

Maintaining Correct Storage Temperature for Medication Policy

This policy describes the requirements, processes and equipment for maintaining correct storage temperature for medication

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Policy on a page

This policy stipulates the process, procedures and equipment required to ensure that medicines requiring refrigeration and those requiring storage at room temperature are managed appropriately.

Summary and aim

In order to maintain safety, efficacy and manufacturer's expiry, certain medicines are required to be stored between 2-8°C at all times whilst others are required to be stored at room temperature up to 25°C. This temperature maintenance extends to transportation too.

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

This policy applies to all medicines that require refrigeration and storage at room temperature.

Target audience

This policy applies to all staff who deal with medicines that require refrigeration and storage at room temperature.

Training

There is no training requirement identified within this policy. Individual services must ensure staff are trained to their local SOP.

For further information contact:

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Introduction and Purpose

In order to ensure safety, efficacy and manufacturer's expiry date, the temperature range of medicines need to be maintained between the required range during every stage of the medicines trail (e.g. storage, transport, packaging etc..). For refrigerated medicine. 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 leads to waste of NHS money as they have to be disposed. A similar fate extends to medicines requiring storage at room temperature as we experience warmer spells.

In addition to their specific temperature requirements, 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 identified a number of incidents related to vaccine cold storage. Themes identified from these reports included: 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.

Various sections in this policy will be divided into two to separately cover correct storage of medicine requiring refrigeration and ambient temperature (not exceeding 25°C).

Policy Requirements and Objectives

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.

Process

Maintaining Correct Storage Temperature of Medication

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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.

Ordering of Stock

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

Care must be taken to order the correct quantity. Some medicines present as single dose units whilst others may come as multiple packs or doses. Ordering excess amounts will make it difficult to house if storage space is restricted. Each service area should have a stock list with desired quantities. Such stock lists should be reviewed at least annually.

Receipt of Stock

Receipt of stock must be carried out by authorised person(s) in a secure area.

Receipt of refrigerated medicines should be prioritised so that they can be placed in the refrigerator immediately.

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

Storage and Security

Medicines requiring cold storage will be kept in refrigerators. Medicines requiring ambient storage will typically be stored in a room or area with lockable cupboards or drawers.

Security of these medicines, along with any keys that provide access to the receptacle or areas, must be maintained in accordance with local SOPs, Trust Policy and Leicestershire Medicines Code.

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 Requiring Refrigeration

Such medicines must be stored in a refrigerator, ideally one that is pharmaceutical grade.

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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.

The opening and closing of refrigerator door must be kept to a minimum.

Medicines Requiring Storage at Ambient Temperature

Typically, such medicines can be stored in the room or space at temperatures up to 25°C.

Care is needed to ensure medicine storage receptacles are not placed in areas where there is prolonged direct sunlight or other heat sources (e.g. hot water pipes).

Refrigerator

Medicines requiring storage between 2-8°C must be stored in specialised medical refrigerators. These are generally of higher specification, lockable and has technology that ensures good air circulation.

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

Annual servicing of refrigerators is desirable, but the precise arrangements should be decided locally. Services that store vast quantities of medicines in the refrigerator may opt to do this annually to mitigate against unforeseen refrigerator malfunction. Equally, some services will opt to do this to meet their regulatory obligation. Records of such service must be kept.

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 required temperature.

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The mains electrical lead should ideally be fitted in a spur point, which should be fused but not switched. If the refrigerator is connected to a power supply through a domestic plug that is visible, 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.

Thermometer and Temperature Monitoring

In inpatient settings, both refrigerator and room temperature (in areas storing medicines) will be monitored by pharmacy using a continuous temperature monitoring device. This takes temperature readings at set intervals, such as every 10 minutes, and has the functionality to raise an alarm if temperature goes outside a pre-determined parameter.

In community settings, room and refrigerator temperature can be monitored using a continuous temperature monitoring device, though typically this will be done manually. Where a manual temperature check is taking place, the refrigerator temperature must be monitored at least once daily (or every working day that the area is occupied) with a maximum–minimum thermometer. The maximum (and up to an extent, minimum) readings are useful as they can inform of any extremes of temperatures between readings. Room temperature can be checked periodically (e.g. once weekly or monthly) due to more leeway in the temperature range. Again, the maximum can be particularly helpful as it will show what the highest recorded reading was since the last reset (though it cannot tell us how long the exposure was). A more frequent ambient room temperature check may be warranted if there is a known or predictable issue (e.g. temperatures approaching the threshold in warmer periods).

Digital thermometers are the most reliable. The service can opt to use the integrated refrigerator thermometer or an external one. The probe of an external thermometer should be carefully secured in an air space that is roughly in the middle of the refrigerator, ensuring it does not touch a surface.

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

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Temperatures must be documented on a chart. 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 to an appropriate standard annually to ensure that they are working to an expected level of accuracy. Note that this would be an essential requirement for a service holding a wholesaler dealer's license. Records of such service must be kept. Alternatively, a new thermometer can be purchased at regular intervals.

Transportation

Medicines Requiring Refrigeration

Medicines requiring cold chain should be transported in validated cool bags to maintain the temperature conditions. 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 destination(s) as soon as possible. Staff must ensure that they carry a sensible quantity of medicines based on their perceived usage. Regular temperature monitoring must be carried out and documented using a portable digital thermometer, unless there is facility to use continuous temperature monitoring. A locally approved procedure needs to be in place to cover all activities, including the return of surplus vaccines to a refrigerator and suitability of re-use depending on the temperature maintenance.

Some medicines can remain potent and safe outside the cold chain for a given period of time. The precise details vary depending on the product, manufacturer and maximum temperature exposure so it is essential this is ascertained first. Every effort should be made to maintain the cold chain during transportation, however, if permissible, and necessary, staff can carry the medicines without a validated cool bag or outside the cold chain for short journeys (this also allows enough time for the medicine to warm up which reduces discomfort from an intra-muscular injection). The decision to do this must be made at an appropriately senior service level with consultation with pharmacy in order to mitigate risks. Staff must ensure that they are aware of how long the medicine can remain outside the cold chain, administer it

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within this time frame and carry a thermometer and a device that tells the time to ensure the maximum specified temperature or time period isn't exceeded.

Medicines Requiring Storage at Ambient Temperature

Such medicines can be carried in a generic, non-specialist receptacle. Care must be taken when transporting medication on warm or sunny days. Medication must not be stored in a vehicle for prolonged periods as temperature within such settings can rise above 25°C. Medicines must not be kept in an unattended vehicle, including overnight.

Packing and Transportation (for distribution to another provider/service)

Validated rigid cool bags should be used to reduce risk of damage. Ice packs from a recognised medical supply company should be used to maintain the cold chain. 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, with additional contingency built in in case of unexpected delays.

Cool bags must be prepared as late as possible before departure to minimise time medicines spend out of the refrigerator. Alternatively, cool boxes can be packed with medicines in advance and stored in the refrigerator if space allows (it will still need ice packs placing as per local SOP once taken out of the refrigerator).

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

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

If reproducible validation has been carried out and the packing methodology can be assured, the temperature in the cool bag need not be monitored regularly throughout its journey. The decision should be taken at a senior service level based on temperature sensitivity of the medicines, quantity being transported, staffing, length of the journey and 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.

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However, minimum and maximum readings should be recorded at the end of the journey to demonstrate that the cold chain remains intact throughout.

The opening of the cool bag must be limited to ensure correct temperature is maintained.

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;
- A space for the recipient to sign;
- Minimum and maximum temperature at the end of delivery.

Management of Temperature Disruption

Medicines Requiring Refrigeration

In an inpatient setting, pharmacy will alert predetermined staff promptly if there is an unresolved temperature deviation (above 8°C) lasting longer than 1 hour.

In non-inpatient settings (e.g. community bases), this may be spotted during routine temperature checks.

When a temperature breach is discovered, an appropriately senior staff must act promptly.

- Check the current temperature to ascertain if it was a glitch / short term issue;
- 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 if the refrigerator is on (e.g. digital temperature displayed, light turns on when door opened);

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- Immediately 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 person’s name;
- Place all medicines in another working refrigerator;
- Inform the line manager or another designated person so that remedial repairs can be carried out as soon as possible;
- Ascertain when the medicines are next required and immediately order replacement stock if needed;
- Complete an electronic incident form;
- Try to ascertain approximately how long it has been outside of the range. This should be straightforward for inpatient areas where temperature is monitored regularly. 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 in cold chain was discovered is the time period of disruption;
- Contact LPT pharmacy for advice on what to do with the medicines. This is because stability data is available for some medicines when stored outside of the cold chain, so they may be suitable for use with additional constraints. 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.

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

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 business continuity planning.

Medicines Requiring Storage at Ambient Temperature

In inpatient settings, pharmacy will be alerted if the temperature rises above 25°C for any period and predetermined ward staff will be notified. Ward staff, supported by the matron, are expected to troubleshoot or address any deficiencies that may be causing the rise (e.g. breakdown in the air conditioning unit). If there is no obvious reversible cause or local fix, a risk may need to be added to the risk register.

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Once a room temperature breach is detected, pharmacy will monitor this carefully to check if there is a deviation for more than 6 hours each day over 7 consecutive days. If there is, pharmacy will intervene by labelling every drug stored under such conditions with a shorter expiry of 30 days. After this point, any remaining exposed drugs will be removed and disposed. Further drugs will be topped up as per established stock levels, however, these may also be revised if there is a persistent issue.

In non-inpatient settings (e.g. community bases) using manual temperature monitoring method, a conversation with pharmacy is recommended immediately upon discovering a breach.

Roles and Responsibilities

Duties within the Organisation

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

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

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.

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;

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 additional local guidance.

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Consent

Clinical staff must ensure that consent has been sought and obtained before any care, intervention or treatment described in this policy is delivered.

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Appendix One: Definitions

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.
Cold chain	Process of keeping medication between 2-8°C throughout its entire life. This includes transportation in a cool bag
Cool bag	A receptacle that has been validated to maintain the required temperature, usually 2-8°C during transit.
Room temperature	For the purpose of storing medication, this is regarded as a temperature below 25°C
SOP	Standard Operating Procedure

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Refrigerator Temperature Record

Year:

[illegible]

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

Review:

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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

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Appendix Three: Maintaining Cold Chain Audit Template

Maintaining Cold Chain Audit Template

Name of Service Date.....

Name of Person Undertaking Audit

Compliance Achieved?					
1	Ordering of Stock	Yes	No	N/A	Comments
1.1	Ordering 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:				

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	medicines and quantity received against the original order or invoice	☐	☐	☐	
	leakage or damage	☐	☐	☐	
	any required security seals still in tact	☐	☐	☐	
2.3	Required medicines refrigerated immediately	☐	☐	☐	
2.4	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
2.5	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 appropriate 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	☐	☐	☐	

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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' calibrated thermometer which is 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	☐	☐	☐	

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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	☐	☐	☐	

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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	☐	☐	☐	

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10.2	There is a locally written and agreed procedure describing this activity	☐	☐	☐	
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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 Four: Governance

Version control and summary of changes

Version number	Date	Description of key change
7	August 2025	Changes to various sections of policy, including title, to incorporate management of medicines requiring storage at room (ambient) temperature.

Responsibilities

Responsibility	Title
Executive Lead	Head of Pharmacy
Policy Author	Tejas Khatus
Advisors	Members of the Pharmacy management team
Policy Expert Group	Pharmacy Management Team

Governance

Governance Level	Name
Level 2 Assurance Oversight	Quality Forum

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Level 3 Delivery Group for policy approval and compliance monitoring	Medicines Management Group
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Compliance Measures

KPI (only need 1-2 KPI's per policy)	Where will this be reported and how often
Room and refrigerator temperature monitoring is carried out as per Policy	Records and incidents Recurring agenda item Medicines Audit group and (by exception) Medicines Safety Group Each meeting (unless exception report)

Training Requirements

Please explain what relevant training is available for staff to support the understanding and implementation of this policy.

References

Immunisation Against Infectious Diseases – “The Green Book”; accessed from <http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/dh4097254>

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

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Leicestershire Medicines Code; accessed from:

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