Livewell Southwest

Medicine Temperature Monitoring and Control for Storage and Transportation: Policy for Handling of Medicines

Version No.1

Review: June 2019

Notice to staff using a paper copy of this guidance

The policies and procedures page of Intranet holds the most recent version of this guidance. Staff must ensure they are using the most recent guidance.

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Asset Number: **929**

Reader Information

Title	Medicine Temperature Monitoring and Control for Storage and Transportation: Policy for Handling of Medicines. V.1.
Asset number	929
Rights of access	Public
Type of paper	Policy
Category	Clinical
Document purpose/summary	To ensure correct handling of medicines that require cold storage
Author	Pharmacist
Ratification date and group	Medicines Governance Group 03/06/16
Publication date	14th September 2016
Review date and frequency (one, two or three years based on risk assessment)	Three years after publication, or earlier if there is a change in evidence
Disposal date	The PRG will retain an e-signed copy for the archive in accordance with the Retention and Disposal Schedule. The Pharmacy Office will retain a signed copy for the archive. All copies must be destroyed when replaced by a new version or withdrawn from circulation.
Job title	Chief Pharmacist
Target audience	All Livewell Southwest staff
Circulation	Electronic: Livewell Southwest intranet and website (if applicable) Written: Upon request to the PRG Secretary on ☎ 01752 435104. Please contact the author if you require this document in an alternative format.
Consultation process	This is an amalgamation of former Livewell and Torbay policies with new information added. Consultation with MGG only.
Equality analysis checklist completed	N/A
References/sources of information	1. National Patient Safety Agency Rapid Response Report NPSA/2010/RRR008 “Vaccine Cold Storage” – Report and Supporting Information 2. Department of Health ‘The Green Book, Immunisation against Infectious Diseases’ Chapter 3 “Storage, distribution and disposal of vaccines” (copy available at www.dh.gov.uk – type in “Green Book” in search box then download chapter from list provided) **3.** Livewell Southwest, Medicines Policy (formerly Safe and Secure Handling of Medicines Policy)

	4. Sussex Partnership NHS Trust Medicines Code 2015-16 Chapter 36 “Safe Handling of Medicines Requiring Cold Storage” 5. MHRA; John Taylor, CChem, FRSC “Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products”
Associated documentation	N/A
Supersedes document	New document produced with reference to the documentation previously in use in the different localities (PCH and SH&WD) prior to 2015
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Document review history

Version no.	Type of change	Date	Originator of change	Description of change
0.1	New document	December 2015	Rhys Ponton (Pharmacist)	New document to cover merger of PCH and SH&WD to form Livewell Southwest.
1.0	Approved	June 2016	S. Cooke	Following MGG 03/06/16

Medicine Temperature Monitoring and Control for Storage and Transportation: Policy for Handling of Medicines.

1 Introduction

1.1 This document details the policy and associated protocols in relation to the control and monitoring of temperature during transport, safe handling and disposal of medicines, by staff working within Livewell Southwest.

1.2 This should be used in conjunction with the Medicines Policy and any other relevant documentation relating to medicine handling, transport, administration or destruction.

1.3 The policy encompasses cold storage / cold chain (2-8˚ C), cool storage (< 15 ˚ C) and controlled room temperature storage (generally <= 25 ˚ C).

1.4 The Medicines Control Agency (MCA) has published guidance for the pharmaceutical industry which has helped to inform the Medicines & Healthcare products Regulatory Agency (MHRA) guide “Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products” (see references). This will be referred to as the “MHRA guide” throughout this policy.

1.5 The cold chain system ensures the on-going quality, safety and efficacy during transportation and use of those treatments and immunisations that require cold storage.

2 Purpose

2.1 Livewell Southwest has a duty to ensure the safe care, custody, administration and destruction of medicines by employees, for the safety of employees, those receiving services and the population at large, and to comply with current legislation pertaining to medicines and their use.

2.2 The role of the employer and employees is identified.

2.3 Medicinal products should be stored and transported under conditions that ensure their quality is maintained. Manufacturers’ recommendations concerning storage temperatures should be observed and this may involve the use of specialised storage and transport facilities.

2.4 The policy is designed to ensure that the patient / client receive medication in optimum condition.

3 Definitions

Cold Chain — The cold chain involves all of the storage and transport facilities necessary to ship a product requiring controlled low-temperature storage from the manufacturer to the end user. 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. Temperature records need to be kept as assurance that the cold chain has been maintained.

MHRA — Medicines and Healthcare products Regulatory Agency

4 Duties & Responsibilities

4.1 The Medical Director has overall responsibility for all aspects of medicine handling by staff employed by Livewell Southwest.

4.2 The Chief Pharmacist has operational responsibility for ensuring appropriate policies, procedures and protocols are agreed and implemented within LSW.

4.3 Locality / service / ward / unit managers are responsible for ensuring their staff follow the guidance in this policy.

4.4 This Policy and protocols applies to all staff, in any environment, who are employed by LSW, whether directly or indirectly, who are authorised to prescribe, dispense, administer, supply or handle medicines.

5. General Principles

5.1 All medicines must be stored according to the manufacturer's instructions. The manufacturer will define the temperature range or maximum temperature that medicines must be stored within on the outer packaging so that the stated expiry date remains valid.

5.2 Some medicines and vaccines must be refrigerated and protected from light. They must not be frozen. The efficacy of the product depends upon their temperature being kept within the range 2-8˚ Celsius between dispatch from the manufacturer and receipt by the patient. Temperatures above this range can reduce the potency of the product leading to failure to produce satisfactory effects. The effect of exposure to temperatures above 8˚C is cumulative and may be considered to start at the point where the manufacturer delivers the product, ending when given to the patient.

5.3 For medicines that should be stored below 15 ˚C this effectively means that they should be stored in a refrigerator as rooms cannot be maintained at such a low temperature. This is only feasible if space in the refrigerator permits and if the product is not adversely affected by storage below 8 ˚C.

Please check with pharmacy if in doubt.

5.4 "Controlled room temperature storage" is used to imply a degree of control over the temperature of the storage environment, such that extremes of hot and cold are not encountered. "Room temperature" and "ambient temperature" are not acceptable terminology for labelled storage recommendations (ref: MHRA guide).

5.5 Unless stated otherwise in product literature and labels, the majority of medicinal products can be stored under conditions of controlled room temperature without compromise to their stability and recommended shelf life. These products are usually labelled as 'do not store above 25 ˚C' or for some products 'do not store above 30 ˚C'[5].

5.6 Freezing can cause deterioration of medicines which can lead to failure to produce clinical benefits and also lead to hairline cracks in the ampoule, vial or pre-filled syringe, which could potentially allow the contents to become contaminated or escape.

5.7 Everyone who is involved in medicines handling must be trained in the need to maintain appropriate temperature during storage and transportation.

5.8 Each site where medicines and vaccines are used will require a named person who is responsible for ordering, receipt and safe storage of the products used at that site. This person should ensure that the required monitoring of temperature is completed and any deviation from the recommended range is reported. There should be a designated person to cover in times of absence. The names of these individuals should be recorded on the form in Appendix B, kept near the fridge with the temperature records.

6. Medicines Refrigerators and the Cold Chain

6.1 Storage

6.1.1 Pharmaceutical grade fridges must be used in all hospitals, health care centres and residential units. Such refrigerators are lockable and usually have an integral fan and maximum / minimum thermometer (digital sensor readout) fitted with an audible alarm. The refrigerator should be sited in a secure area away from any sources of heat and should be kept locked at all times. **Ordinary domestic refrigerators must not be used.** Domestic fridges are not designed for the storage of vaccines and other medicines requiring cold storage as temperature in different parts of the fridge may vary.

6.1.2 The fridge must be registered with the Estates Department and serviced and calibrated as per service schedule and the Medical Devices and Equipment Management Policy. Calibration of maximum and minimum thermometers must also occur – seek advice from the Corporate Risk and Compliance team.

6.1.3 The accidental interruption of the electricity supply should be prevented by using a switchless socket or by placing cautionary notices on plugs and sockets.

6.1.4 Consideration should be given to the fitting of a 24 hour alarm system where the refrigerator regularly stores large quantities of vaccines or high cost medicines requiring cold storage.

6.1.5 Refrigerators must be cleaned and defrosted once a month and records kept of this on the temperature monitoring form.
To maintain the cold chain, alternative methods of cold storage are required during the defrosting process i.e. either another refrigerator or validated cool box. Please note that some pharmaceutical refrigerators self-defrost. If you are unsure the product literature or manufacturer must be consulted.

6.1.6 The refrigerator seal must be inspected monthly and replaced immediately if damaged or not intact.

6.1.7 There should be an agreed alternative storage arrangement for use in the event of a power failure or fridge breakdown.

6.1.8 The refrigerator must not be used to store anything other than medicines and/or transportation cool packs. It must not be used to store specimens, blood products, food or drink.

6.1.9 Vials, ampoules or pre-filled syringes must not be taken from their packaging during storage. In addition to possible loss of information on batch number, expiry date etc., this could lead to damage of the products by exposure to light.

6.1.10 Place medicines requiring cold storage **immediately** into the designated refrigerator. Medicines requiring cold storage must not be left at room temperature.

6.1.11 The refrigerator must not be overfilled. Adequate air must be allowed to circulate inside the refrigerator for temperature stability. To achieve this stock should only fill up to half of the internal space of the fridge. For vaccines, normally no more than two to four weeks stock (in line with expected usage) should be kept at any time.

6.1.12 Vaccines and medicines requiring cold storage should not be stored within the compartments in the refrigerator door or near to a freezer compartment (if fitted). Stocks of cold storage medicines should be monitored carefully to avoid over-stocking and stock should be rotated to ensure the oldest is used first. Expiry dates should be checked regularly (once a week) by a named / designated member of staff.

6.2 Record Keeping

6.2.1 The medicines fridge must have its own record system or book for stock received or removed (see pro-forma Appendix E).

6.2.2 Specifically upon receiving products the designated / named person must record:

- The name of the product, form and strength
- The date and time they were put in the fridge
- The quantity received
- The batch number, expiry date
- The name and signature of the designated person receiving the product

6.2.3 Staff removing products from fridge must record:

- The name and batch number of the product removed
- The date and time removed
- The quantity removed
- The name and signature of the clinician

6.2.4 When stocking or removing products from the fridge remember to open the door for the minimum time to prevent temperature fluctuations (see 6.2.6).

6.2.5 The designated / named person is responsible for maintaining and monitoring the fridge temperature on each working day, using the integral maximum / minimum thermometer. Instructions for taking temperature readings will be on the door of the fridge, if in doubt contact Pharmacy. Each fridge must have a LSW “Medicine refrigerator temperature record” log completed (Appendix C), with the following recorded every working day:

- The date and time of monitoring
- The current fridge temperature (which must be between 2-8˚celsius)
- The maximum and minimum temperature since the last reset
- Confirmation of the thermometer reset
- The name and signature of the designated person performing the monitoring
- Comments to include for example: reason for temporary high temperature and actions taken when reading is outside 2-8 °C

6.2.5.1 Record log forms are to be kept for a minimum of one year, or for the life of the products stored within (if longer).

6.2.6 Keep door openings to a minimum as these will cause the temperature to rise. Ensure the door is firmly closed after use. If the current temperature rises above 8°C temporarily following opening of the door, an entry should be made on the recording form. This should include a reason for the high temperature and the time the temperature was out of range for. A reset should be performed when the temperature is back in the range 2-8°C.

6.2.7 If the fridge is not maintaining the correct temperature or is thought to be malfunctioning the following actions should be taken:

- Inform line manager who should check the concern.
- If the problem appears to be mechanical (rather than the door having been left open or the fridge unplugged), call Estates Immediately for the fridge to be checked.
- If the products in the fridge have been exposed to a temperature outside the range 2-8˚C for more than an hour the stability of the products may be compromised, in which case contact Pharmacy 34723/5/6 for advice.

6.2.8 Maintenance, PAT testing and calibration of refrigerators will be carried out by Livewell Southwest Estates Department under the supervision of the Corporate Risk and Compliance Team as outlined it the Medical Devices and Equipment Management Policy.

6.3 Packaging and transport to external sites

6.3.1 A health professional giving injections or a vaccination at an external site is solely responsible for ensuring the correct transportation of vaccines and maintenance of the cold chain during this process.

6.3.2 Only the minimum quantity of medicines or vaccine should be taken to clinics at other sites.

6.3.3 Validated rigid type cool boxes and packaging material should be used for transportation of cold chain medicines to other sites. Commercial, not domestic cool packs, should be used. Validation records of all equipment should be kept and maintained by the manager of the team.

6.3.4 Cool boxes and packaging material should be stored at the lowest possible temperature prior to packing with the medicines.

6.3.5 Medicines should be packed in the cool box as late as possible and packed / transported according to the cool box and manufacturers' instructions.

6.3.6 Refrigerated cool packs should be used wherever possible. They must be insulated to prevent direct contact with the medicine. Medicines should be insulated to prevent direct contact between cool packs and medicines, i.e. by using polystyrene chips (refer to cool box instructions). Frozen cool packs must be avoided.

6.3.7 Cool packs should be arranged so that one is at the bottom of the cool box and another is at the top.

6.3.8 On arrival at the external site medicines should be transferred to a refrigerator if available. Otherwise they must be left in the closed cool box until needed.

6.3.9 Any unused products which have been involved in transportation may be placed back into stock provided they are intact, within their original packaging and the registered professional can guarantee that the cold chain has not been broken. If the cold chain has been broken, please follow the process in the next section.

6.4 Disruption of the cold chain

6.4.1 Ensure individuals understand **when and how to take action** if readings are outside of the 2-8°C range.

- Record known reasons for temperature fluctuation e.g. when re-stocking the refrigerator.
- For technical faults with medicine refrigerators please contact Estates helpdesk on 35091 or 35100.

6.4.2 If there has been any break in the cold chain, for example through equipment failure or equipment electrical disconnection, quarantine and do not use any medicines that require cold storage until seeking further advice.

- Contact Pharmacy Services or a member of the pharmacy team for advice (internal: 34723/4/5/6). Alternatively contact Medicines Information at Derriford Pharmacy Tel. 39976.
- In exceptional circumstances, if pharmacy services are closed, or unavailable, the manufacturer of the medicine can provide advice with regards their specific product (Please note: each product has different stability data). The following information is likely to be required:
    - How long the medicine has been out of the cold chain
    - The temperature that the products have reached (i.e. room temperature), or the actual, minimum and maximum temperature readings recorded on the fridge thermometer
    - When the correct temperatures were last recorded
- **Ensure all advice received is documented (use the comments section on the temperature reading form).**

6.4.3 If advised that the medicine may still be used, ensure that these medicines are used first before any newer stock that is subsequently received. This may be done by marking the outer packaging.

6.4.4 Manufacturers of some products state that they are safe to use, however the fact that they have been stored outside of the temperature range specified means their use becomes unlicenced. In these circumstances the patient should be informed before receiving a dose from such stock. A DH leaflet is available to give to parents/patients under these circumstances.

6.4.5 Arrange for vaccines and medicines requiring cold storage to be returned to

correct storage conditions immediately. If the issue with temperature control cannot be resolved promptly another suitable location will need to be identified for storage of medicines.

6.4.6 All vaccines, insulins and many other medicines which may have been frozen by storage at temperatures below 2˚Celsius will be inactivated and will require destruction.

Contact pharmacy services to notify them of the event and of the products involved (these will need to be reordered to replace lost stock) they will then give advice with regard to disposal.

6.4.7 Take action to avoid future breaks in the cold chain for example by preventing electrical disconnection as detailed in Section 6.1.3 above.

6.5 Disposal

6.5.1 All medicines must be disposed of in accordance with the organisation waste management policies (Refer to Medicines Policy (formerly Safe and Secure Handling of Medicines)).

6.5.2 Any prepared or opened vaccine or medicine requiring cold storage must be disposed of at the end of the administration session, or sooner if the manufacturers recommended limits have expired.

6.5.3 In the case of any unsealed but unused, or partially used, vaccine or medicine (prefilled syringes, ampoules, vials), these should be disposed of in the appropriate waste bin.

6.5.4 Any contaminated waste and expired medicines must be disposed of in the appropriate waste bin.

6.5.5 Sharps bins used at external sites should be returned to the base clinic after each session unless they can be stored in a suitable locked cupboard with a key held by approved personnel.

6.6 Dealing with Spillages

6.6.1 Please refer to section 15.6 of the Medicines Policy (formerly Safe & Secure Handling of Medicines Policy) for advice on spillage (although written for waste pharmaceuticals this applies equally to spillage of stock pharmaceuticals).

7. Medicines in Drug Cupboards / Trolleys

7.1 Medicine cupboards or trolleys should not be placed near sources of heat e.g. windows or radiators.

7.2 If there are sources of heat in an enclosed space then it is advised that heat

mapping of the room should be carried out. This will identify the most suitable area for medicines storage.

7.3 Weekly temperature records should be taken and recorded using a calibrated electronic temperature gauge with current / maximum / minimum settings.

7.4 Temperatures should be recorded on the form in Appendix D, to include:

Date and time
Current temperature
Maximum and minimum temperature
Name and sign
Tick to indicate reset
Any comments

7.5 The thermometer probe should be placed within the stock in the cupboard as this will provide the most accurate measure of the actual temperature of the medicines.

7.6 If the maximum temperature reading reaches 24 ˚C (including during warm spells in between the weekly monitoring) then the frequency of readings should be increased to daily. If possible install a portable air-conditioning unit.

7.7 If the maximum temperature exceeds 25 ˚C for 7 days or more (or over 30 ˚C for one day) then Pharmacy should be contacted for advice on medicines and estates for advice on reducing the room temperature.

7.8 Once maximum temperatures drop to below 24 ˚C, temperature monitoring may revert to weekly.

8. Training implications

8.1 It is the responsibility of the service manager to ensure that all staff have knowledge of this policy and are competent in maintaining the cold chain for medicines requiring cold storage.

9. Monitoring Compliance

a. An annual audit should be undertaken of all sites where cold storage is required.
b. In addition, cold storage will be assessed as part of safe and secure audits conducted by the pharmacy services team.

All policies are required to be electronically signed by the Lead Director. Proof of the electronic signature is stored in the policies database.

The Lead Director approves this document and any attached appendices. For operational policies this will be the Locality Manager.

The Executive signature is subject to the understanding that the policy owner has followed the organisation process for policy Ratification.

Signed: Dr Adam Morris, Medical Director

Date: 09/08/16

Appendix A

Temperature monitoring of medicines on wards / units

The enclosed policy has been updated in accordance with the Departmental of Health "Green Book" and the MHRA guide "Recommendations on the control and monitoring of storage and transportation temperatures of medicinal products".[(5)] These principles apply to any medicinal product requiring cold storage including vaccines and also for medicines in cupboards / trolleys in clinic rooms.

1. Each ward / unit / practice that stores or uses medicines, should have one trained individual, with at least one trained deputy, responsible for the receipt and storage of medicines requiring cold storage (including vaccines) and for the recording of refrigerator temperatures. The person will also be responsible for temperature monitoring of medicines stock in cupboards and trolleys in clinic rooms. This person does not have to be clinically trained, but should receive training as detailed below.

Ward / Unit / Practice.....

Member of staff responsible …….

Deputies:……..……..

2. Training should include:
   - Reading and understanding of the importance of the LSW Policy "Medicines Temperature Monitoring and Control for Storage and Transportation: Policy for the Handling of Medicines"
   - If storing vaccines, read and understand Chapter 3 of 'The Green Book, Immunisation against Infectious Diseases' (see reference no.2)
   - The products kept on the individual ward / unit / practice to which this guidance applies.
   - Procedures for receipt and issue of stock and stock rotation.
   - How to read and re-set the maximum/minimum thermometer and how to complete the monitoring form.
   - Retention periods for the monitoring form
   - Actions required if temperature readings are outside of stated range
   - Ensuring a deputy carries out these duties during their absence.
   - Temperature monitoring of stock cupboards / trolleys in clinic rooms where appropriate.

Appendix B

REFRIGERATOR TEMPERATURE MONITORING
(Display this notice on or near the medicine refrigerator)

The temperature of the medicines refrigerator should be monitored and recorded daily by a named designated person, using a maximum/minimum thermometer. The temperature should be checked daily (preferably the same time of day) on each working day.

Member of staff responsible for taking temperature readings:

……

Deputies who will complete this task when the above is absent:

……

Most pharmaceutical products that require refrigeration should be stored within the range 2 – 8 °C, but always check the pack to confirm.

In order to spot any problems that have occurred overnight, the temperature should be checked daily (preferably at the same time each day).

Record the date, time, and current/ maximum /minimum thermometer readings on the Temperature Record Sheet and sign the form. Reset the thermometer after taking the reading and tick the reset column.

Keep the Record Sheet on or near the refrigerator.

Most medicines refrigerators are fitted with integral digital maximum / minimum thermometers. Please follow the instructions for taking temperature readings and resetting on the front of the refrigerator.

In the event of temperature readings outside of the range 2 – 8 °C or refrigerator failure, then advice from Pharmacy Services (34723/4/5/6) or Derriford Hospital Trust Medicines Information Department should be sought.

Retain the monitoring forms for a minimum of one year, or for the life of the products stored within (if longer).

Medicine Refrigerator Temperature Record Form

Ward / Unit / Practice……..Month…….Year……..

Date	Time	Current °C	Max °C	Min °C	Confirm reset (√)	Name	Signature	Comments

Fridge cleaning / defrost (if applicable) carried out by_____ Date_____

Appendix D. **Medicine Clinic Room Temperature Record Form**

Ward / Unit / Practice……..Month……Year……..

Record temperature of probe in medicine stock once weekly until temperature reaches 24C or higher then record daily (see section 6.2)

Date	Time	Current **°C**	**Max °C**	**Min °C**	**Confirm reset (√)**	**Name**	**Signature**	**Comments**

Appendix E Medicines Refrigerator Stock Record Form

Name of product_____ **Form**_____**Strength**_____

Receipts (R)						Issues (I)					R	I
Date / time	Quantity	Batch / expiry	Staff Name	Signature		Date / time	Quantity	Batch / expiry	Staff Name	Signature	Stock balance	