Lincolnshire Community Health Services NHS Trust

Maintaining the Cold Chain: The control and monitoring of storage temperatures of medicinal products

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Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/ Amended by
1	All	New document	November 2013	C Day
2	Appendix E	Replaced with current Equality Analysis	March 2015	L Roberts
2.1		Extended	May 2017	L Roberts
2.2		Extended	Feb 2018	Corporate Assurance Team
3	Throughout	Updated policy template Update terminology. Replace 'pharmaceutical' with 'medicines management'.	June 2017	L Adlington
	Section 11 and Throughout	References updated.		
	Section 4	Highlight need for designated person		
	Section 5	Updated guidance re domestic fridges		
	Section 7	Updated guidance re storage conditions		
	Section 8	Updated guidance re transport containers		
	Section 9	Additional advice regarding cold chain breach		
	Section 10	New section - disposal		
	Appendix A / B	Revised and updated		
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Lincolnshire Community Health Services NHS Trust

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Guidance Statement

Background	The purpose of this guidance is to implement a co-ordinated approach for the transportation and storage of medicinal products which requiring refrigeration on LCHS premises.
Statement	This guidance is comprehensive, formally approved and ratified, and disseminated through approved channels. It will be implemented for Lincolnshire Community Health Services NHS Trust.
Responsibilities	Compliance with the guidance will be the responsibility of all Trust employed clinical staff.
Training	Support and guidance can be offered by the Medicines Management Team for the Trust.
Dissemination	Via Website.
Resource implication	This guidance has been developed in line with the NHS Litigation Authority and current Department of Health guidelines to provide a framework for staff within NHS Organisations to ensure the appropriate production, management and review of organisation-wide policies.

Maintaining the Cold Chain:
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1. Introduction

This document details the requirements for cold chain maintenance for Lincolnshire Community Health Services NHS Trust (hereafter referred to as the Trust) employees. This guidance should also be read in conjunction with the Department of Health's 'Immunisation against Infectious Diseases' 2013 (The Green Book), the Trust Safe and Secure Handling of Medicines Policy, appropriate Patient Group Directions and manufacturer Summary of Product Characteristics (SPC).

Medicinal products should be stored and transported under conditions which ensure that their quality is maintained. Maintenance of the cold chain is required for both the storage and transportation of some medicinal products.

There are an increasing number of medicinal products requiring controlled storage and transit conditions. Among the cold-chain items are high-risk products such as vaccines, insulins, blood products and other proteinaceous materials, which normally require storage between 2ºC and 8ºC. These products must be protected from freezing; even a brief period at sub-zero temperatures may irreversibly denature the protein, leading to a loss of efficacy. There are also products such as emulsion systems and solutions of sparingly soluble components which may become physically unstable at sub-zero temperatures.

At every point in the chain precautions should be taken to minimise the effect of adverse external conditions on the quality and stability of that product. Where relevant, records should be maintained to provide evidence of compliance with the labelled storage recommendations for those in whose care the product is at the time and to other interested parties who may seek this assurance, such as the recipient and/or marketing authorisation holder.

2. Purpose of the guidance

This guideline aims to:

- Ensure that heat labile medicinal products are stored handled in a safe and appropriate manner.
- Ensure that appropriate monitoring processes are in place.

3. Key personnel responsibilities

3.1 Managers

Managers must ensure that:

- Staff are aware of, have access to and comply with the guidance.
- The manager of each clinic/surgery/service should be aware of their responsibilities in ensuring that they understand the importance of this policy, including the clinical and financial implications of breaching the cold chain. A sample temperature chart is provided at appendix A and is the preferred organisational recording tool.

3.2 Employees

All employees have a responsibility to abide by this guidance and any decisions arising from the implementation of them.

Any decision to vary from this guidance must be fully documented with the associated rationale stated.

3.3. Medicines Management Team

- Will provide advice and guidance with regard to medicines storage, transportation and disposal.
- Will monitor adverse incidents and audit outcomes.
- Will support review of the guidance where indicated.

4. Audit and assurance

Each site should have a designated person who is responsible for the management of all medicines within the cold chain – this will include ordering, receipt, storage and monitoring.

The manager of each clinic/surgery/service should ensure that the designated person and their deputy receive appropriate Trust Immunisation and Vaccination Training. The details of training attended will be recorded on the ESR for the individual.

Each manager of clinic/surgery/service should audit the procedures in this guideline quarterly. See appendix B for sample of audit. Completed audits are returned to the Medicines Management Team for collation of results, monitoring and review.

5. Pharmaceutical storage and transportation equipment

Ensuring that the equipment used to store the medicines is an essential core component. Goods should be stored and transported in such a way that the minimum/maximum recommended storage temperature is not exceeded.

5.1 Pharmaceutical fridges

Refrigerators are available which are specially designed for the storage of medicinal products and their use is required for all products requiring storage between 2°C and 8°C.

5.2 Domestic fridges

Domestic refrigerators should not be used for medicines storage because they may not have the precise electronic control necessary to maintain the temperature within the required range.

5.3 Freezers

A small number of products must be stored frozen. These will be labelled store below -5º (freeze) or below -15º (deep freeze) or they may show a range (e.g. -15º to -20º).
Storage units must be capable of maintaining the required temperature in all parts of the load, and load temperatures should be monitored and recorded daily in line with appendix A. The units should be routinely maintained and temperature probes calibrated.

6. Temperature monitoring

The refrigerator must be capable of maintaining the temperature of its contents between 2°C and 8°C with the minimum of intervention. Temperature monitoring should be by electronic max/min thermometer, with an accuracy of + 0.5°C, which should where possible be readable from outside the refrigerator. It is advised that the thermometer has a battery back-up (if mains powered) so that it will continue to function for 48 hours in the event of a power failure. The probe should be placed within the load (or within a suitable buffer) to record the load rather than the air temperature, and the max/min temperatures should be recorded daily.

The device must be calibrated annually against a certificated thermometer. Records of such should be maintained. The unit should have an auto-defrost facility and the temperature within the unit should not be affected during the defrost cycle. If an alarm is fitted, the correct functioning of the alarm should be checked annually at the high and low set points. It is preferred that a power failure alarm be fitted and that the thermostat which controls the chiller unit should fail safe - i.e. the temperature does not decrease if the thermostat fails.

Care should be exercised when placing goods in refrigeration units. If they are placed next to, or allowed to come into contact with, the chiller plate or coil, their temperature may fall below the minimum recommended by the manufacturer. This is particularly relevant in the case of high risk products.

Sufficient space should be maintained between the goods and the internal surfaces of the unit to permit adequate air circulation, but if the unit is regularly filled to capacity, the effect on temperature distribution should be investigated.

7. Storage conditions

Most refrigerators will function efficiently in an external environment of between 10°C to 32°C. Ideally the refrigerator will be placed in the clinical room or similar location where the environment is clean, public access can be controlled and where the ambient temperature does not affect the temperature control within the unit i.e. do not site next to a radiator/in front of a window. Ensure adequate air circulation around the back of the fridge.

- The refrigerator must be located inside a locked room not directly accessible to the public.
- Open the fridge as infrequently as necessary.
- Food and specimens must not be stored in a pharmaceutical fridge.
- Vaccines must not be stored in the door, or next to the freezer plate.
- The fridge must not be overfilled.
- The fridge must be regularly defrosted (if not self-defrosting).
- Accidental interruption of the electricity supply should be prevented by using a hardwired socket.
- Records must be maintained with regard to defrosting, servicing, calibration, and maximum/minimum /actual temperatures.
- The internal temperature (maximum/minimum/actual) must be recorded daily (an example form is available at appendix A). The thermometer must be reset after recording.
- Advice should be sought from the Medicines Management team if the temperature falls outside of the required range of 2-8ºC.
- Medicines should be stored in their original containers so that they retain their batch number and expiry date. The packaging also protects the product from light.
- Regular stock checks should be carried out, to include expiry date checks, and recorded.

Advice should be sought immediately from the Medicines Management team if:

• The thermometer is reading a current temperature above 8ºC which has not corrected within an hour.
• The thermometer is reading a maximum temperature above 8ºC when the fridge has not been opened.
• Any temperature reading below 2ºC
• A temperature reading greater than 8ºC at the end or start of a day

An incident should be reported via Datix.

8. Transport containers (for domiciliary visits)

If transportation of heat labile medicinal products is required (e.g. vaccines) a validated cool box/cool bag must be used.

Staff must ensure they carry only the quantity of medicines required based on their perceived usage.

Vaccines should never be stored out of the fridge. Vaccines kept for long periods at high temperatures are rendered ineffective and may develop dangerous toxins. Cumulative exposure to suboptimum storage temperatures reduces potency of the product.

For transportation of small quantities of heat labile medicines (e.g. vaccines) needed for a domiciliary visit the following applies:

- Cool boxes and bags should contain an ice pack to reduce the risk of temperature fluctuations affecting the load. The ice pack should not be stored within a food fridge. The contents of the cool box/bag should be protected from direct contact with the ice pack (e.g. use of insulating material: bubble wrap, polystyrene etc.).

- Medicines should be kept in their original packaging.

- The vaccine and the cool box/bag must be stored at the lowest possible temperature prior to packing and during transportation and be loaded as late as possible before departure to minimise exposure time out of the fridge.

- It is recommended that cool boxes/bags are transported out of public view and in the boot of the vehicle.

- On arrival at the vaccination session, vaccines should be transferred to a refrigerator where available otherwise they must be left in the closed cool box until they are required.

- A maximum and minimum thermometer should be available for each cool bag. The temperature should be recorded each time the bag is used.

- Any vaccine taken on a domiciliary visit and not used must be discarded.

9. Adverse storage incident/ cold chain breach

Medicines that have been taken out of the cold chain may remain stable for a limited period (or even until the manufacturer's expiry date). A decision will need to be made on a case by case basis using

information concerning the product, time out of the cold chain and the storage environment details i.e. temperature range. The above will vary depending on the medicine and therefore this information must be ascertained before returning any medicines back into the refrigerator.

When a cold chain breach has been identified at any level it is important that all the vaccines/medicines exposed to temperatures outside recommended range are labelled and isolated and wherever possible maintained in a functioning monitored fridge.

Vaccines/medicines should not be discarded until directed to do so as they may still be viable.

All staff within the organisation should be advised the fridge is embargoed until further notice, ensuring the vaccines are not used.

The incident should be reported via Datix.

The incident will be notified to the Medicines Management Team who will support any subsequent investigation. Guidance is provided at appendix C with regard to information to be collated.

Other agencies (e.g. Public Health England) may be invited to assist with any subsequent investigations and outcomes related to the cold chain breach.

Where appropriate, medicines that are taken out of the cold chain and subsequently returned back into the refrigerator must be clearly marked specifying how long the medicine spent outside the cold chain (and the expiry date if different from the manufacturer's expiry). This is because any subsequent breach of the cold chain occurring for these medicines may have a cumulative effective which could affect their stability and efficacy.

10. Disposal

All reconstituted and opened single and multi-dose medicines vials must be disposed of by sealing in a puncture – resistant sharps box intended for this purpose, if not used within the manufacturers recommended time period. Disposal bins must be disposed of when two thirds full. Expired medicines must be disposed in the same manner.

Any wastage of vaccine as a result of disruption of the cold chain must be reported to the NHS England Screening and Immunisation Team via the Immunisation Coordinator on 01162 950890. If the vaccine has been ordered from ImmForm then the wasted vaccine needs to also be recorded on the ImmForm site.

11. Bibliography/acknowledgments

Department of Health (2013) Immunisation against Infectious Diseases (The Green Book) Accessed on 16th June, 2017

Guidelines on good distribution practice of medicinal products for human use (94/C 63/03) accessed on 16th June, 2017

Health Protection Agency (2010) Vaccine Incident Guidance accessed on 16th June, 2017

LCHS 2016 Safe and Secure Handling of Medicines Compendium.

NHS England 2015 Policy and procedure for maintaining the vaccine cold chain. https://www.england.nhs.uk/mids-east/wp-content/uploads/sites/7/2015/07/cold-chain.pdf Accessed on 16th June. 2017.

Appendix A **Refrigerator Temperature Record Chart.**

Location / site name…… Month and year…….

Fridges must be monitored on each working day using a digital maximum / minimum thermometer, which also records the actual temperature.

The temperature should be between +2°C and +8°C. If the temperature is outside the recommended range, take appropriate action as indicated within the guidance and complete a Datix incident.

Date	Current temperature	Minimum Temperature	Maximum Temperature	Thermometer reset (date / time)	Escalated if out of recommended range (date / time)	Reading recorded by:
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						
Date defrosted if not an automatic function						

Temperature record sheets must be retained on site for 3 years after completion

Appendix B **Quarterly Cold Chain Audit Tool**

Service area…… Date……..

Standard	Yes	No	N/A	Comments
1. Staff have read the Cold Chain Guideline and understand the requirements for safe storage and transportation				
2. There is a named responsible person that has overall responsibility for the monitoring and storage of heat labile medicines/vaccines				
3. Heat labile medicines are transferred immediately on receipt into a dedicated fridge				
4. The fridge is fit for purpose and is NOT a domestic refrigerator				
5. The fridge is used for the storage of pharmaceutical products ONLY				
6. The refrigerator is hardwired with an uninterrupted electrical supply				
7. The fridge is defrosted at least monthly and process recorded (applicable non-auto defrost units only)				
8. The refrigerator has a maximum and minimum digital thermometer (ideally can be read without opening the door of the unit)				
9. Temperature checks are recorded at least daily and detail actual/max/min temperature readings (except when service not open)				
10. Recorded temperatures are within the 2 - 8°C range				
11. All medicines are in date and expired stock has been removed				
12. Vaccines are not stored in the door or in a separate drawer at the bottom of the fridge				
13. The fridge is not overfull and permits circulation of air around the products				

Standard	Yes	No	N/A	Comment
14. Alternative suitable storage is available in the event of a breakdown or repair of the unit				
15. The domiciliary visit transport containers are of a design approved by the immunisation lead				
16. The transport container has a dedicated maximum/minimum thermometer				
17. Icepacks are available for use with the transport containers				
18. All equipment is clean and functional				

Overall score (yes answers)	
Total 'No' answers	
Percentage (Total number of yes answers) x 100 Total yes/no answers	
The audit will be non-compliant if there is no alternative storage or is not hardwired.	

Name of Auditor **……**

Please retain a copy for your files and send a copy to:

- **Your line manager**
- **Medicines Management Team**
- **Audits are to be reported quarterly through Clinical Goverance and Risk Forums.**

Appendix C

Preliminary Investigation following a Cold Chain Incident

Check list for responding to an adverse storage incident/cold chain breach where vaccines have been given

1. Embargo Fridge

- When a cold chain breach has been identified at any level it is important that all the vaccines exposed to temperatures outside recommended range are labelled and isolated and wherever possible maintained in a functioning monitored fridge.
- Vaccines should not be discarded until directed to do so as they may still be viable.
- All staff within the organisation should be advised the fridge is embargoed until further notice, ensuring the vaccines are not used.
- The incident should be reported via Datix.

2. Confirm and Define the Incident

- The refrigerator temperature records should be checked and the cold chain practice prior to this event discussed with staff to establish if there any explanations for temperature discrepancies? E.g. stock delivery, evidence thermometer was not being re-set, untrained staff monitoring fridge.
- The accuracy of current thermometer/s in use should be confirmed with the supplier if this has not already been done prior to use.
- The general condition of the fridge should be documented. Is it a purpose built vaccine fridge? Are there any obvious signs of freezing? Is it placed in a well ventilated area? Is it used for any other purpose than vaccine storage?
- A check of the fridge service history may give some indication when the fridge was last working properly if the incident is over an extended period of time. No service history may give a concerning indication of how vaccines have been managed prior to this incident.
- The current fridge temperatures should be confirmed and where possible continuous temperature logging using a data logger should be carried out for a 48 hour period to establish temperature patterns of the fridge.

3. Collect as much information as possible

This should include:

- What monitoring has taken place? (max/min/current thermometer readings)
- When was the cold chain last guaranteed?
- What time period(s) are involved? (hours/days/months)
- What is the temperature range during this period?
- Identify all vaccines stored in the fridge, the time they have been stored there, usual stock turn over and expiry dates
- Identify whether vaccine potency is likely to have been affected by the storage conditions identified. (May need to contact vaccine manufacturers).
- Vaccines against the same disease but from different manufacturers must be considered individually.

Depending upon the extent/severity of the incident an incident team may need to be convened.

Appendix D: Auditing and Monitoring

Minimum requirement to be monitored	Process for monitoring e.g. audit	Responsible individuals/ group/ committee	Frequency of monitoring/audit	Responsible individuals/ group/ committee (multidisciplinary) for review of results	Responsible individuals/ group/ committee for development of action plan	Responsible individuals/ group/ committee for monitoring of action plan
The compliance with the maintenance of the cold chain	Self audit of day to day record log	Medicines Management	Annual	Individual service Clinical Governance and Risk Group	Individual service Clinical Governance and Risk Group	Safeguarding and Patient Safety Committee.

Appendix E: Equality Analysis

A.	Briefly give an outline of the key objectives of the policy; what it's intended outcome is and who the intended beneficiaries are expected to be	The purpose of this guidance is to provide guidance on the management of the cold chain In relation to medicines. .		
B.	Does the policy have an impact on patients, carers or staff, or the wider community that we have links with? **Please give details**	Impacts on all LCHS NHS clinical staff		
C.	Is there is any evidence that the policy\service relates to an area with known inequalities? **Please give details**	None Known		
D.	Will/Does the implementation of the policy\service result in different impacts for protected characteristics?			
		Yes	No	
	Disability		x	
	Sexual Orientation		x	
	Sex		x	
	Gender Reassignment		x	
	Race		x	
	Marriage/Civil Partnership		x	
	Maternity/Pregnancy		x	
	Age		x	
	Religion or Belief		x	
	Carers		x	
	If you have answered 'Yes' to any of the questions then you are required to carry out a full Equality Analysis which should be approved by the Equality and Human Rights Lead – please go to section 2			
The above named policy has been considered and does not require a full equality analysis				
Equality Analysis Carried out by:		Lorna Adlington		
Date:		16th June 2017		