Lincolnshire Community Health Services
NHS Trust

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

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Lincolnshire Community Health Services NHS Trust
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Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/ Amended by
G_IPC_34 – Guidance document				
1	All	New document	June 2011	C Day
2	All	Update of formatting and replace "LCHS" with "The Trust"	March 2013	C Day
	Appendix D/E	Insert auditing and equality analysis sections	March 2013	C Day
3	Appendix E	Replaced with current Equality Analysis	March 2015	L Roberts
4	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		
5	Section 3	Update responsibilities	April 2019	Medicines team
	Section 4	Update audit expectations		
	Section 5	Confirm safe / secure storage		
	Section 6	Addition of data logger		
	Section 7	Clarify fridge reset		
	Section 9	Clarify incident reporting / action		
	Appendix B	Revise audit tool		
		Update reference throughout.		
5.1	Section 7	Clarity regarding storage conditions	July 2020	Medicines team
5.1	Section 9	Clarity regarding storage of vaccines during a break in the cold chain, refrigeration breakdown or interruption of electrical supply. Reference to Safe and Secure Handling of Medicines (P-CIG-20)	July 2020	Medicines team
5.1	Section 11	References Updated	July 2020	Medicines team

Change of guideline G_IPC_34 to policy				
1	Section 3	Clarification; IPC team role	April 2021	Sarah Fixter
1	Section 4	Addition; information relating delegation of fridge checking and the 'four Rs'	April 2021	Medicine Team
1	Section 6	Clarification data logger should be in place in all medicines fridges and should be set to record as a minimum 6 hourly New link to purchasing a data logger Records to be kept for five years.	April 2021	Medicine Team
1	Section 7	Addition; Designating areas within the refrigerator for different vaccines so that all staff know where specific vaccines are stored. Glass doors or labels on the outside of fridges can reduce the time the door needs to be open	April 2021	Medicine Team
1	Section 8	Addition; Cool boxes temperatures should be recorded at the start and end of each session	April 2021	Medicine Team
1	Section 9	Addition; Returned vaccines should be used at the earliest opportunity	April 2021	Medicine Team
1	Appendix One	Records to be kept for five years.	April 2021	Medicine Team
1	Appendix Two	Updated to include if temperature shows out of range, evidence of, escalation and actions taken, transport containers to be approved by IPC team	April 2021	Medicine Team

Contents

Section number	Section	Page number
	Version control sheet	
1	Introduction	6
2	Purpose of the guidance	6
3	Key personnel responsibilities 3.1 Managers 3.2 Employees 3.3 Medicines Management Team	6
4	Audit and Assurance	7
5	Pharmaceutical storage and transportation equipment 5.1 Pharmaceutical fridges 5.2 Domestic fridges 5.3 Freezers	8
6	Temperature monitoring	8
7	Storage conditions	9
8	Transport containers (for domiciliary visits)	10
9	Adverse storage incident / cold chain breach	11
10	Disposal	12
11	References	12
	Appendix One – Temperature record chart	13
	Appendix Two – Cold Chain Audit Tool	14
	Appendix Three – Preliminary Investigation for cold chain incidents	15
	Audit and Monitoring	17
	Equality Impact Analysis	18

Lincolnshire Community Health Services NHS Trust

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

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 and has been developed in line with the Department of Health (2014) 'Green Book' and Public Health England (2014) 'Protocol for Ordering, Storing and Handling Vaccines'.
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	No additional training needs identified. Support / advice can be sought from the IPC and Medicines Management (MM) team.
Dissemination	Via Website.
Resource implication	No additional resources required

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

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 and 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:

- All 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.
- Service managers should ensure easy access to a backup fridge, assurance of daily and quarterly monitoring.
- The manager of each clinic/surgery/service should ensure that health professionals administering vaccines receive appropriate Trust Immunisation and Vaccination Training. The details of training attended will be recorded on the ESR for the individual.

- Managers should give consideration to stock levels and the financial impact of a break in the cold chain.

3.2 Employees

- All employees have a responsibility to abide by this guidance and any decisions arising from the implementation of them.
- Completion of daily monitoring and quarterly audit.
- Escalation of breaks to the cold chain and implementation of appropriate actions.
- Have a responsibility to ensure that medicinal items for refrigeration are stored appropriately at all times including on receipt of stock.
- Designated staff are responsible for maintenance of stock levels and stock ordering
- 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.

3.4. Medical devices team / infection prevention team (IPC)

- The medical devices team will provide advice and guidance with regards to the procurement of clinical equipment.
- The IPC team will support the manufactures guidance on the cleaning and maintenance of fridges .

4. Audit and assurance

All staff are responsible for the management of all medicines within the cold chain – this will include storage and monitoring. Monitoring will include the ability to reset the fridge

Designated staff members should be responsible for ordering and receipt of medicines within the cold chain.

All staff are responsible for completion of daily monitoring, weekly downloads of USB data and escalation of any concerns around the cold chain.

Named staff can delegate the monitoring of refrigerator 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 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

Within each clinic/surgery/service all staff have responsibility to ensure that the audit of procedures in this guideline is completed 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.

All fridges and freezers should be cleaned at least monthly during the defrosting process. They should be emptied and cleaned with a neutral detergent solution and left to air dry including all the sides and shelves.
The integrity of all the seals should be also checked if there is a breech in the integrity then the fridge should not be used.

All medicines fridges should be locked and secured within a locked clean room.

5.1 Pharmaceutical fridges

Refrigerators are available which are specially designed for the storage of medicinal products only 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. The data logger should be placed within the load 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 and stored locally for a period of 2 years.

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 good practice 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.

A Refrigeration USB data logger should be in place in all medicines fridges. These should be set to record as a minimum 6 hourly and be downloaded every 7 days. This device will provide secondary information regarding any potential breaks in the cold chain and confirm temperature range over a sustained period of time. Escalation and appropriate action should be taken whenever any break in the cold chain is suspected or evidenced. These devices can be accessed via NHS Supply Chain (https://my.supplychain.nhs.uk) There is no requirement to store this data centrally but it should be saved locally on electronic folders for five years.

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 an environment which 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. For optimal efficiency 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.
- Designating areas within the refrigerator for different vaccines so that all staff know where specific vaccines are stored.
- Glass doors or labels on the outside of fridges can reduce the time the door needs to be open
- 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 - allow space around the packaging for air to circulate.
- The fridge must be maintained and regularly defrosted (if not self-defrosting) in line with the manufacturers' guidelines. Ice should not be allowed to build up as this reduces effectiveness
- As a minimum the fridge should be serviced annually and the temperature gauge calibrated
- Documentation should be maintained to demonstrate regular servicing, defrosting and cleaning
- Accidental interruption of the electricity supply must be prevented by using a hardwired socket.
- Records must be maintained with regard to defrosting (if not self 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 and after any prolonged period of opening.
- 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. As a minimum this should be once per week.

NB. Fridge temperature may momentarily rise above 8^0C after opening the door but should return to 2 – 8^0C within a few minutes. It is therefore important to open the door as little as possible.

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**

All cold chain incidents should be reported via Datix and appropriate action taken.

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;

- Only contain an ice pack to reduce the risk of temperature fluctuations affecting the load x manufacturer's instructions specifically state that ice packs should be used.
- Individual manufacturer's instructions should be strictly adhered to
- The cool box manufacturer should also provide sufficient evidence for assurance that a stable temperature within the range of the cold chain can be maintained for several hours.
- 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.
- A maximum and minimum thermometer should be available for each cool bag. The temperature should be recorded each time the bag is used
- Temperatures should be recorded at the start and end of each session

All transportation fridge / devices should;

- Be recalibrated annually.
- Be at optimum temperatures prior to use.
- 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 all transportation devices (cool boxes/bags/fridges) 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 closed in the chosen transportation device until they are required.

Any vaccine for which a cold chain cannot be assured after a vaccination session should 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 to ensure clear identification and isolated from other vaccines 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.

In the event of refrigeration breakdown or interruption in electricity supply then arrangements must be in place for alternative storage facilities to be made available, service managers should ensure easy access to a backup fridge, with assurance of daily and quarterly monitoring.

The incident should be reported via Datix and appropriate actions taken. Any medicines destroyed must be named within the datix and financial loss detailed.

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). Returned vaccines should be used at the earliest opportunity 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.

Any disruption to the cold chain must be recorded as an incident in accordance with the Organisations incident reporting policy.

Further guidance on monitoring of Vaccine Stock refer to Safe and Secure Handling of Medicine (P-CIG-20)

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 or following six weeks of being in use. 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. References

Department of Health (2014) Immunisation against Infectious Diseases (The Green Book)

Guidelines on good distribution practice of medicinal products for human use (94/C 63/03)

Public Health England (2020) Vaccine Incident Guidance Responding to errors in vaccine storage, handling and administration

LCHS Safe and Secure Handling of Medicines Policy (P-CIG-20).

Nigels Surgery 17: Vaccine storage and fridges in GP practices / CQC.

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.

Public Health England (2014) 'Protocol for Ordering, Storing and Handling Vaccines' accessed via http://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines.

Public Health England (2014) 'ImmForm Helpsheet 18. Fridge failures and stock incidents'

Appendix 1 **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) and action taken	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 and cleaned if not an automatic function.						

Temperature record sheets must be retained on site for 5 years after completion

Appendix 2 **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. A refrigeration USB data logger is in place.				
9. The refrigerator has a maximum and minimum digital thermometer (ideally can be read without opening the door of the unit)				
10. Temperature checks are recorded at least daily and detail actual/max/min temperature readings (except when service not open)				
11. Recorded temperatures are within the 2 - 8°C range				
12.If record of temperature shows out of range, evidence of, escalation and actions taken				
13. All medicines are in date and expired stock has been removed				
14. Vaccines are not stored in the door or in a separate drawer at the bottom of the fridge				
15. The fridge is not overfull and permits circulation of air around the products				

Standard	Yes	No	N/A	Comment
16. Alternative suitable storage is available in the event of a breakdown or repair of the unit				
17. The domiciliary visit transport containers are of a design approved by the IPC team				
18. The transport container has a dedicated maximum/minimum thermometer				
19. Icepacks are available for use with the transport containers				
20. 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 (eg score of 15 yes answers out of a total of 20 - 15 divided by 20 x 100 - = 75%)	
The audit will be non-compliant if there is no alternative storage or is not hardwired. Non -returns will be non - compliant	

Name of Auditor **…….**

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

- **Your line manager**
- **Medicines Management Team for inclusion in Medicine Reports**
- **Audits are to be reported QAG**

Appendix 3

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 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 data logger 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.
- What, who and how many patients may have been affected by this break in the cold chain?

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

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	Quarterly audit	MM Officer/Lead Individual service Quality and Governance groups	Individual service Quality and Governance Group	DTG

Equality Impact Analysis Screening Form

Title of activity	Maintaining the Cold Chain: The control and monitoring of storage temperatures of medicinal products		
Date form completed	06.05.2021	Name of lead for this activity	Helen Oliver

Analysis undertaken by:		
Name(s)	Job role	Department
Helen Oliver	MM Skills Facilitator	Medicine Management

What is the aim or objective of this activity?	The purpose of this policy is to implement a co-ordinated and standardised approach for the transportation and storage of medicinal products which requiring refrigeration within all services within Lincolnshire Community Health Services NHS Trust
Who will this activity impact on? *E.g. staff, patients, carers, visitors etc.*	The content is relevant to all staff and service users

Potential impacts on different equality groups:

Equality Group	Potential for **positive** impact	**Neutral** Impact	Potential for **negative** impact	Please provide details of how you believe there is a potential positive, negative or neutral impact (and what evidence you have gathered)
Age	☐	☐	☐	No differences within age groups
Disability	☐	☐	☐	No differences with disability groups
Gender reassignment	☐	☐	☐	No differences
Marriage & civil partnerships	☐	☐	☐	No differences
Pregnancy & maternity	☐	☐	☐	No differences
Race	☐	☐	☐	No differences
Religion or belief	☐	☐	☐	No differences
Sex	☐	☐	☐	No differences
Sexual Orientation	☐	☐	☐	No differences

Additional Impacts ***(what other groups might this activity impact on? Carers, homeless, travelling communities etc.)***	☐	☐	☐	This document has considered all groups of staff employed and patients being cared for within LCHS

If you have ticked one of the above equality groups please complete the following:

Level of impact

	Yes	No
Could this impact be considered direct or indirect discrimination?	☐	☒
If yes, how will you address this?		

	High	Medium	Low
What level do you consider the potential negative impact would be?	☐	☐	☒

If the negative impact is high, a full equality impact analysis will be required.

Action Plan

How could you minimise or remove any negative impacts identified, even if this is rated low?
How will you monitor this impact or planned actions?
Future review date: