

Standard Operating Procedure

Fridge and Clinical Room Temperature Monitoring for Safe Storage of Medicine

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Consultation groups	Medicines Committee
Approved by (Sponsor Group)	Medicines Committee
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Services	Applicable
Trustwide	x
Mental Health and LD	
Community Health Services	

Version Control Summary

Version	Date	Author	Status	Comment
1	01/07/10	Shameem Mir	Chief Pharmacist	
2	02/11/12	Reviewed by Rachel Stevens	Chief Technician Medicines Management	Review – no changes
3	11/10/13	Reviewed by Louise Missen	Clinical Pharmacist	Fridge monitoring removed from 3 monthly pharmacy CD audit. Added info about checking for expired/unneeded fridge medication
4	27/10/14	Reviewed by Andrea Okolokwe	Lead Pharmacist, Newham	Addition of clinical room temperature monitoring to SOP
5	26/10/20	Reviewed by Nicola Horan	Senior Pharmacy Technician	Additional clinical room temperature monitoring and reducing expiry dates to SOP

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Purpose	To ensure that medicines stored in fridge and in clinical rooms are at the appropriate temperature so that they maintain their stability and integrity.
Scope	This procedure covers the monitoring of fridge and clinical room temperatures for medicines supplied by the pharmacy department and patient's own drugs that have been assessed as appropriate to use and stored in a ward or community either in a fridge or in the clinical room.
Responsibility	The senior nurse is responsible for ensuring that all medicines within his/her clinical area are stored in the appropriate conditions. The ward must have one trained individual with at least one trained deputy, responsible for the recording and monitoring of the ward environment.
Process stages	<ul style="list-style-type: none"> • Monitor the temperature in the fridge and clinical room using a maximum-minimum thermometer once a day on every working day. • Room temperature monitoring best if monitored same time each day and the thermometer should be reset after each reading. • Advice on how to use the thermometer can be obtained from the pharmacy department • Record the actual, minimum and maximum temperatures on the recording chart (attached). • Sign the fridge and clinical room chart with name as well as signature and record on the chart that the thermometer has been reset. • The record should be readily accessible for easy reference and retained until the next audit. • Pharmacy will review the temperature charts as part of the 3 monthly Controlled Drug audit cycle. • Temperature charts must be stored for a minimum of 2 years. • The fridge should be defrosted (if not automatically defrosting) and cleaned once a month. This should be documented on the recording chart. • If the fridge temperature is outside the range of 2 – 8 °C first reset thermometer then check minimum thirty minutes later. If still outside the recommended range, quarantine the medicines and contact pharmacy for advice. • If the clinical room temperature is above 25 °C first reset thermometer then re-check. If temperature still remains above 25 °C for 7 consecutive days then report to pharmacy for an estimate on reduction in shelf life of medicines.
Known risks	<ul style="list-style-type: none"> • Specialised refrigerators are available for storage of pharmaceutical products, and must be used. Ordinary domestic refrigerators must not be used. • Food, drink, and clinical specimens must never be stored in the same refrigerator as medicines. Opening of the refrigerator door should be kept to a minimum. • The accidental interruption of the electricity supply can be prevented by using a switchless socket or by placing cautionary notices on plugs and sockets. • Refrigerators should not be situated near a radiator or any heat source that could affect their working, and should be appropriately ventilated. • Ice should not be allowed to build up within the refrigerator as this reduces effectiveness. Records should be kept of regular servicing, defrosting and cleaning. • An approved cool box or alternative refrigerator should be used to store medicines during defrosting of the main refrigerator. After defrosting, medicines should only be replaced once the refrigerator has returned to the correct temperature. • Digital thermometers are the most reliable. Sufficient space should be allowed in the refrigerator so that air can circulate freely. Over-packed refrigerators lead to poor air flow, potential freezing and poor stock rotation. • Stocks should be stored within the refrigerator so that those with shorter expiry dates are used first. • Medicines must be kept in their original packaging when stored so that they retain information on batch numbers and expiry dates. The packaging is also part of the protection against light and changes in temperature. • Medicines must not be stored in the door, in the bottom drawers, or adjacent to the freezer plate of the refrigerator. If there are temperature variations outside of the recommended +2C° to +8°C C range, they usually occur in these parts of the refrigerator.

Refrigerator temperature monitoring chart (print page 5 & 6)

Ward /Community Team _____

Name of person(s) responsible for monitoring _____

MONTH & YEAR _____ Defrosted on: _____ (if applicable)

Date	Time	Actual	Min	Max	Reset (Y/N)	All temperature readings between 2 – 8 °C (Y/N)	What action taken if temperatures are outside 2-8°C	Name and signature
03	09.00	10	3	8	Y	N	Contacted pharmacy	A.N OTHER
01								
02								
03								
04								
05								
06								
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Additional reading carried out

Date	Time	Actual	Min	Max	Reset (Y/N)	All temperature readings between 2 – 8 °C (Y/N)	What action taken if temperatures are outside 2-8°C	Name and signature

Information

1 **If ANY of the readings are outside the 2-8°C range do not use medication, contact your local pharmacy department immediately for advice.**

2. Refrigerator readings must be carried out on each working day by a nominated person or a deputy in their absence.

Named Person: _____

Named Deputy: _____

3. The ACTUAL, MINIMUM & MAXIMUM temperatures must all be read.

4. The following information must be recorded on the monitoring chart overleaf including

- Date (already printed on monitoring chart)
- Time
- ACTUAL, MINIMUM, MAXIMUM temperatures
- Whether temperatures are within 2-8°C range
- Action taken if outside range
- Name and signature of person carrying out reading

5. Thermometer(s) must be rest after readings have been recorded.

6. ALL readings should be between 2 – 8°C, if outside this range see point 1 above.

7. Logs must be kept in a secure place for a minimum of 2 years or sent to Pharmacy MEH.

Clinical Room Temperature Monitoring Chart (print page 7 & 8)

Ward /Community Team _____

Name of person(s) responsible for monitoring _____

MONTH & YEAR _____

Date	Time	Actual	Min	Max	Reset (Y/N)	All temperature readings 25 °C (Y/N)	What action taken if temperatures are outside 25°C	Name and signature
03	09.00	10	3	8	Y	N	Contacted pharmacy	A.N OTHER
01								
02								
03								
04								
05								
06								
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09								
10								
11								
12								
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Additional reading carried out

Date	Time	Actual	Min	Max	Reset (Y/N)	All temperature readings between 25 °C (Y/N)	What action taken if temperatures are outside 25°C	Name and signature

Information

1 **If ANY of the readings are outside the 25°C range for 7 consecutive days do not use medication, contact your local pharmacy department immediately for advice.**

2. Clinical room readings must be carried out on each working day by a nominated person or a deputy in their absence.

Named Person: _____

Named Deputy: _____

3. The ACTUAL, MINIMUM & MAXIMUM temperatures must all be read.

4. The following information must be recorded on the monitoring chart overleaf including

- Date (already printed on monitoring chart)
- Time
- ACTUAL, MINIMUM, MAXIMUM temperatures
- Whether temperatures are above 25°C range
- Action taken if outside range
- Name and signature of person carrying out reading

5. Thermometer(s) must be rest after readings have been recorded.

6. ALL readings should be 25°C, if outside this range for 7 consecutive days, see point 1 above.

7. Logs must be kept in a secure place for a minimum of 2 years or sent to Pharmacy MEH.

Estimating the impact in terms of reduction in shelf life

In the event of medicines being stored at higher temperatures than the range stated on their packaging it is possible to estimate the reduction in shelf life using a Q10 estimation (Simonelli & Dresback).

- if continuous readings of $>25^{\circ}\text{C}$ but $<30^{\circ}\text{C}$ are recorded for a 7 day period a reduction of 2 weeks on the manufacturer's expiry date should be made.
- If continuous readings of $>30^{\circ}\text{C}$ but $<35^{\circ}\text{C}$ are recorded for a 7 day period a reduction of 4 weeks on the manufacturers expiry date should be made.
- If greater temperatures are recorded staff are advised to contact Pharmacy Department immediately for advice.
- Following discussion with the Pharmacy Department and to reduce repeated actions, over the warmer months a reduction of 3 months can be made to the manufacturer's expiry date.
- Stickers can be attached to each item detailing the reduction in the stated expiry date, the original manufacturers expiry date and batch number must not be deleted
- On occasion it is necessary for health care professionals to remove medicines from temperature monitored areas e.g. for the purpose of domiciliary visits or ease of access of emergency medicines in resus trolleys. E.g. Adrenaline injection. In these situations an expiry of 6 months will be given from the date the medicine is removed from the temperature monitored area. The medication must be labelled to this effect.
- Medication brought onto in-patient wards by service users is their own property. The Trust has no assurance of storage conditions prior to admission and would make the assumption that the integrity of the medication has not been compromised unless lead to believe otherwise. The medication is intended to be used for the service user and the expiry date need not be altered.

As a general rule medicines should be stored at a room temperature not exceeding 25°C

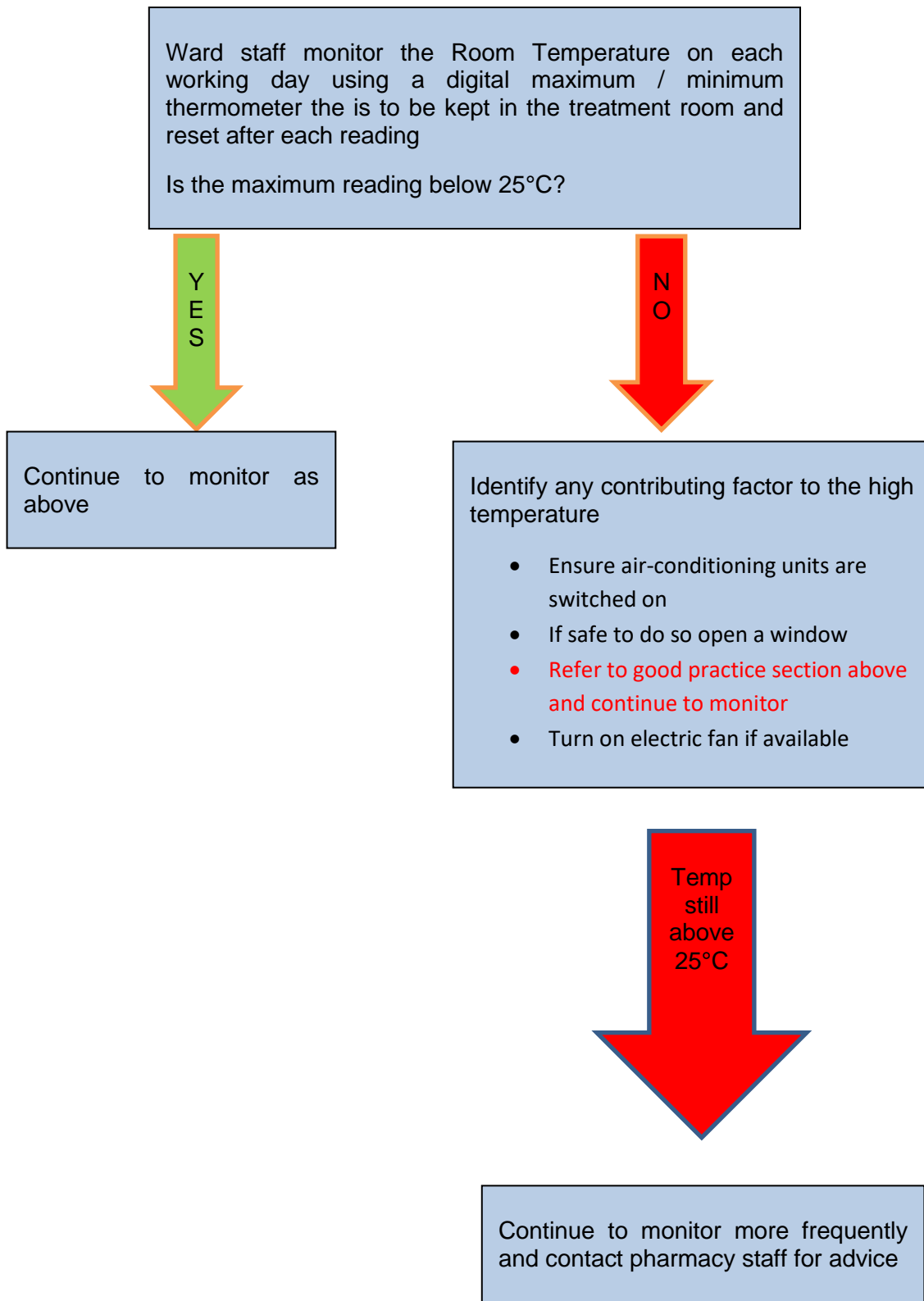
Room Temperature		Number of days with continuous high temperature	Manufacture Expiry
$>25^{\circ}\text{C}$	$<30^{\circ}\text{C}$	7 days	Reduce expiry by 2 weeks
$>30^{\circ}\text{C}$	$<35^{\circ}\text{C}$	7 days	Reduce expiry by 4 weeks

Limitations & assumptions

The method described is based on the assumption that the reaction kinetics for the degradation does not change with temperature changes. This can be considered valid for small changes in temperature but users should be wary of applying this method to temperatures above 40°C .

This extrapolation does not take into account humidity, so be wary of applying this to medicines that have been removed from their primary packaging.

Appendix 1



Do not discard medication before seeking advice from the Pharmacy Department

Appendix 2

Action to be taken if Room Temperature remains above 25 °C

If temperature readings continue to be above 25°C for a continuous 7 day period and steps have been taken to reduce the temperature, contact the Pharmacy Department



The following information should be recorded

1. Actual room temperatures and maximum temperature recorded
2. Times of recording temperatures
3. List of any short dated stock (<6 months expiry remaining)
4. List of any high cost and low usage drugs



Pharmacy will assess the risk of using the medication and where appropriate will implement the reduction of expiry dates agreed at a local level.



Before any decision to discard medication is made data loggers will be used to assess the length of time within a 24 hour period the temperature deviates from the range.

References

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- 1) Policy for Temperature Monitoring of Medicinal Products, NHS Dorset CCG, 2013.
- 2) Guidance for reducing the shelf life of medicines in the event of a heat wave, QC North West England Medicines Management Team, July 2014.
- 3) Guidance from NWBH on the Management of Medicines and Wound Care Products Stored in Clinical Areas- Temperature Control
- 4) FRIDGE MONITORING PROCEDURE AND COLD CHAIN' STANDARDS FOR MEDICINES IN WARDS AND CLINICS, CNWL, 2018
- 5) Monitoring Clinic and Treatment Room Temperatures, CNWL, 2018
- 6) Room Temperature monitoring for storage of medicines, NELFT, 2016
- 7) Temperature monitoring of refrigerators used for storage of medicines, NELFT, 2016