to-date with infor delivery of vaccine stock and records of temper		Yes No								
Comr	ments:										
7.	Is the vaccine transported from the supplier in a container?	validated insulated	Yes No								
Comr	ments:										

No.	Questions	Answer
8.	Are vaccines transported to and stored in outlying clinics/schools/clinic rooms within the Practice in a validated insulated container?	Yes No Not applicable
Comr	nents:	
9.	When you use a validated insulated container, do you adhere to the manufacturer's instructions to ensure that these are being used appropriately?	Yes No Not applicable
Comr	nents:	
1st Fric	dge	
Refrig	erator Location: (please identify and audit each refrigerator)	
1.	Is a medical refrigerator in use? - (A domestic refrigerator is not acceptable as the temperature cycles between -1.5°C and +4°C).	Yes No
2.	Are there safeguards to prevent the refrigerator accidentally being switched off?	Yes No
3.	Is the refrigerator packed correctly? Not more than 50% full and items away from refrigerator walls and cold air vents.	Yes No
4.	Are the vaccines in their original packaging? (They should not be stored in solid plastic trays/containers within the refrigerator).	Yes No
5.	Does the refrigerator have only medical products? That is, no food, drinks, specimens.	Yes No
6.	Is an externally-situated maximum/minimum thermometer present? (irrespective of whether the refrigerator incorporates a temperature indicator). The sensor should be in the centre of the refrigerator.	Yes No
If no p	please explain:	
7.	Are the temperature ranges documented at least daily?	Yes No
8.	Is there an alternative refrigerator or validated insulated container for use during defrosting to ensure that the temperature of vaccines does not exceed the range as specified in the manufacturer's SPCs?	Yes No
9.	Is there evidence of stock rotation?	Yes No
10.	Is there an appropriate maintenance contract in place for the refrigerator and temperature gauges?	Yes No
11.	Are there records of regular: servicing, calibration, cleaning and defrosting?	Yes No

2nd Fridge

Refrig	erator Location: (please identify and audit each refrigerator)	
1.	Is a medical refrigerator in use? - (A domestic refrigerator is not acceptable as the temperature cycles between -1.5°C and +4°C).	Yes No
2.	Are there safeguards to prevent the refrigerator accidentally being switched off?	Yes No
3.	Is the refrigerator packed correctly? Not more than 50% full and items away from refrigerator walls and cold air vents.	Yes No
4.	Are the vaccines in their original packaging? (They should not be stored in solid plastic trays/containers within the refrigerator).	Yes No
5.	Does the refrigerator have only medical products? That is, no food, drinks, specimens.	Yes No
6.	Is an externally-situated maximum/minimum thermometer present? (irrespective of whether the refrigerator incorporates a temperature indicator). The sensor should be in the centre of the refrigerator.	Yes No
If no p	please explain:	
7.	Are the temperature ranges documented at least daily?	Yes No
8.	Is there an alternative refrigerator or validated insulated container for use during defrosting to ensure that the temperature of vaccines does not exceed the range as specified in the manufacturer's SPCs?	Yes No
9.	Is there evidence of stock rotation?	Yes No
10.	Is there an appropriate maintenance contract in place for the refrigerator and temperature gauges?	Yes No
11.	Are there records of regular: servicing, calibration, cleaning and defrosting?	Yes No

3rd Fridge

Refrig	gerator Location: (please identify and audit each refrigerator)	
1.	Is a medical refrigerator in use? - (A domestic refrigerator is not acceptable as the temperature cycles between -1.5°C and +4°C).	Yes No
2.	Are there safeguards to prevent the refrigerator accidentally being switched off?	Yes No
3.	Is the refrigerator packed correctly? Not more than 50% full and items away from refrigerator walls and cold air vents.	Yes No
4.	Are the vaccines in their original packaging? (They should not be stored in solid plastic trays/containers within the refrigerator).	Yes No
5.	Does the refrigerator have only medical products? That is, no food, drinks, specimens.	Yes No
6.	Is an externally-situated maximum/minimum thermometer present? (irrespective of whether the refrigerator incorporates a temperature indicator). The sensor should be in the centre of the refrigerator.	Yes No
If no p	please explain:	
7.	Are the temperature ranges documented at least daily?	Yes No
8.	Is there an alternative refrigerator or validated insulated container for use during defrosting to ensure that the temperature of vaccines does not exceed the range as specified in the manufacturer's SPCs?	Yes No
9.	Is there evidence of stock rotation?	Yes No
10.	Is there an appropriate maintenance contract in place for the refrigerator and temperature gauges?	Yes No
11.	Are there records of regular: servicing, calibration, cleaning and defrosting?	Yes No

If more than three fridges, please copy the above and continue auditing the other fridges.

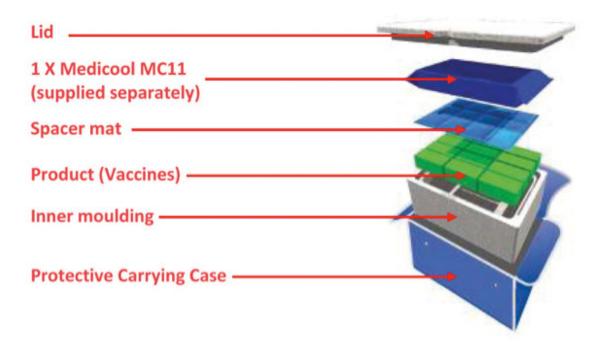
Cold chain report

Inspection Date:	Auditor:	
Practice / Venue:		
Audit result:		
Identified areas in need of improvement:		
Resources required:		
Agreed plan of action:		
Agreed plan of detion.		
Re-audit date:		
Total number of Yes responses on form		
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Total number of questions completed		
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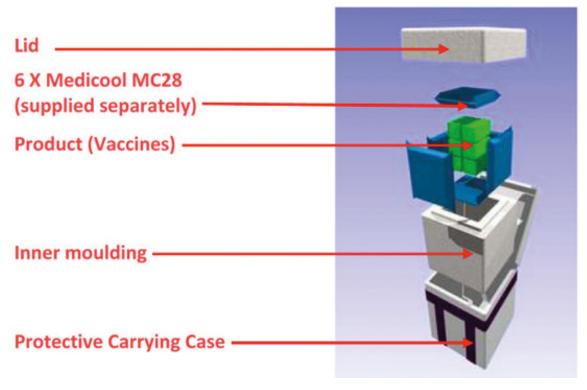
Sample: Manufacturer's instructions for use of a vaccine porter

Helapet offer a comprehensive range of fully validated VaccinePorter® Carrier Systems, for the controlled transit of vaccines that require storage between +2°C and +8°C. https://www.helapet.co.uk/catalog/product.php?Cl_ID=355

Mini vaccine porter



Vaccine porter 9



Images taken from Clinimed instruction manuals

Guidance - correct storage and monitoring of temperature sensitive drugs

Check the storage conditions of each drug/vaccine or other product that you store - this information should be on the patient information leaflet or can be found on the electronic Medicines Compendium in section 6 of the Summary of Products Characteristics (SPC). If the products are not stored according to the manufacturer's SPC, the product becomes unlicensed. If you use it and there is an adverse event, the prescriber and the person administering the drug/vaccine are personally accountable. The manufacturer will not indemnify the product unless you can prove that the product has been stored strictly to the licensing requirements.

Top tips:

- Ensure that the electricity supply cannot accidentally be disrupted
- The fridge should not be placed in direct sunlight or near a heat source
- The fridge needs to be less than 50% full so that air can circulate freely
- Keep in original packaging until ready to use
- If you need to segregate types of drugs/vaccines use a basket, not a solid tray
- Food and samples should not be stored in a drug fridge
- Products must not touch the sides or back or be placed on the bottom of the fridge and should be away from cold air vents
- Do not store in door compartments if present
- Make checks at least once a week to rotate stock so that products with the shortest expiry date are easily accessible and used first
- A battery operated thermometer needs to be situated on the outside of the fridge with the probe in the centre of the fridge - make sure that the thermometer probe cable does not interfere with the door seal, causing the temperature to fall outside the permitted range
- Read and record the actual, minimum and maximum temperatures twice a day using the standardised recording form
- ALWAYS clear the memory/reset the thermometer after each recording
- If the fridge door is open for any length of time the temperature will rise temporarily return to the fridge after about 10 to 20 minutes and reset the thermometer once the actual temperature has settled within the 2°C to 8°C range. If you do not do this at the next routine temperature recording time you will be recording a high maximum temperature that is not a significant harm to the products
- If your recordings are not within the 2°C to 8°C range (and this is not because of the situation described above) you must alert your Line Manager or other person in charge and an investigation needs to be undertaken. The event needs to be recorded as an untoward incident. Do not use any of the products until the manufacturer advises that it is safe to do so or reorder new supplies accordingly.

Remember: READ, RECORD, RESET, REACT

References and Useful Links

Storage, distribution and disposal of vaccines: The Green Book, chapter 3

https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Protocol for ordering, storing and handling vaccines

https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

Vaccine incident guidance: responding to vaccine errors

https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

Vaccines stored outside the recommended temperature range: leaflet

https://www.gov.uk/government/publications/vaccines-stored-outside-the-recommended-temperature-range-leaflet

National Patient Safety Agency advice on vaccine cold storage

http://www.nrls.npsa.nhs.uk/alerts/?entryid45=66111

Keep your vaccines healthy: poster

https://www.gov.uk/government/publications/keep-your-vaccines-healthy-poster

The Policy should be known and used by staff dealing with vaccines. It has been updated to depersonalise data, reflect the Green Book (27/06/16) and to provide useful current links.

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The information in this leaflet can be provided in large format or in audio format on request



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