Leicestershire Partnership NHS Trust

Maintaining Cold Chain of Medicines Policy

This policy describes the requirements, processes and equipment for maintaining the cold chain of medicines

Key Words:	Cold chain	
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Adopted by:	Quality Assurance Committee	
Date Adopted:	19 June 2018	
Name of Author:	Tejas Khatau	
Name of responsible Committee:	Patient Safety Group	
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Target audience:	Any staff required to handle medicines requiring cold storage	
Type of Policy	Clinical √	Non-clinical √
Which Relevant CQC Fundamental Standards?		

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Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
Version 1, Draft1	25/01/2010	Adapted from Policy and Procedure for Maintaining Vaccine Cold Chain for staff employed by Leicestershire County and Rutland PCT
Version 1, Draft 2	February 2010	Changes made following comments from Teresa Scott (Child Health Operational Manager), Shelley Jacques (Clinical Governance Operations Lead, Adults)
Version 1, Draft 3	25th March 2010	Correct reference to the Incident reporting policy and sharps policy.
Version 2	January – March 2012	Policy reformatted to LPT standard and harmonised. Comments received from Policy Group on 14/3/2012
Version 3	March 2015	Minor changes to section 5.4 and 5.6. Appendix 3 (staff signature sheet) removed in line with other policies.
Version 4	February 2018	Minor changes in sections 4.6, 4.7 and 4.10

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Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area.

This applies to all the activities for which LPT is responsible, including policy development and review.

Due Regard

LPT must have **due regard** to the aims of eliminating discrimination and promoting equality when policies are being developed (**see section 2 of the template for further information)**

Definitions that apply to this Policy

CASE	Clinical Audit Standards and Effectiveness
COSHH	Control of Substances Hazardous to Health
NPSA	National Patient Safety Agency
POM	Prescription Only Medicines
MHRA	Medicine and Health Care Products Regulatory Agency
Due Regard	Having due regard for advancing equality involves: • Removing or minimising disadvantages suffered by people due to their protected characteristics. • Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. • Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low.

1.0. Purpose of the Policy

This policy stipulates the process, procedures and equipment required to ensure that medicines requiring cold storage are managed appropriately.

This policy applies to outcome 9B of the Care Quality Commission which asks that the organisation has clear procedures for medicines handling that include safe storage.

2.0. Summary and Key Points

In order to maintain safety, efficacy and manufacturer's expiry, certain medicines are required to be stored between 2-8^{o}C at all times.

Failure to ensure appropriate storage can result in loss of NHS money and large scale recalls as the efficacy of the medicine cannot be guaranteed.

This policy applies to all medicines that require storage between 2-8^{o}C.

This policy stipulates the process, procedures and equipment required to ensure that medicines requiring cold storage are managed appropriately.

3.0. Introduction

In order to ensure safety, efficacy and manufacturer's expiry date, the temperature range of certain medicines need to be maintained between 2-8^{o}C during every stage of the medicines trail (e.g. storage, transport, packaging). This is often referred to as "maintaining the cold chain." If the cold chain is broken (i.e. if the medicines become too hot or too cold at any time), such medicines may lose their effectiveness quickly or become potentially dangerous. This also leads to waste of NHS money.

In addition to requiring a cold chain, many of these medicines are also Prescription Only Medicines (POM) and therefore need to be stored securely.

National Patient Safety Agency (NPSA) Rapid Response Report 008 has identified a number of incidents related to vaccine cold storage. Themes identified from these reports include: delay in storage of vaccines (especially after delivery); storage at wrong temperature; fridge switched off (in error) or broken; power cut or fridge door left open; no temperature monitoring; inadequate or missing equipment; and inappropriate use of domestic fridges.

4.0 Maintaining Cold Chain of Medicines

The general principals of maintaining security and cold chain are detailed below.

It is good practice to have locally written and approved procedures for all activities concerning medicines. Such procedures should specify what should be done and by whom.

4.1 Ordering and Monitoring of Stock

Ordering and monitoring of stock levels must be carried out by authorised person(s).

Care must be taken to order the correct quantity, especially as some medicines are packed in multiple quantities.

Each service area should have a stock list with desired quantities. Such stock lists must be reviewed at least annually.

Full documentation of all orders placed must be kept for at least 2 years.

It is good practice to carry out and document regular stock checks of the physical quantities against the theoretical quantities, especially when the service is dealing with large quantities of medicines.

4.2 Receipt of Stock

Receipt of stock must be carried out by authorised person(s).

Staff must ensure that they check the following before signing for the medicines:

- Check the medicines and quantity received against the original order or invoice for any discrepancies;
- Check for any leakage or damage;
- Check that any required security seals are still intact;
- There is no reason to suspect that the cold chain has been disrupted

Medicines must be refrigerated immediately on receipt.

Stock with the longest expiry date must be put at the back. This ensures good stock rotation and prevents medicines from expiring.

All invoices for receipt of stock medicines received must be kept for at least 6 years after the end of the financial year to which they relate.

4.3 Refrigerator

Medicines requiring storage between 2-8^{o}C must be stored in specialised medical refrigerators. These are generally of higher specification, lockable and may incorporate an internal fan.

Ordinary domestic refrigerators must not be used for the day to day storage of medicines.

Large refrigerators and walk-in units should be subject to regular (at least annual) servicing. Records of such service must be kept. Consideration should be given to servicing smaller refrigerators at least annually to ensure continued suitability for use. All refrigerators should be cleaned and disinfected regularly to prevent mould growth.

Refrigerators should not be situated near a radiator or any other heat source that could affect their working, and should be appropriately ventilated.

Opening of the refrigerator door should be kept to a minimum in order to maintain constant temperature.

The mains electrical lead should ideally be fitted in a spur point, which should be fused but not switched. If an on/off switch exists, there must be clear signage to ensure that the power supply is not accidentally switched off.

Ice should not be allowed to build up within the refrigerator, as this reduces effectiveness.

Refrigerators that develop ice build-up must be defrosted regularly. Records of defrosting and cleaning should be kept. Contingency plans should be made for defrosting activities.

4.4 Thermometer

The temperature within the refrigerator must be continually monitored with a maximum–minimum thermometer. Digital thermometers are the most reliable.

Thermometers should be reset and replaced according to the manufacturer's guidance.

Temperatures in the refrigerator must be monitored and recorded at least once each working day, and documented on a chart for recording temperatures. An example can be found in appendix 4.

The records should be readily accessible for easy reference and retained for one year.

Consideration should be given to servicing and calibrating thermometers annually to ensure that they are working correctly. Note that this would be an essential requirement for a service holding a wholesaler dealer's license. Records of such service must be kept.

4.5 Storage and Security

Many medicines requiring cold storage and all vaccines are prescription only medicines, therefore they need to be stored securely, especially when not in use. Medicines must be stored in a locked refrigerator. The refrigerator must be located inside a lockable room which is not directly accessible by the public.

Keys to refrigerator must be kept on the designated person during normal operating hours. The keys must be locked in a draw or safe outside of working hours.

Medicines must be stored in their original container so that they retain their batch number and expiry date. The packaging also protects the product against light.

Medicines must not be stored in the door, in the bottom drawers or adjacent to the freezer plate of the refrigerator.

Sufficient space should be allowed in the refrigerator so that air can circulate freely and items can be easily removed.

Food, drink and clinical specimens must never be stored in the same refrigerator as medicines.

Regular expiry date checks must be carried out and documented.

4.6 Transport by Community Staff

Community staff must transport medicines in their original packaging, out of sight from the public (e.g. in the boot of the car or glove compartment) and take it to the patient for administration as soon as possible. Staff must ensure that they carry only the required quantity of medicines based on their perceived usage.

Medicines can remain potent and safe outside the cold chain for a given period of time depending on the product and manufacturer. Staff must ensure that they are aware of how long the medicine can remain outside the cold chain and administer it within this time frame. Where small quantities are involved and administration is almost certain (e.g. a nurse doing a pre-planned home visit), it is not necessary to transport the vaccines in a special temperature-controlled container.

4.7 Packing and Transport (for distribution to another provider/service)

Validated rigid cool boxes should be used to reduce risk of damage and ice packs from a recognised medical supply company should be used. Individual manufacturers' instructions should be strictly adhered to.

A validation exercise must be done to ensure current provisions maintain the medicines within the required temperature range for the whole duration of the journey.

Cool boxes must be prepared as late as possible before departure to minimise time medicines spend out of the fridge. Alternatively, cool boxes can be prepared in advance and stored in the refrigerator if space allows. Items inside the cool box must be clearly labelled with storage requirements.

Medicines must be kept in the original packaging. Bubble wrap (or similar insulation material) must be placed around ice packs in order to prevent direct contact with the medicines.

Sufficient space should be left in the cool box allow air to circulate freely and items to be easily removed.

If reproducible validation has been carried out and the packing methodology can be assured, the temperature in the cool box need not be monitored regularly throughout its journey. The decision should be taken locally based on temperature sensitivity of the medicines, quantity being transported, staffing, length of the journey any potential delays. It is good practice to have the evidence for this decision to be recorded in a risk assessment that is annually reviewed. However, minimum and maximum readings should be recorded to demonstrate that the cold chain remains intact.

The opening of the cool box must be limited to ensure constant temperature.

When supplying medicines to another service, a delivery note must be supplied detailing:

- Name of medicine, strength and formulation being transported;
- Quantity;
- Batch number and expiry date;
- Destination;
- Signature of recipient;
- Minimum and maximum temperature at the start and end of delivery.

4.8 Spillages

Refer to Policy for Control of Substances Hazardous to Health (COSHH) for further information.

Staff must wear gloves when cleaning such spillages. Additional personal protective equipment such as aprons and face masks may be required depending on the nature of the medicine and manufacturer's recommendations. Spillages must be cleared up quickly using absorbent paper towels.

Spillages on skin should be washed with soap and water. Spillages coming into contact with the eyes should be washed with sterile sodium chloride solution 0.9% and immediate medical advice sought. When seeking such advice, it is helpful to know the name of the medicine.

Any waste created from cleaning spillages must be sent for incineration.

4.9 Disposal

All reconstituted and opened single and multi-dose medicines vials must be disposed of in an approved sharps bin if not used within the recommended time period. Expired medicines must be disposed in the same manner.

Temporary closure on the sharps bin must be used where available. Sharps bins which are two thirds full must be replaced. Refer to Infection Prevention and Control Policy for the Management of Sharps and Exposure to Blood Borne Viruses in Community Health Services, Inpatient Facilities and primary Care.

4.10 Disruption of Cold Chain

Medicines can remain safe and effective if stored outside of the cold chain for a given period of time. There can be a number of reasons why a cold chain is breeched, ranging from a broken down refrigerator, power failure through to medicines being accepted after delivery and left outside. Regardless of the reason, medicines requiring cold chain can be immediately placed back in the (working) refrigerator but clearly marked and segregated so that they are not inadvertently used. If unsure, advice should be sought from pharmacy before using the medicine. Once information is ascertained and the medicine is suitable to use, it must be clearly marked and the expiry date stated if different from the manufacturer's expiry. This is so that these products are used as soon as possible. Any subsequent breach of the cold chain occurring for these medicines may have a cumulative effective which could affect their stability and efficacy. Often, data is lacking on stability of products that have had more than one temperature breech.

It is important to note that disruption of the cold chain will render the medicine "off label" as it has been stored outside of the manufacturer's recommendations.

In the event of disruption to the cold chain due to refrigerator breakdown/power failure, prompt immediate action needs to be taken followed by longer term considerations.

Prompt Immediate Action:

- Check the plug and power supply to the refrigerator in case it has been switched off or disconnected by mistake;
- Check other electrical appliances sharing the same power supply to ascertain if the failure is isolated to the refrigerator only or a more widespread problem;
- Check the minimum and maximum temperature inside the fridge and try to ascertain approximately how long it has been outside of the range. If this is difficult to establish, the safest approach is to look at the last time when the refrigerator temperature was recorded as being within range and assume that the period of time following this record till when the disruption of cold chain was discovered is the time period of disruption of cold chain;
- Inform the line manager or another designated person so that repairs to the refrigerator can be carried out as soon as possible;
- Pack all the medicines in the affected refrigerator into transparent bag(s), stick a label to say "cold chain disrupted – do not use until further advice" along with the date, time and persons name;
- Place all medicines in another working refrigerator;

- Contact the individual companies or the pharmacy for advice on what to do with the medicines;
- Ascertain when the medicines are next required and order replacement stock if needed.

Once the refrigerator has been fixed and is working normally, ensure that the temperature within the refrigerator returns to between 2-8^{o}C before using it.

Complete an incident form.

Longer term considerations will focus on the cause(s) of the disruption and how this can be prevented in the future.

Services that keep large quantities of medicines must give due consideration to having a process in place to deal with disruption of cold chain in the out of hours period.

5.0 Duties within the Organisation

5.1 The Trust Board has a legal responsibility for Trust policies and for ensuring that they are carried out effectively.

5.2 Trust Board Sub-committees have the responsibility for ratifying policies and protocols.

5.3 Divisional Directors and Heads of Service are responsible for ensuring there are appropriate resources provided within their service area to implement and adhere to the policy.

5.4 Managers and Team leaders will be responsible for:

- Ensuring this policy is implemented in their area of responsibility.
- Ensuring that their staff are appropriately trained in line with the requirements of this policy;

5.5 Responsibility of Staff:

- It is the responsibility of the individual staff who manage such medicines to ensure that they follow the procedure described in this policy and local guidance.

6.0 Training

There is no training requirement identified within this policy.

7.0 Monitoring Compliance and Effectiveness

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
4.3-4.5	Full compliance	4.3-4.5	Part of Medicines Storage audit	Medicines Risk Reduction Group	Yearly
4	Full compliance	Whole of section 4	Audit for Unit C18	FYPC CASE	Yearly
4	Full compliance	Whole of section 4	Inspection for Unit C18	Responsible Person	Yearly
4	Full compliance	Whole of section 4	MHRA	MHRA	Every 2-3 years

8.0 Standards/Performance Indicators

TARGET/STANDARDS	KEY PERFORMANCE INDICATOR
Leicestershire Medicines Code and Care Quality Commission	Medicines are stored securely and at the correct temperature. Temperature is recorded and appropriate action taken if there is a deviation.

9.0 References and Bibliography

Policy was drafted with reference to the following:

Immunisation Against Infectious Diseases – "The Green Book"; accessed from http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/dh_4097254

The Safe and Secure Handling of Medicines: A Team Approach accessed from; http://www.rpsgb.org.uk/pdfs/safsechandmeds.pdf

Vaccine Cold Storage; NPSA Rapid Response Report 008; accessed from: http://www.nrls.npsa.nhs.uk/resources/?entryid45=66111

Leicestershire Medicines Code

Incident Reporting and Management Policy

Taylor, J. Recommendations on the Control and Monitoring of Storage and Transportation Temperatures of Medicinal Products; The Pharmaceutical Journal, volume 267, pp. 128-131.

Appendix 1

Due Regard Screening Template

Section 1	
Name of activity/proposal	Maintaining cold chain of medicines
Date Screening commenced	23/09/2015
Directorate / Service carrying out the assessment	N/A
Name and role of person undertaking this Due Regard (Equality Analysis)	Tejas Khatau
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS:	
OBJECTIVES: :	
PURPOSE: **PURPOSE:** •.	

Section 2		
Protected Characteristic	**Could the proposal have a positive impact Yes or No (give details)**	**Could the proposal have a negative impact Yes or No (give details)**
Age	No	No
Disability	No	No
Gender reassignment	No	No
Marriage & Civil Partnership	No	No
Pregnancy & Maternity	No	No
Race	No	No
Religion and Belief	No	No
Sex	No	No
Sexual Orientation	No	No
Other equality groups?	No	No

Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please <u>tick</u> appropriate box below.			
High risk: Complete a full EIA starting click here to proceed to Part B		Low risk: Go to Section 4.	**X**

Section 4
If this proposal is low risk please give evidence or justification for how you reached this decision: Following national best practice. Policy covers equipment and

processes rather than people.			
Signed by reviewer/assessor	Tejas Khatau	**Date**	28/02/2018
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		**Date**	

Appendix 2

The NHS Constitution

The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services

Shape its services around the needs and preferences of individual patients, their families and their carers	√
Respond to different needs of different sectors of the population	√
Work continuously to improve quality services and to minimise errors	√
Support and value its staff	√
Work together with others to ensure a seamless service for patients	√
Help keep people healthy and work to reduce health inequalities	√
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	√

Appendix 3

Stakeholders and Consultation

Key individuals involved in developing the document

Name	Designation
City and County Health Services policies harmonised	Tejas Khatau (City Policy) Jenny Dowling (County Policy)

Circulated to the following individuals for comment

Name	Designation
Members of the LPT Patient Safety Group	

Appendix 4

Refrigerator Temperature Record

Name of Service: **Month:** **Year:**

Date	Max Temp ^{o}C	Min Temp ^{o}C	Action taken if outside range 2-8^{o}C	Checked by (initials)	Thermometer reset (tick)

Please record the date(s) the fridge was defrosted:

Review:

Has the fridge temperature been checked every day? Yes ☐ No ☐

Has any necessary action been taken? Yes ☐ No ☐

If yes, what was the action?

Reviewed by: …… Date:……

If the fridge temperature is outside of the stated range (+2°C and +8°C) then refer to Policy for Maintaining Cold Chain.

*taken from Royal Pharmaceutical Society of Great Britain

Appendix 5

Maintaining Cold Chain Audit Template

Name of Service …… Date…….

Name of Person Undertaking Audit ……

	Compliance Achieved?				
1	**Ordering and Monitoring of Stock**	**Yes**	**No**	**N/A**	**Comments**
1.1	Ordering and monitoring of stock levels carried out by authorised person(s)	☐	☐	☐	
1.2	Service has stock list with desired quantities	☐	☐	☐	
1.3	Stock list reviewed at least yearly	☐	☐	☐	
1.4	Documentation of orders placed kept for 2 years	☐	☐	☐	
1.5	Regular stock check is carried out and documented	☐	☐	☐	
1.6	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
1.7	Other:	☐	☐	☐	

	Compliance Achieved?				
2	*Receipt of Stock*	**Yes**	**No**	**N/A**	**Comments**
2.1	Receipt of stock must be carried out by authorised person(s).	☐	☐	☐	
2.2	Staff check the following:				
	• medicines and quantity received against the original order or invoice	☐	☐	☐	
	• leakage or damage	☐	☐	☐	
	• any required security seals still in tact	☐	☐	☐	
2.3	Medicines refrigerated immediately	☐	☐	☐	

2.4	All invoices for receipt of stock medicines received must be kept for at least 6 years	☐	☐	☐	
2.5	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
2.6	Other:	☐	☐	☐	

Compliance Achieved?					
3	*Refrigerator*	**Yes**	**No**	**N/A**	**Comments**
3.1	Specialised medical refrigerator used	☐	☐	☐	
3.2	Refrigerator lockable	☐	☐	☐	
3.3	Records of annual servicing as per manufacturer's instructions	☐	☐	☐	
3.4	Temperature mapping completed and satisfactory for each refrigerator	☐	☐	☐	
3.5	Records of annual calibration of refrigerator thermometers to Blood Safety and Quality Regulations 2005 standard	☐	☐	☐	
3.6	Temperature of refrigerator is monitored regularly	☐	☐	☐	
3.7	Refrigerator situated away from heat source and well ventilated	☐	☐	☐	
3.8	Opening of refrigerator door kept to a minimum	☐	☐	☐	
3.9	Mains electrical lead fused but not switched	☐	☐	☐	Compliance required with either
	Main electrical lead with an on/off switch has clear signage indicating power supply is connected to refrigerator	☐	☐	☐	
3.10	No ice build up	☐	☐	☐	
3.11	Refrigerator defrosted regularly and records kept	☐	☐	☐	
3.12	Contingency plans for defrosting activities	☐	☐	☐	
3.13	There is a locally written and agreed	☐	☐	☐	

	procedure describing this activity				
3.14	Other:	☐	☐	☐	

Compliance Achieved?					
4	*Portable Thermometer*	**Yes**	**No**	**N/A**	**Comments**
4.1	A digital minimum and maximum thermometer is used	☐	☐	☐	
4.2	There is a 'master' thermometer which his less than 1 year old	☐	☐	☐	
4.3	Thermometers calibrated annually against 'master' thermometer and records kept of such activity	☐	☐	☐	
4.4	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
4.5	Other:	☐	☐	☐	

Compliance Achieved?					
5	*Storage and Security*	**Yes**	**No**	**N/A**	**Comments**
5.1	Refrigerators are locked when not in use	☐	☐	☐	
5.2	Refrigerators are located inside a lockable room which is not directly accessible by the public	☐	☐	☐	
5.3	Medicines stored in their original packaging	☐	☐	☐	
5.4	Medicines not stored in the door, in the bottom drawers or adjacent to the freezer plate of the refrigerator	☐	☐	☐	
5.5	Refrigerator not overfilled	☐	☐	☐	
5.6	No food, drink or clinical specimens stored in the same refrigerator	☐	☐	☐	

5.7	Keys to refrigerator kept on designated person during normal operating hours	☐	☐	☐	
5.8	Keys locked in a draw or safe outside of working hours	☐	☐	☐	
5.9	Regular expiry date checks carried out and documented	☐	☐	☐	
5.10	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
5.11	Other:	☐	☐	☐	

Compliance Achieved?					
6	*Transport*	**Yes**	**No**	**N/A**	**Comments**
6.1	Medicines are transported in validated cool boxes	☐	☐	☐	
6.2	Cool boxes are packed in a consistent manner	☐	☐	☐	
6.3	Medicines are kept in their original container	☐	☐	☐	
6.4	Medicines are protected from coming into contact with ice packs	☐	☐	☐	
6.5	Temperature in the cool box is monitored throughout the journey	☐	☐	☐	
6.6	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
6.7	Other:	☐	☐	☐	

Compliance Achieved?					
7	*Spillages and Disposal*	**Yes**	**No**	**N/A**	**Comments**
7.1	There is a locally written and agreed procedure describing how to deal with spillages	☐	☐	☐	
7.2	Sharps bins are available for safe disposal of sharps	☐	☐	☐	

Compliance Achieved?					
8	*Disruption of Cold Chain and Emergency Plan*	**Yes**	**No**	**N/A**	**Comments**
8.1	The emergency lighting is in working order	☐	☐	☐	
8.2	There is a locally written and agreed procedure describing this activity	☐	☐	☐	

Compliance Achieved?					
9	*Pest Control*	**Yes**	**No**	**N/A**	**Comments**
9.1	Pest control measures have been implemented in the last year	☐	☐	☐	

Compliance Achieved?					
10	*Medicines Recall*	**Yes**	**No**	**N/A**	**Comments**
10.1	The medicines re-call systems have been tested in the last year	☐	☐	☐	
10.2	There is a locally written and agreed procedure describing this activity	☐	☐	☐	

Compliance Achieved?					
11	*Education and Training*	**Yes**	**No**	**N/A**	**Comments**
11.1	Staff have had tailored training on medicines management in the last 3 years	☐	☐	☐	
11.2	Staff have read the most up-to-date SOP and signed the document	☐	☐	☐	

Appendix 6

PRIVACY IMPACT ASSESSMENT SCREENING

Privacy impact assessment (PIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet individual's expectations of privacy. The first step in the PIA process is identifying the need for an assessment. **The following screening questions will help decide whether a PIA is necessary. Answering 'yes' to any of these questions is an indication that a PIA would be a useful exercise and requires senior management support, at this stage the Head of Data Privacy must be involved.**			
Name of Document:	**Maintaining Cold Chain of Medicines**		
Completed by:	**Tejas Khatau**		
Job title	**Lead Pharmacist - FYPC**	**Date**	**12/03/2018**
			Yes / No
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.			**No**
2. Will the process described in the document compel individuals to provide information about themselves? This is information in excess of what is required to carry out the process described within the document.			**No**
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?			**No**
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?			**No**
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.			**No**
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?			**No**
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.			**No**
8. Will the process require you to contact individuals in ways which they may find intrusive?			**No**
If the answer to any of these questions is 'Yes' please contact the Head of Data Privacy Tel: 0116 2950997 Mobile: 07825 947786 **Lpt-dataprivacy@leicspart.secure.nhs.uk** **In this case, adoption n of a procedural document will not take place until approved by the Head of Data Privacy.**			
IG Manager approval name:			
Date of approval			

Acknowledgement: Princess Alexandra Hospital NHS Trust