Southern Health
NHS Foundation Trust

SH CP 87

Temperature Management of Medicines: Storage and Transport

Version: 10

Summary	To ensure the efficacy and safety of medicines by adhering to Department of Health guidance and medicines' Summary of Product Characteristics	
Keywords	Cold chain, vaccine, storage, refrigeration, transport, medicines, medication, ambient, temperature, fridge	
Target audience	All staff and their managers who handle medicines, especially vaccines.	
Date issued	July 2020	
Approved & Ratified by	Medicines Management Committee	**Date of meeting:** 15 July 2020
Next review date	July 2023	
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Equality Impact Assessment (for policies only)
The Equality Impact Assessment has been completed. The assessment document is held centrally and is available by contacting policies@southernhealth.nhs.

Version Control

Change Record

Date	Author	Version	Page	Reason for Change
March 2011	Steve Mennear	1	ALL	Initial version in response to NPSA alert RRR008 (2010) HCHC/CLI/97/V1.00
January 2013	Steve Mennear	1	ALL	Transferred to SHFT template as **SH CP 87**
March 2015	Steve Mennear	2	ALL	Review date reached. Wording amended to encompass all refrigerated medicines.
May 2016	Steve Mennear	3	17 10 11 7; 5.3.9	Appendix 3. Actions taken if temperature out of range added. Current temperature deleted. SH CP1 added. March 2013 deleted 'Chapter' deleted at end of first reference Changes to appendix 3
June 2016	Ewan Maule	3	All	Name and content changed to reflect updates arising from CQC action plan, and to broaden scope to include monitoring of ambient room temperatures
April 2017	Francis Johnson	4	16	Removed Estates as contact and replaced with BCAS – Appendix 3
Sept. 2017	Steve Mennear	5	17	Appendix 3 updated & tested to ensure temperature recording of 3 readings and appropriate actions taken when temperature exceeded.8^{o}C column changed to amber. Appendix 4 added for cool boxes. 5.3 amended to ensure integral thermometer display used routinely to record temperatures. 5.5.2.11 amended to avoid wasting vaccine if maintained in cold chain.
Jan18	Vanessa Lawrence	6	Append ix 3	Appendix 3 updated. Amber columns removed. Information on what to do when temperatures are out of range made clearer.
March 18	Steve Mennear	7	5.2.1 (h) A3 & 4	Amended from 3-yearly PAT testing to annual Electrical Safety Test. Advice in Appendix 3 updated. Appendix 4 amended to record only current temperature & amber columns removed.
14/6/18	V Lawrence	7	1	'fridge' added to keywords
August 2018	Steve Mennear	8	10 & 13	Section 6 updated: use of Temperature Excursion Risk Assessment' tool removed. Advice in Appendix 3 simplified
June 2019	Steve Mennear	9	10 & 13	Actions for temperature excursions amended. Advice in Appendix 1 simplified. Section 11 references updated. TNA and EqIA removed
July 2020	Steve Mennear	10	10 & 12	Section 6 & appendix 1 updated to require maximum room temperature to be recorded each working day. Transferred onto new template
15/9/20	Steve Mennear	10	11	Appendix 1 - addition of 'MAX' to CLINIC ROOM TEMP column

Reviewers/contributors

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Contents

Temperature Management of Medicines Storage and Transport

1. Introduction

1.1 This policy sets standards of practice to ensure that all medicines are stored within the manufacturers' recommended temperature range. This minimises the risk of compromising the efficacy and safety of medicines, especially vaccines which are of high cost, stored in large quantities and temperature labile (i.e. safety & efficacy may be compromised by excessive heat or freezing).

1.2 This policy primarily focuses on the transport and storage of vaccines but the same basic principles also apply to all other medicines, including those requiring refrigeration.

1.3 Failure to store medicines according to manufacturers' recommendations can invalidate the expiry date and cause manufacturers to disclaim responsibility for any apparent failure of the medicine as the safety and efficacy of such medicines can be significantly compromised or unknown. This can cause avoidable waste, often at considerable expense.

1.4 Refrigerated medicines must be stored at 2-8ºC. Most non-refrigerated medicines must be stored at less than 25°C. However, some medicines can be stored at up to 30°C. Sensitivity to changes in temperature varies depending on the medicine.

1.5 Current practice should comply with national policy as stated in:

a) the latest version of Immunisation against infectious disease, Chapter 3, "Storage, distribution and disposal of vaccines" (Public Health England)
b) the conditions specified in manufacturer's product licence (SPC)
c) The Safe and Secure Handling of Medicines guidance, Royal Pharmaceutical Society / Royal College of Nursing, 2018.
d) National Patient Safety Agency Alert Vaccine cold storage, 2010.

2. Scope

2.1 This policy is to be followed by all Trust employees involved with handling medicines. It should be used along with the Medicines Policy (SH CP 1), "Immunisation against infectious disease" (Green Book), Department of Health and the Nursing and Midwifery Council (NMC) Standards of proficiency for registered nurses and nursing associates.

3. Definitions

3.1 **Cold Chain -** maintenance of the temperature of medicines, including vaccines, between 2 ºC and 8ºC at all times during storage and transport.

3.2 **Room Temperature** - below 25°C for most medicines, although some are stable up to 30°C

4. Duties / Responsibilities

4.1 Each clinical setting where medicines are stored must have (a) one trained and designated individual (this may include administrative staff) and (b) one trained deputy to be responsible and accountable for:

- receipt and storage of vaccines/heat sensitive medicines
- monitoring and recording of fridge and ambient room temperatures
- all actions in section 4.3
- audit and evaluation of training needs for staff using or involved in use of these products

4.2 The designated person and/or their deputy should be easily identifiable by recording the name on temperature monitoring records.

4.3 The designated person or deputy (in their absence) is responsible for the following:

- Checking the contents of a delivery of medicines for expiry, damage, leakage and correct transportation (i.e. evidence that the cold chain has been maintained where appropriate)
- Signing to acknowledge correct (corresponds to order) and safe receipt
- Immediate secure storage of products in the designated place e.g. storage refrigerator or medicines cupboard
- Completing a vaccine log where appropriate
- Ensure overstocking does not take place
- Exercising stock rotation to prevent wastage from out of date products
- Removal and safe disposal of expired or damaged stock
- Maintaining accurate and legible records of temperature monitoring for audit purposes
- Ensuring **immediate action** is taken if the fridge thermometer reading is or has been outside the recommended range (between 2ºC and 8ºC). See section 5.6.

4.4 Service and ward managers are responsible for:

a) ensuring that all their staff adhere to the standards in this policy.
b) maintaining medicines storage temperature management as part of the organisation's business continuity plans e.g. refrigerator breakdown, loss of electricity supply, ward closure.

5. Procedure & Standards for management of Refrigerated medicines

5.1 Receiving refrigerated medicines

5.1.1 When expecting a delivery of a vaccine or medicine requiring storage at 2-8ºC the designated accountable person or deputy must ensure that whoever accepts the delivery is aware of the need to maintain the cold chain and check the order for leakage, damage and discrepancies.

5.1.2 All deliveries of refrigerated medicines must be unpacked immediately on arrival and placed in a pharmacy/vaccine refrigerator i.e. **not** left at room temperature. Items must remain in the manufacturer's original packaging to protect them from light.

5.1.3 Vaccines delivered by Movianto:
a) Check the delivery against the order whilst the driver is still present so that any errors in supply can be resolved immediately with Movianto
b) If there is any concern that the cold chain has been broken prior to delivery, do not accept the delivery and report the reason for non-acceptance to the distributor. An incident report should be completed using the Ulysses Safeguard reporting system.

5.1.4 Retain delivery notes containing vaccine batch numbers and expiry dates for 2 years from date of receipt.

5.2 Refrigerated Storage

5.2.1 Refrigerators used for storage of medicines must:

a) Be designed specifically for that purpose. Domestic refrigerators are not suitable for this purpose.
b) Be of an appropriate size for the quantity of stock to be stored i.e. filled to no more than 75% capacity to allow adequate air circulation. Order frequency should be increased rather than compromising air flow by filling the refrigerator.
c) Be kept locked or in a locked room (with no public access) when not occupied by a member of staff, as all prescription only medicines (POMs) must be stored under locked conditions. This also discourages unnecessary opening of the fridge door. Keys to the refrigerator must be stored securely e.g. in a key safe only accessible to authorised staff or with a senior nurse on duty.
d) Be reserved exclusively for the storage of vaccines and other pharmaceutical products requiring storage between 2ºC and 8ºC.
e) Not be used to store food, blood, milk, drink or specimens.
f) Be sited in a well-ventilated room maintained between 10 ºC and 25 ℃, away from external windows and all heat sources e.g. radiators, direct sunlight, at least 5-10 cm from walls and other units.
g) Be defrosted every 6 to 8 weeks if not self-defrosting or has an automatic defrosting mechanism.
h) Be wired into a switch-less fused socket to avoid being switched off accidentally and connected to an essential services electricity supply, if available. If this is not possible, cover the plug and socket and label it with a recommended cautionary notice e.g. “Pharmacy fridge: Do NOT switch off”. An Electrical Safety Test is required annually.
i) Be serviced according to manufacturer’s instructions to ensure an operating temperature of 2ºC to 8ºC is maintained at all times whilst storing refrigerated medicines.
j) Have its integral thermometer independently calibrated at least annually to ensure readings are true.
k) Have an independently powered digital maximum and minimum thermometer which also records the current temperature, regardless of the existence of an integral refrigerator thermometer.

5.3 Refrigerator Temperature Monitoring

The four R’s: Read – Record – Reset – React.

5.3.1 Refrigerator temperature readings must be monitored regularly (see 5.3.4) by the designated person or deputy using the integral thermometer display.

5.3.2 If the refrigerator is not in continuous use, it can be switched off when not in use. Staff must ensure that the refrigerator temperature is between 2-8ºC before it is used to store refrigerated medicines.

5.3.3 All fridges should ideally have two thermometers, one of which is a maximum-minimum thermometer independent of the mains power, the other being built into the refrigerator. The independently powered thermometer with a probe should be arranged so that it can be read without opening the refrigerator door. The probe should be placed at the centre of the refrigerator in an empty vaccine box or similar container. The aim of this is to mimic medicines storage temperature and reduce the number of temperature spikes caused by simply opening and closing the fridge door.

5.3.4 The designated person or deputy at each base must **read** and **record** the maximum, minimum and current temperature of each refrigerator at least once during each working day, preferably at the same time(s) of day each day.

5.3.5 The thermometer must always be **reset** after recording each reading by following the manufacturer's instructions.

5.3.6 Refrigerator temperature readings falling outside the range 2°C to 8°C must be reported to the service/ward manager for risk assessment and appropriate action. See section 5.6.

5.3.7 The current refrigerator temperature should also be visually checked before removing any vaccine or at the start of an immunisation session.

5.3.8 If there is more than one refrigerator in the same room, each one should be clearly labelled and identified (e.g. Fridge1, Fridge 2 etc.) and cross referenced to the appropriate temperature monitoring sheet and operating manuals.

5.3.9 The recommended temperature recording sheet should be used (see Appendix 1) to record refrigerator temperatures. Records should be kept for at least 2 years (5 years where vaccines are stored) and stored close to the referenced fridge.

5.3.10 The designated person and deputy must have training in the principles of the cold chain, how to **read** and **reset** the thermometer and how to **react** when the temperatures are outside the correct range.

5.4 Refrigerator Content

5.4.1 All medicines should be stored in the manufacturer's original packaging as this is printed with the expiry date and batch number, contains a patient information leaflet and administration instructions and protects products from light and damage.

5.4.2 Fridge contents should be evenly distributed to allow air to circulate around items and shelves thus enabling the temperature to remain constant throughout the fridge.

5.4.3 Medicines should be stored in the main body of the fridge, not in the bottom drawer or door where the temperature can be higher. Storage adjacent to a freezer compartment or freezer packs should also be avoided.

5.4.4 Stock must be rotated according to expiry date and older stock placed at the front of the fridge to be used first to avoid medicines waste.

5.4.5 Expired stock must be removed as soon as possible and safely destroyed according to the Handling and Disposal of Healthcare Waste Policy SH NCP 47.

5.4.6 Fridge contents should not occupy more than 75% of the volume of the main body of the fridge i.e. the fridge must not be overfilled so that air flow is not compromised. An overfilled fridge can also create potential for freezing and lead to poor stock rotation.

5.5 Transporting Refrigerated Medicines

Validated cool boxes and cool packs from a recognised medical supply company should be used in conjunction with validated maximum – minimum thermometers to ensure the cold chain is maintained during transport. Ice packs and frozen cool packs should **not** be used unless indicated by manufacturer's instructions. The time between removing vaccines from refrigerated storage and administration must be kept to a minimum.

5.5.1 **Domiciliary Visits**

5.5.1.1 Vaccines must be kept in the original packaging and placed in a cool box to ensure vaccine potency is maintained.

5.5.1.2 If the vaccine is not administered to the patient within one day of being in the cool box it should be disposed of in the appropriate sharps bin and not returned to the stock supply in the fridge.

5.5.1.3 Other medicines may only be returned to the fridge if conditions stated in manufacturers' information are met.

5.5.1.4 Cool boxes must be transported out of direct sunlight and secured in the boot of employees' car (not on a car seat) to ensure vaccines are not damaged and the cold chain is maintained.

5.5.2 **School Immunisation Sessions & Clinic Sessions**

5.5.2.1 Cool boxes should be packed immediately before dispatch to the clinic/school immunisation session.

5.5.2.2 Vaccines must be kept in the manufacturer's original packaging, wrapped in bubble wrap or similar insulation material, and placed in a cool box with cool packs at fridge temperature as recommended by the manufacturer's instructions.

5.5.2.3 Place a thermometer probe at the centre of each cool box and monitor and record the temperature on arrival at the immunisation site, every two hours thereafter and on arrival back at base using Appendix 2. Temperature logs should be filed together with refrigerator monitoring logs from where the vaccine was obtained.

5.5.2.4 If there is no fridge at a vaccination site, vaccines must be stored in the cool box until used.

5.5.2.5 Keep vaccines as cool as possible for the duration of a session i.e. cool boxes must be kept away from direct sunlight and other heat sources and the lid kept in place as much as possible.

5.5.2.6 Replace the lid and cool packs immediately after removing any vaccine from the cool box.

5.5.2.7 Cool boxes and cool packs used for school immunisation sessions are designed to maintain the cold chain for up to eight hours if the lid is kept in place.

5.5.2.8 Ideally each vaccine should be taken directly from the cool box for each administration. However, when it is necessary to expedite a mass immunisation session, it may be necessary to remove a given number of doses. These doses should be kept under 25^{o}C until administered.

5.5.2.9 Vaccines not administered within 2 hours of removal from cold storage should be disposed of in the appropriate sharps bin.

5.5.2.10 Any unused vaccine that has been maintained in the cold chain in cool boxes should be returned to the fridge at the end of a session. Each vaccine must be marked "use first" and marked with the date it was returned to stock.

5.5.2.11 Marked stock must be used as early as possible at the next immunisation session or at the earliest opportunity as long as vaccines have remained in the cold chain.

5.6 **Incidents: Fridge failure or Cold chain disruption**

5.6.1 Service managers should ensure business continuity plans are in place for storing refrigerated medicines, including vaccines, in the event of refrigerator breakdown, loss of electricity supply or other disruptions to the cold chain. This should be implemented immediately to prevent loss of stock and disruption of immunisation sessions.

5.6.2 If there is any breach of the cold chain, i.e. any current temperature record falling outside 2ºC to 8ºC as in 5.6.1, report the incident on the Trust incident system after the fridge contents have been safely stored.

5.6.3 Vaccines and other refrigerated medicines that have been stored outside of specified storage requirements should not be used without a risk assessment, based on a thorough understanding of the likely impact of the temperature variation on their efficacy and safety. These medicines should be quarantined within the cold chain and neither used nor destroyed until advice has been obtained (see section 5.7).

5.6.4 If the fridge current temperature is within the range 2ºC to 8ºC but maximum or minimum readings are outside of this range try to establish how long the temperature may have been outside the acceptable range. Seek advice on further action from either of the sources in section 5.7.
N.B. Fridge temperature may momentarily rise above 8ºC after opening the door but should return to 2-8C within a few minutes. It is therefore important to open the door as little as possible.

5.6.5 If it is necessary to move stock to alternative cold storage, it should be separated from other stock and clearly marked to indicate it should not be used until confirmed as safe to do so. If immediate transfer is not possible, keep the fridge door closed and regularly monitor and **record** the temperature up to the time of transfer using the independently powered thermometer.

5.6.6 If the electricity supply to the fridge has been disconnected **record** (a) the current fridge temperature using the independent thermometer and (b) time of recording and keep the door closed. **Reset** the thermometer (maximum/minimum readings should be the same as current fridge temperature). If the temperature and the maximum/minimum readings are between 2ºC to 8ºC reconnect the power supply, if possible. No further action is necessary.
If any reading is outside this range reconnect the power supply and record the time of reconnection. Try to establish how long the temperature has been outside this range and seek advice from either of the sources in section 5.7. If it is not possible to reconnect the fridge to the power supply consider moving the contents to alternative cold storage using validated cool boxes as in 5.6.5.

5.6.7 If the fridge is faulty contact BCAS Biomed (see 5.7 c) to correct the fault and use an independent thermometer to verify it is operating correctly before returning any vaccines or medicines to it.

5.6.8 Vaccine wastage must be reported to Public Health England

5.7 **Information Sources**

The following sources can be consulted in the event of a potential breakage of the cold chain:

a) Health Protection Unit: 0345 055 2022 (vaccines only). **Out of hours advice** 0844 9670082.
b) Medicines Information department of product manufacturer (refer to BNF or product SPC)
c) BCAS Biomed 01494 529527 callout@bcasbiomed.co.uk

d) Trust Medicines Management Team

5.8 **Clinical Trials**

5.8.1 Clinical trials should be monitored following local procedure.

6. Ambient Clinic Room Temperature Monitoring

6.1 The maximum ambient (air) temperature of any room used to store medicines outside of a refrigerator must be monitored and recorded at least once each working day using a digital thermometer. The maximum room temperature should be documented on the medicines storage temperature monitoring sheet (Appendix 1).

6.2 It is advisable to allocate a regular time each day to record the maximum room temperature so that each reading covers the previous 24 hours. The thermometer must be reset after recording each reading.

6.3 Where the ambient clinic room temperature is at risk of exceeding 25°C, action should be taken locally to reduce this by e.g. opening windows (whilst not compromising medicines security), removing any heat sources, moving medicines to alternative secure storage sites or switching on available ventilation or air conditioning units. Contact the Estate Services Helpdesk on 0300 300 36 36 for advice on alternative ventilation or storage sites.

6.4 If the above measures are insufficient to maintain the temperature below 25°C inform the Medicines Management Team. If the room temperature is recorded as 25ºC or above for 14 or more days in any 30 day period the expiry date of all medicines stored in the area must be reduced by 6 months at the end of a heatwave i.e. when ambient temperatures return to below 25ºC.

7. Training Requirements

7.1 Cold chain maintenance training is:
(a) included in the Safer Use of Medication Medicines Management training – mandatory for all registered healthcare professionals handling medicines in the Trust.
(b) an integral part of the Health Protection Agency's Core Curriculum for Immunisation Training (Core Topic 8) which is delivered within local Immunisation Essentials training events. All staff who administer immunisations and vaccinations are required to complete Immunisation Essentials training and appropriate update training (appendix 1).

7.2 If any training associated with this policy forms part of the statutory and mandatory* training provision for the Trust or other training 'required by role'* then employees will complete this as per their role and contractual requirements. Please refer to your LEaD home page for all your statutory, mandatory and role requirements. If training associated with this policy is a professional and/or developmental requirement this will be identified with your line manager.

*If the policy author/s have identified a need for an element of training associated with this policy to gain mandatory status then they must contact LEaD at LEAD@southernhealth.nhs.uk to ensure that they complete the relevant application form and follow the process for consideration for mandatory status and where appropriate executive approval.

8. Monitoring Compliance

8.1

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Policy compliance	Service & ward managers	Self-audit tool	Annual	Medicines Management Committee
	Medicines Management Team	Safe & Secure handling of medicines audit tool	Every 18 months	Medicines Management Committee
Incidents reported on cold chain breakage	Medication Safety Officer	Safeguard Ulysses	As they occur	Divisional Governance team

9. Policy Review

9.1 The policy and procedures contained within it will be in place for four years following approval. An earlier review will take place should exceptional circumstances arise resulting from this policy; in whole or in part, being insufficient for the purpose and/or if there are changes in national guidance.

9.2 This policy will be reviewed by the Medicines Management Team prior to presentation for ratification and approval by the Medicines Management Committee.

10. Associated Documents

1. Medicines Policy SH CP1
2. See section 1.5

11. Supporting References

1. Department of Health. Immunisation against infectious disease – 'The Green Book'
2. Public Health England. Protocol for ordering, storing and handling vaccines, March 2014
3. National Patient Safety Agency Rapid Response Report: Vaccine cold storage; NPSA/2010/RRR008 ,January 2010
4. The Safe and Secure Handling of Medicines guidance, Royal Pharmaceutical Society / Royal College of Nursing, 2018
5. Standards of proficiency for registered nurses and nursing associates, Nursing and Midwifery Council, 2018

Appendix 1

Designated Person:

Southern Health NHS Foundation Trust

MEDICINES STORAGE TEMPERATURE MONITORING SHEET

WARD_____MONTH_____YEAR_____ **Read – Record – Reset – React**

DAY ↓	FRIDGE TEMPERATURE (ºC) RECORD MINIMUM AND MAXIMUM TEMPERATURES									CURRENT FRIDGE TEMP	MAX CLINIC ROOM TEMP	Thermometer RESET (Initials)	RECORDED BY: (Initials)
	LESS THAN 2.0	2	3	4	5	6	7	8.0	OVER 8.0				
1													
2													
3													
4													
5													
6													
7													
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	Keep fridge door locked. Inform ward/dept manager. Fridge contents must not be used until advice has been obtained from the supplying pharmacy, a Trust pharmacist or the product manufacturer. **RESET** the max/min thermometer (max/min/current should read the same). Move fridge content to alternative pharmacy fridge if possible. Record current temperature using independent thermometer at least hourly if not 2-8ºC (use Appendix 2). Record the minimum/maximum temperatures after 24 hours. If temperature does not return to 2-8ºC contact BCAS Biomed, telephone: 01494 529527, email: callout@bcasbiomed.co.uk. **Record actions** taken below and submit an incident report.
	Continue to record temperatures **DAILY.**
CLINIC ROOM	Record **MAXIMUM** clinic room temperature **DAILY.** If it exceeds 25°C ask Medicines Management team for advice.
	THIS RECORD MUST BE KEPT FOR 2 YEARS

Use box below to **record actions** taken in response to temperatures out of range. Continue on a separate sheet if necessary

Date	Action taken (e.g. reported to BCAS/pharmacy, medicines quarantined)	Signature/name

Designated Person: **Appendix 2**

Southern Health NHS Foundation Trust

VACCINE COOL BOX TEMPERATURE MONITORING SHEET

Cool Box No:….. **Read – Record – Reset – React**

WORK BASE:……...

RECORD CURRENT TEMPERATURE ONLY.

On arrival at the immunisation site(s), then every two hours and on arrival back at base

DATE	TIME	COOL BOX TEMPERATURE (ºC)									RECORDED BY: (Initials)
		LESS THAN 2.0	2	3	4	5	6	7	8.0	OVER 8.0	

	Do NOT administer any vaccine in the box. Keep box closed. Inform line manager. Seek advice from a Trust pharmacist, Health Protection Unit, or the product manufacturer before using any affected product. **RESET** the max/min thermometer and record temperature hourly until it is between 2 to 8ºC or vaccines are transferred to a pharmacy fridge. Arrange alternative vaccine supply. **Record actions** taken below and submit an incident report.
	Continue to monitor temperature as per usual routine.
THIS RECORD MUST BE KEPT FOR 2 YEARS	

Use box below to **record actions** taken in response to temperatures out of range. Continue on a separate sheet if necessary

Date	Action taken (e.g. reported to BCAS/pharmacy, medicines quarantined)	Signature/name