The Royal Wolverhampton NHS Trust

MP10
Temperature Management for Medicines Storage

Contents

1.0 Policy Statement

This policy covers the receipt, storage, transportation and monitoring of temperatures for medicines in The Royal Wolverhampton NHS Trust.

All medicines, including vaccines and biologics, should be stored under conditions which ensure that their quality and effectiveness is maintained. Medicines are assigned storage conditions and shelf lives by the pharmaceutical manufacturer based upon:

- Chemical degradation of the active ingredient or any of the other ingredients (excipients),
- Physical degradation of the medicine or the container,
- Whether the medicine or the container may be damaged by freezing, and
- Whether it is necessary to prevent microbial growth.

Manufacturers can disclaim responsibility for any product stored outside of the manufacturer's authorisation.

This policy has been developed to ensure adherence to manufacturers' storage recommendations thereby reducing risk of compromising the quality and safety of products administered to patients.

Compliance with this policy is mandatory for all staff employed by and, or working within The Royal Wolverhampton NHS Trust. It is the professional responsibility of all staff to update themselves on this policy on an annual basis.

The policy is supported by procedures which are listed as hyperlinked documents at the end of the policy and referred to in the policy text where appropriate.

In adhering to this Policy, all applicable aspects of the Conflicts of Interest Policy must be considered and addressed. In the case of any inconsistency, the Conflicts of Interest Policy is to be considered the primary and overriding Policy.

2.0 Definitions

Ambient temperature – A general term used to describe room temperature storage

conditions falling between 15°C and 30°C.

Chief Technician for Purchasing and Distribution – The pharmacy technician who is the lead for purchase, receipt and distribution of medicines and who is also the named Responsible Person on the Trusts MHRA Wholesaler Distribution Authorisation.

Clinical Area – All areas where medicines are stored: in-patient wards, theatres, out-patient clinics, community clinics, health centres, primary care premises.

Clinical Director of Pharmacy – The pharmacist who is the professional head and manager of the pharmaceutical service of The Royal Wolverhampton NHS Trust.

Cold Chain - The storage and transportation of pharmaceuticals requiring controlled low temperature storage between 2 and 8°C from manufacturer until the point of administration to a patient.

Directorate Pharmacist – A senior pharmacist with responsibility for a specific clinical directorate within the Royal Wolverhampton NHS Trust.

Good distribution practice (GDP) - GDP is a quality system which includes standards for purchase, receiving, storage and transport of medicinal products for use in patients.

Healthcare Professional – A term used to describe a person where more than one particular professional group may undertake a task described in the policy.

Midwife – A midwife registered on the Nursing and Midwifery Council (NMC) register and who has a legal right to practice.

Nurse – Any member of the nursing profession, including nurses in training and nurse associates.

Nurse in Charge – A nurse or midwife with operational responsibility for the Ward or Clinical Area during a shift.

Pharmacist – A person registered by the General Pharmaceutical Council (GPhC) in the register of Pharmacists.

Pharmacy Technician – A person registered by the General Pharmaceutical Council (GPhC) in the register of Pharmacy Technicians.

3.0 Accountabilities

3.1 Corporate Responsibility

The Trust Chief Executive is responsible for ensuring that medicines management within the Trust conforms to best practice at all times. This responsibility is delegated to the Clinical Director of Pharmacy, who is the medicines management lead for the Trust. This policy and associated procedures are guided by legislation, governmental directives, the General Pharmaceutical Council's (GPhC) guidance, and local policies and procedures agreed by the Trust's Medicines Management Group (MMG).

3.2 Receipt

The Chief Pharmacy Technician for Purchasing and Distribution is responsible for the receipt of medicines into the Trust from external suppliers and onward distribution from pharmacy to clinical areas.

3.3 Storage

Clinical area leads are responsible for the appropriate storage of medicines within their

department.

3.4 Temperature Monitoring

Clinical area leads are responsible for monitoring ambient and fridge temperatures, and ensuring backup systems are in place should the fridge fail, or ambient temperatures exceed 30°C. Temperature monitoring can be delegated to suitably trained healthcare professionals, including nursing and midwifery staff, healthcare assistants and pharmacy staff.

Clinical area leads are responsible for ensuring staff have received appropriate training to provide competence with temperature monitoring.

Clinical area leads also have responsibility for cascading any relevant information regarding the use of fridges and temperature monitoring equipment.

All staff with responsibility for temperature monitoring are responsible for implementing necessary action in the event of the fridge temperature being too high or too low, or ambient temperature being too high, and completing a Trust incident form (Datix) to record the event.

The Pharmacy Department is responsible for the provision of accurate and up to date advice regarding the use of medicines which have been stored outside of the manufacturers recommended temperature range.

4.0 Policy Detail

4.1 Medicine Storage in Trust Pharmacy

4.1.1 Receipt of Refrigerated Products

The Responsible Person for the Trust Medicines and Healthcare Products Regulatory Agency (MHRA) Wholesale Dealers Authorisation checks that all wholesalers and suppliers from which medicines are obtained have a manufacturers or wholesale dealers license and a certificate of Good Distribution Practice. This is checked annually to ensure all suppliers are bona-fide and working within current legislation in accordance with local pharmacy standard operating procedures.

Refrigerated items must be placed in the goods receipt fridge immediately upon delivery, removing all excess packaging but leaving the item within the original manufacturer's packaging. Refrigerated items must not be exposed to room temperatures for prolonged periods of time. Stock is managed in accordance with local pharmacy standard operating procedures.

All orders must be checked on receipt for leakage, damage and discrepancies before accepting and signing for the delivery. In the event of a discrepancy, do not sign for the order but contact the supplier and follow their instructions.

It is the responsibility of the named individuals within Pharmacy to ensure that all documentation in relation to orders and receipts is accurate and up to date.

The delivery note must be retained on site for 2 years.

4.1.2 Temperature Monitoring and Recording within Pharmacy

All temperatures within the Pharmacy Department are continually monitored by the Hanwell EMS system. Temperatures are monitored in accordance with local pharmacy standard operating procedures. Electronic records are maintained for the duration the temperature probe is active within the Hanwell system. Records of inactive probes are stored in a temperature archive folder.

Records of temperature monitoring within the Clinical Trials Room will be maintained indefinitely, and at least until the designated sponsor timeline has elapsed.

Ambient temperature within the medicines storage areas of the Pharmacy Department will be maintained within the parameters of 15 to 25°C.

All refrigerators used to store medicinal products will be maintained within the parameters of 2 to 8 °C.

In the event that a temperature goes outside the normal range for longer than 5 minutes, the alarm will be activated, and the allocated persons will be notified.

Between the hours of 5pm and 9am, issues identified by the Hanwell EMS will be communicated to Trust Switchboard via the DRAX system. Switchboard will contact the on-call pharmacist who will attend site to investigate and address the issue identified.

The system is also set up to email all the authorised system administrators to make them aware of any deviations in temperature, and to forward text messages to those members of staff that have this application designated to them. These alerts are set up for use 24 hours a day, therefore no alarm will be missed.

Temperature deviations will be investigated in accordance with local pharmacy standard operating procedures.

4.2 Temperature Management for Medicine Storage in Clinical Areas

4.2.1 Ambient Storage Conditions in All Clinical Areas

Medicines manufacturers may define ambient storage temperature as being within a variety of different ranges from 8 °C to 30 °C. If there are specific requirements this will be stated on the packaging. Ideally all medicines storage areas would be controlled between 15 °C and 25 °C, which is suitable for all ambient medicines. In practice, many locations do not have air conditioning that gives this level of control, nevertheless steps can be taken to optimise ambient storage areas, which include:

- Air conditioning should be installed if possible.
- Radiators should be switched off in medicines storage areas.
- Medicines should be stored away from sources of heat and direct sunlight. Reflective film can be added to windows.

- Keep windows and doors closed. Windows may be opened to aid cooling but only if it is cooler outside and it doesn't pose a security risk.

The ambient temperature should be maintained within the range 15ºC to 25ºC. For practical reasons, in areas which do not have air conditioning, ambient temperatures will be accepted to a maximum of 30 ºC where a risk assessment is in place.

A risk assessment template has been produced and should be completed by each clinical area with the support of the Pharmacy Team (Appendix 1: Risk Assessment for Medicines Storage at Ambient Temperatures up to 30ºC).

4.2.2 Refrigerated Storage Conditions in All Clinical Areas

The fridge must be a specialised refrigerator for storage of pharmaceuticals or vaccines between 2ºC and 8ºC (aim for midpoint 5ºC). Newly purchased fridges must have an integral data logger for the constant monitoring of the temperature range. Ordinary domestic fridges must not be used. The Pharmacy Team can be contacted for advice on fridges suitable for drugs.

The fridge must be dedicated to storing pharmaceutical products only. Food, drink and clinical specimens must never be stored in the same refrigerator as medicines.

All medicine fridges must be kept locked.

The fridge must be opened only when absolutely necessary and, for as short a time as possible.

The fridge must not be sited in front of a radiator.

The fridge must be of the correct size so that there is enough space for air to circulate freely around the back of the fridge.

The fridge plug must be secured to avoid accidental disconnection (i.e., wired directly into a switchless socket) or labelled prominently with "Do not switch off".

Regular visual inspections must be done to ensure the fridge is safe and fit for purpose.

A maintenance contract must be in place to ensure yearly servicing of the fridge and calibration of the thermometer. All servicing and calibration checks must be documented and kept by the fridge.

The fridge must be regularly cleaned and defrosted according to the manufacturer's instructions and records kept by the fridge. A record of the cleaning or defrosting must be made on the Fridge Temperature Monitoring Record (Appendix 2). If the fridge is not self-defrosting, the cold chain must be maintained whilst defrosting the fridge by moving all stock to another fridge.

The contents must be evenly distributed within the fridge to allow air to circulate. Products must not be placed in the door. The fridge must not be overfilled.

Stock must be rotated according to expiry date and the older stock positioned at the front of the fridge.

The required specifications for medicines refrigerators can be found in Appendix 3.

Reconstituted Vaccines

Some vaccines need reconstituting with a diluent. It is not good practice to do this in advance of administration, however if using a multidose vial it may be considered. Any reconstituted vaccine that is not administered straight away should be labelled with the time, date and initials of the person who reconstituted the vial and the subsequent expiry, and then stored following the manufacturers' guidance and local policies. Please note that the storage conditions and expiry of a reconstituted vaccine may be different.

4.3 Thermometers

4.3.1 Ambient Temperature Thermometers

A calibrated maximum, minimum and current temperature digital thermometer must be available in **every** room storing stock medication, including fluid rooms, sited in an area recommended by a Pharmacy Technician or Pharmacist. The thermometer must be calibrated annually, or in line with the manufacturers recommended interval.

Pharmacy approved thermometers can be obtained from the Procurement Department.

Electronic continuous ambient temperature monitoring by a Pharmacy approved system is also acceptable (see section 4.4.1).

4.3.2 Fridge Thermometers

Fridges must be monitored with an integrated digital maximum and minimum thermometer. Where using a maximum and minimum thermometer, the probe must be positioned in the middle of the fridge amongst the medicines. The probe must not rest on, or be near, the fridge light and not be near the door.

New fridge models must have an integrated method of continuous temperature monitoring e.g., using an SD card. Clinical areas which are unmanned for extended periods of time are encouraged to install a calibrated data logger for continuous temperature monitoring. In the event of a temperature deviation, Medicines Information will request the data stored on these devices in order to give accurate advice regarding safety and use of affected medicines.

Electronic continuous ambient temperature monitoring by a Pharmacy approved system is also acceptable (see section 4.4.1).

4.4 Monitoring and Recording Ambient and Refrigerator Temperatures

MP10 Temperature Management for Medicines Storage Standard Operating Procedures 1 and 2 provide the standard instructions to be followed for the monitoring of ambient and medicines fridge temperatures. (See Appendix 4: The Monitoring and Recording of Ambient (Room) Temperatures, and Appendix 5: The Monitoring and Recording of Fridge Temperatures.)

A nominated individual must be responsible for monitoring the ambient and fridge temperatures and ensuring action is taken in the event of a deviation. Temperature monitoring can be delegated to suitably trained staff members.

The clinical area must have backup systems in place should the fridge fail e.g., clinical areas located geographically close together must agree a backup plan to be implemented in the event of refrigerator breakdown.

Temperatures must be checked and recorded daily. Clinics which do not operate daily must check temperatures at the start of each working day. It is mandatory that areas which do not operate daily, and keep stock stored in a fridge, have an SD card or USB stick *in situ* so that an accurate record of temperature can be maintained when the area is unmanned.

Temperatures must only be recorded on Trust approved paperwork. Medicines Fridge Temperature Monitoring Record (Appendix 2) and Ambient (Room) Temperature Monitoring Record (appendix 6) can be ordered from Clinical. The record is supplied as a booklet of 12. One record must be maintained for each fridge and each room where medicines are stored.

The following must be monitored using the maximum and minimum digital thermometer and recorded each working day on the Ambient (Room) Temperature Monitoring Record or Fridge Temperature Monitoring Record:

a. The maximum temperature;

b. The minimum temperature;

c. The actual (current) temperature;

d. The time the temperature was recorded;

e. Action taken if recorded temperature is outside recommendations.

The digital thermometer **must** be reset after each reading is made. Records should be easily accessible for reference.

Temperature monitoring records must be stored in the clinical area for 2 years as evidence of safe and secure handling of medicines. When medicines for clinical trials have been stored in ward or clinical area fridges, the receiving ward must contact the Research Nurses as soon as possible in order that the appropriate records can be maintained as per the designated sponsor definition.

4.4.1 Clinical Areas with Digital Temperature Monitoring Systems

In areas where an electronic temperature recording system has been installed, the clinical area lead is responsible for temperature management within the area.

The area must have a local standard operating procedure for the monitoring and management of the system, including the roles and responsibilities of staff. The SOP must be shared with the Pharmacy Department for comment, prior to directorate approval. The area will be responsible for managing temperature deviations, and business continuity in the event of a

deviation.

4.5 Temperature Deviations

Temperature deviations (i.e., ambient temperatures above 30ºC, or fridge temperatures outside of the recommended range of 2ºC to 8ºC) must be managed following the appropriate standard operating procedure:

Temperature Management for Medicines Storage Standard Operating Procedure 3: Action to be Taken Following AMBIENT (Room) Temperature Deviations above 30ºC (Appendix 7);

Temperature Management for Medicines Storage Standard Operation;

Procedure 4: Action to be Taken When Medicine Fridge Temperatures are Outside of the Recommended Range of 2ºC to 8ºC. (Appendix 8).

For medicines fridge temperature deviations follow the 'Fridge Temperature Discrepancy' flowchart (Appendix 9).

Pharmacy may request completion of a Fridge Temperature Excursion Proforma (Appendix 10).

4.6 Transporting Refrigerated Medicines

An approved, designated medicines cool box or cool bag must be used for transporting products requiring cold storage. Domestic cool boxes must not be used. The time between removing products from cool storage and use must be kept to a minimum.

Any unused products from a clinic session which have been stored between 2ºC and 8ºC may be returned to the fridge for future use. If the storage criteria have not been met during a session, stock must not be returned for reuse. To reduce waste, a minimum amount of stock should be removed from the fridge or cold box at a time.

Standard cool box and cool bag specifications are detailed in Appendix 11.

5.0 Financial Risk Assessment

1	Does the implementation of this policy require any additional Capital resources? No – if a Trustwide solution can be found for the continuous monitoring of fridge and ambient temperatures a business case would be required at that point.	Yes – No
2	Do the implementation revenue resources of this policy require additional expenditure? No – USB data loggers for fridges without SD cards (mandatory in clinical areas with prolonged periods unmanned) should already have been purchased by the clinical areas affected.	Yes - No
3	Doe the implementation of this policy require additional manpower?	Yes - No

4	Does the implementation of this policy release any manpower costs through a change in practice? No – although Medicines Information respond to many temperature related enquiries, it is not possible to determine if the policy will reduce the number of enquiries.	Yes - No
5	Are there additional staff training costs associated with implementing this policy which cannot be delivered through current training programmes or allocated training times for staff?	Yes - No
	Other comments	

6.0 Equality Impact Assessment

An equality analysis has been carried out and it indicates that:

Tick	Options
√	A. There is no impact in relation to Personal Protected Characteristics as defined by the Equality Act 2010.
	B. There is some likely impact as identified in the equality analysis. Examples of issues identified, and the proposed actions include: •

7.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the policy up to date. Any revisions to the policy will be reviewed by the Trust's Medicines Management Group before being submitted through the Trust's policy approval procedure. The attached standard operating procedures provide detail regarding the content within this policy. Any revisions to the standard operating procedures will be approved through the Trust's Medicines Management Group and ratified by the Policy Review Committee.

8.0 Communication and Training

Appendix 4 of Trust policy OP41 contains training needs analysis of healthcare staff in relation to this policy.

Ward and departmental managers are responsible for ensuring that all healthcare professionals involved in the use of refrigerated medical products are trained to be competent to do so.

Divisional and departmental managers have a responsibility to ensure that copies of the Temperature Management for Medicines Storage Policy are available to their staff, and they must ensure that staff are fully aware of all the relevant procedure applicable to their ward/department/clinical area.

9.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Committee
Daily records maintained by ward/clinic staff	Ward based pharmacists	Ward Storage Audit – Rolling programme of monitoring against regional checklist	Annual	Medicines Management Group
Daily records maintained by ward/clinic staff	Ward based technicians	Ward weekly tasklist	Weekly	Feedback provided to ward managers at point of audit
Incident reports and temperature management enquiries	MSO	Datix Records and Medicines Information Enquiries recorded on Mi Databank	Quarterly	Medicines Safety Group

10.0 References - Legal, professional or national guidelines

https://www.cqc.org.uk/guidance-providers/adult-social-care/medicines-requiring-fridge-storage

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf

https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Part A - Document Control

To be completed when submitted to the appropriate committee for consideration/approval

Policy number and Policy version: MP10 Version: 2.0	**Policy Title** **Temperature Management for Medicines Storage**	**Status:** Final		**Author:** **Medication Safety Officer** **Chief Officer Sponsor:** **Chief Medical Officer**
Version / Amendment History	Version	Date	Author	Reason
	1	February 2019	MSO	Original policy
	1.1	June 2019	MSO	Virtually Approved - Appendix 6 has been separated into 2 separate SOPs
	1.2	March 2022	MSO	Reviewed by Chief Medical Officer – Extended to August 2022 pending full review
	1.3	October 2022	MSO	Reviewed by Chief Medical Officer – Extended to March 2023 pending full review
	1.4	November 2022	MSO	Reviewed by Chief Medical Officer – Extended to November 2023 pending full review
	2.0	March 2023	MSO	Full Review – Updated to include ambient temperature monitoring
Intended Recipients: All Trust employees with responsibility for the safe and secure storage of medicines.				
Consultation Group / Role Titles and Date: Pharmacy Management Team, Medicines Management Group, Policy Review Group				

Name and date of Trust level group where reviewed	Version 1: Trust Policy Group - February 2019 Chief Medical Officer Table-Top Review November 2022 Version 2: Medicines Management Group April 2023 Trust Policy Group September 2023
Name and date of final approval committee	Trust Management Group – September 2023
Date of Policy issue	October 2023
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated – see section 3.8.1 of Attachment 1)	September 2026 - Every 3 years
Training and Dissemination: Via Trust Internet Bulletin, Via Divisional and Management Forums	
To be read in conjunction with: MP01 – Prescribing, Administration and Storage of Drugs MP04 – Management of Medication Errors Pharmacy Department Only - Quality Management System Documents and Good Distribution Practice (GDP)	
Initial Equality Impact Assessment (all policies): Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904	
Monitoring arrangements and Committee	Divisional Governance Groups Pharmacy Governance Group Medication Safety Group Medicines Management Group

nent summary/key issues covered.

olicy sets out the standards for all Trust employees involved in the handling of medicines and the appropriate temperature storage conditions.

The policy defines standards for Trust clinical areas in:

- Receipt of medicines to the Trust
- Storage
- Monitoring of refrigerator and ambient temperatures

These standards have been developed to ensure that manufacturers storage recommendations are adhered to, thereby reducing the risk of compromising the quality and safety of products administered to patients.

Key words for intranet searching purposes	Ambient, Fridge, Temperature, Thermometer,

Risk Assessment for the management of medicines stored at ambient temperatures.

The Royal Wolverhampton NHS
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Refer to the guidance before completing and use a separate form for each risk. After completing Sections A-C please give this form to your manager. Thank you.

SECTION A: Initial Assessment Details		
Date of Assessment:	April 2023	**Risk Assessor(s):-** Paula Haydon Ward/Clinical Area Pharmacist: Ward/Clinical Area Manager:
Directorate / Specialty:	Pharmacy Department	
Location:	Trust wide Medicines Storage Areas	

SECTION B: Risk – Medicines stored at temperatures outside of the manufacturers recommendations

Provide a description of the local hazard, problem or concern (potential dangers / harm of risk): identified from your service activity or the trigger lists provided in HS 01 Management of Health and Safety Policy. Trigger lists are available for: Workplace, Manual Handling, COSHH, DSE, Work Equipment, and Slips, Trips and Falls. (Attach Risk Assessment to trigger sheet where applicable).

Medicines specify the required storage temperature on their packaging or labelling and in their Summary of Product Characteristics (SmPC). For ambient storage medicines it is usually stated as a maximum of 25^{O}C or 30^{O}C. In some instances, there are no special storage requirements. This may be stated on the packaging or may only be stated on the pack leaflet or SmPC. All medicines in this category are relatively robust and are usually allocated a long shelf life (typically 2 years). Medicines that are susceptible to degradation by high ambient temperatures over a relatively short period will have more stringent requirements e.g. store in a refrigerator or a cool room, and generally have shorter shelf lives.

Medicines may be stored at ambient temperature in a variety of different areas including:

- a pharmacy store or dispensary,
- a ward or clinic medicines cupboard,
- an ambulance and
- a GP surgery.

Ideally, all medicines storage areas would be controlled between 15ºC and 25ºC, which is suitable for all ambient medicines. Pharmacy departments are expected to be able to provide this level of temperature control for medicines. In practice, many locations do not have air conditioning that gives this level of control. Nevertheless, there are steps that can be taken to optimise ambient storage areas.

Mandatory Actions:

1. Take actions to reduce ambient temperature in the room:
   a. Turn off radiators,
   b. Insulate hot water pipes and hot air pipes,
   c. Install window blinds and, or heat reflecting window film,
   d. Install portable air conditioning units, and

e. Re-route air handling.

2. Take actions to reduce stock holding in the area to a minimum:
   a. Review stock lists every 6 months to ensure stock turnover is such that the stock will be used within the manufacturer's expiry date,
   b. Identify temperature sensitive stock, and
   c. Strict stock rotation.
3. Contact the Pharmacy Team for additional support and advice if the ambient temperature exceeds 30 ºC.

What is affected:

- Medicines stored in clinical areas without air conditioning.

What is the potential outcome(s)?

Cost implications

Risk of litigation

How was the risk identified:
Routine ambient temperature monitoring in area storing medicines

Control Measures in Place	Circle	Responsible/Lead for Control	Date Started	Gaps in Controls
Radiators turned off	Yes No N/A			
Hot water pipes/ hot air pipes insulated against heat loss	Yes No N/A			
Windows covered with blinds or heat reflecting foil	Yes No N/A			

Install portable air conditioning units	Yes No N/A			
Re-route air handling in area	Yes No N/A			
Review stock levels every 6 months. Reduce holding when indicated.				
Strict stock rotation.				
Temperature sensitive medicines identified, and levels reduced to minimum.				

Initial Risk Evaluation with controls: (Please use the Trust Categorisation Matrix and circle below)				
Likelihood: 1 2 **3** 4 5	*Consequence:* 1 2 3 **4** 5	*Severity:* (1-3) Green	(4-6) Yellow	**(8-12)** **Amber**	(15+) Red

SECTION C: Treatment Plan (Further measures required to reduce the risk)

Action No	Action Required	Responsible/Lead for implementation	Timescale for completion (MUST have date, NOT on-going)	Date Action Complete
1	Notify all trust staff via Medical Director memo			
2				
3				

SECTION D: To be completed by the areas Lead Manager for Risk / Head Nurse.				
Risk Re-Evaluation after Action(s) Implemented: (Please use the Trust Categorisation Matrix and circle below) i.e. the target risk score once actions are in place				
Likelihood: 1 **2** 3 4 5	*Consequence:* 1 2 **3** 4 5	*Severity:* (1-3) Green	(4-6) Yellow	(8-12) Amber	(15+) Red

Recommended actions in Section C are agreed and I have added as necessary			
Full Name:		**Designation:**	**Clinical Director of pharmacy**
Signature:		**Date:**	

Date for Review:	

SECTION E: RISK ASSESSMENT REVIEW SHEET

Treatment Plan (Further measures required to reduce the risk)

Date of Review	Actions required/brought forward from last review (state action numbers)	Changes to/or new controls	Grade	Responsible / Lead for Implementation of Action	Timescale for Completion	Date Action Complete	Managers Signature for RA & Actions	Comments (Barriers / Progress)

Date of Review	Actions required/brought forward from last review (state action numbers)	Changes to/or new controls	Grade	Responsible / Lead for Implementation of Action	Timescale for Completion	Date Action Complete	Managers Signature for RA & Actions	Comments (Barriers / Progress)

Next Review Date:

Date of Review	Actions required/brought forward from last review (state action numbers)	Changes to/or new controls	Grade	Responsible / Lead for Implementation of Action	Timescale for Completion	Date Action Complete	Managers Signature for RA & Actions	Comments (Barriers / Progress)

Next Review Date:

The Royal Wolverhampton Hospitals NHS
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Risk Assessment Form: Guidance for Completion

This form is to be used by those who have the responsibility and have had training to undertake risk assessments. A new form must be completed for each new risk identified. All sections of this form are mandatory.

SECTION A: Assessment Details

Date of Assessment: The date the assessment was undertaken.

Directorate/Specialty: The directorate/specialty that the risk assessment is being conducted by or on behalf of.

Location: The exact location that the risk assessment is focused on, where applicable.

Risk Assessor(s): Please list the name(s) and job title(s) of all people involved in producing the risk assessment.

SECTION B: The Risk

Hazard, Problem or Concern: A hazard is any substance, process, action, inaction and/or object that could have a consequence, which may cause danger or harm to an individual, be it staff, patient, visitor or other; or damage to property or equipment.

It is important to remember that hazards may be many and varied within your area of work.

- Staff shortages
- Manual handling
- Trailing leads
- Poor office environment
- Poor access
- Insufficient equipment

Use the trigger lists/pre-assessment forms referred to in HS01 to assist with identifying the hazards associated with your service.

A hazard could have a number of potential outcomes. Therefore identify the potential consequence, danger or harm that the identified hazard may cause. A hazardous process can be broken down into its component parts, each of which will have its own danger. Having identified the dangers, you can now assess the risk for each identified danger.

How was risk identified: Please indicate from what source the risk has been identified e.g.

- ✓ In-house specialist knowledge.
- ✓ Incidents / complaints / claims.
- ✓ Internal / external audit / assurance reports
- ✓ Business Plan

Include details of the identified Underlying Causes.

Control Measures already in place: Please list all controls that are *already* in place to reduce the identified risk.

Description: A description of the control identified.

Responsible/Lead: The individual responsible for the identified control, include both name and job title.

Date Started: When was the control started.

Gap in Controls: Any identified barriers encountered when trying to perform the identified control. Or an indication that the control is failing to achieve its objective.

Initial Risk Evaluation: This is the initial assessment of risk with the control(s) in place. To assist in scoring the risk please use the Trust's Categorisation Matrix that has been provided to all areas in wall-chart format. Using the descriptors given identify the hazard/consequence and likelihood of occurrence. The combination of these will give you a severity grade which indicates the priority of the risk.

Please circle the likelihood, consequence and severity attributed.

When scoring the risk please do not go for the worst case scenario, the aim of a risk assessment is to identify what is reasonably likely to occur and how often.

SECTION C: Treatment Plan

Now that the consequence, danger or harm and the likelihood of occurrence have been identified, action to eliminate or reduce the risks needs to be identified.

The aim of any action in the first instance, if possible, is to eliminate the risk entirely. Thereafter the aim will be to reduce the risk to its lowest.

Actions should be SMART and have objectives:

- ✓ Specific;
- ✓ Measurable;
- ✓ Agreed;
- ✓ Realistic;
- ✓ Time bounded

Actions need to be in place to reduce both likelihood and consequence.

Treatment Plan: All fields are mandatory for each action identified.

Action Required: A description of the action identified, including what objective the action will achieve.

Responsible/Lead: A person must be empowered to undertake and be responsible for the identified action, include both name and job title.

Timescale for Completion: When the action has been identified it must be given a realistic date for commencement and completion. The greater the risk the sooner the start and completion date.

SECTION D: To be completed by Manager

A Senior Manager within the area of work must sign to agree the actions and risk scoring. They should also use their knowledge to complete and supplement the Treatment Plan identified in Section C.

Risk Ref: Located in the top left-hand corner. Please number each risk assessment with your own unique identification; this will make it easier for you to identify your assessments.

Date for Review: This should be no greater than 12 months

Risk Re-Evaluation: What will the risk score be (i.e. Target score) when all of the identified actions have been completed. Ideally this should be lower than the previous score.

SECTION E: Risk Assessment Review Sheet

This section is to be used each time you review and monitor your risk assessment and must be completed following your Governance meeting discussion.

Once completed please send this risk assessment to your Line Manager for review and Governance Officer for consideration.

The Royal Wolverhampton NHS Trust

Medicines Fridge Temperature Monitoring Record

Adapted with the permission of Worcestershire Acute Hospitals NHS Trust

Ward	
Fridge Location / Number	
Year	
Month	

Refer to the following Medicines Policies for additional information:

- **MP10 – Medicine Cold Chain MP10:**
  http://trustnet.xrwh.nhs.uk/strategies-policies/clinical-policies-procedures-guidelines/medicines-policies/mp10/
- **MP01 – Prescribing, Storage and Administration of Drugs MP01:**
  http://trustnet.xrwh.nhs.uk/strategies-policies/clinical-policies-procedures-guidelines/medicines-policies/mp01/

MEDICINES FRIDGE Temperature Monitoring Record

Record MIN & MAX temperatures with a '**X**' and CURRENT temperature with a '•'. If temperature outside the green range TAKE ACTION (see overleaf).

Month:	Year:	Ward / Dept:	Room Name / No.:

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BLUE ZONE ACTIONS: Any Temperature < 2°C	RED ZONE ACTIONS: If MAX or CURRENT temperature >8°C
• **Inform the Nurse in Charge** • **ACTION: QUARANTINE** affected medicines in another working medicines fridge in a clearly marked SEALED bag or container. • **ADJUST** fridge temperature following manufacturers instructions • **RESET** thermometer and inform **Pharmacy** for medicine assessment • **DOCUMENT** actions & settings in the table below **IF STILL <2°C >1hr contact Estates for repair or replacement and inform Nurse in Charge, Pharmacy and complete a Datix form**	• **Inform Nurse in Charge** • **ACTION:** Is the fridge plugged in? Is the fridge switched on? Is the door tightly shut? • **If NO – CORRECT, RESET** the thermometer and RECHECK the fridge temperature in 30 minutes. • **DOCUMENT** actions & settings in the table below. **IF STILL >8°C >30 minutes and NOT IMPROVING: QUARANTINE affected medicines in another working medicines fridge in a clearly marked SEALED bag or container. Inform Nurse in charge, Pharmacy, Estates**

NOTE: Fridges that do not form a seal or are opened too frequently will not maintain their set temperature. Thermostat Settings are individual to the manufacturer. Read the instructions to check if dial is up or down to warm or cool, alter by 1 setting at a time, keep shut and re-check within 1 hour. Frequently too warm? Consider: Is the door shutting properly? Does the fridge need a service or replacement? Could a second fridge reduce the frequency it is accessed? Is the room too warm? Escalate concerns.

Date	Time	Action Taken	Who Reported To	Sign	Follow Up
Example	*10.00*	*Door not closed properly, closed at 11am. Reminder to staff to check door is shut put in the communications book.*	*Nurse in Charge informed*	*J.Cue*	*Max temperature 5C when rechecked at 1pm.*

MEDICINES FRIDGE Temperature Monitoring Record

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IF STILL <2°C >1hr contact Estates for repair or replacement and inform Nurse in Charge, Pharmacy and complete a Datix form

RED ZONE ACTIONS: If MAX or CURRENT temperature >8°C

- **Inform Nurse in Charge**
- **ACTION:** Is the fridge plugged in? Is the fridge switched on? Is the door tightly shut?
- **If NO – CORRECT, RESET** the thermometer and RECHECK the fridge temperature in 30 minutes.
- **DOCUMENT** actions & settings in the table below.

IF STILL >8°C >30 minutes and NOT IMPROVING: QUARANTINE affected medicines in another working medicines fridge in a clearly marked SEALED bag or container. Inform Nurse in charge, Pharmacy, Estates

NOTE: Fridges that do not form a seal or are opened too frequently will not maintain their set temperature. Thermostat Settings are individual to the manufacturer. Read the instructions to check if dial is up or down to warm or cool, alter by 1 setting at a time, keep shut and re-check within 1 hour. Frequently too warm? Consider: Is the door shutting properly? Does the fridge need a service or replacement? Could a second fridge reduce the frequency it is accessed? Is the room too warm? Escalate concerns.

Date	Time	Action Taken	Who Reported To	Sign	Follow Up
Example	*10.00*	*Door not closed properly, closed at 11am. Reminder to staff to check door is shut put in the communications book.*	*Nurse in Charge informed*	*J.Cue*	*Max temperature 5C when rechecked at 1pm.*

MEDICINES FRIDGE Temperature Monitoring Record

Record MIN & MAX temperatures with a '**X**' and CURRENT temperature with a '•'. If temperature outside the green range TAKE ACTION (see overleaf).

Month:	Year:	Ward / Dept:	Room Name / No.:

Date	E.g.	Temperature °C	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Time	1pm																																
Too HOT	MAX X	>10°C																															
		10																															
		9																															
OK	CURRENT TEMP •	8																															
		7																															
	MIN	6																															
		5																															
		4																															
		3																															
		2																															
Too COLD		1																															
		0																															
Thermometer reset	✓																																
Check fridge locked	✓																																
Check for expired stock	✓																																
Initial	RKM																																

If any temperature recorded sits on the border between blue and green or green and red repeat temperature monitoring in 30 minutes and document result.
Keep this record sheet as evidence for the annual Safe and Secure Medicines Audits.

BLUE ZONE ACTIONS: Any Temperature < 2°C

- **Inform the Nurse in Charge**
- **ACTION: QUARANTINE** affected medicines in another working medicines fridge in a clearly marked SEALED bag or container.
- **ADJUST** fridge temperature following manufacturers instructions
- **RESET** thermometer and inform **Pharmacy** for medicine assessment
- **DOCUMENT** actions & settings in the table below

IF STILL <2°C >1hr contact Estates for repair or replacement and inform Nurse in Charge, Pharmacy and complete a Datix form

RED ZONE ACTIONS: If MAX or CURRENT temperature >8°C

- **Inform Nurse in Charge**
- **ACTION:** Is the fridge plugged in? Is the fridge switched on? Is the door tightly shut?
- **If NO – CORRECT, RESET** the thermometer and RECHECK the fridge temperature in 30 minutes.
- **DOCUMENT** actions & settings in the table below.

IF STILL >8°C >30 minutes and NOT IMPROVING: QUARANTINE affected medicines in another working medicines fridge in a clearly marked SEALED bag or container. Inform Nurse in charge, Pharmacy, Estates

NOTE: Fridges that do not form a seal or are opened too frequently will not maintain their set temperature. Thermostat Settings are individual to the manufacturer. Read the instructions to check if dial is up or down to warm or cool, alter by 1 setting at a time, keep shut and re-check within 1 hour. Frequently too warm? Consider: Is the door shutting properly? Does the fridge need a service or replacement? Could a second fridge reduce the frequency it is accessed? Is the room too warm? Escalate concerns.

Date	Time	Action Taken	Who Reported To	Sign	Follow Up
Example	*10.00*	*Door not closed properly, closed at 11am. Reminder to staff to check door is shut put in the communications book.*	*Nurse in Charge informed*	*J.Cue*	*Max temperature 5C when rechecked at 1pm.*

MEDICINES FRIDGE Temperature Monitoring Record

Record MIN & MAX temperatures with a '**X**' and CURRENT temperature with a '•'. If temperature outside the green range TAKE ACTION (see overleaf).

Month:	Year:	Ward / Dept:	Room Name / No.:

Date	E.g.	Temperature °C	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Time	1pm																																
Too HOT	MAX X	>10°C																															
		10																															
		9																															
OK	CURRENT TEMP •	8																															
		7																															
	MIN	6																															
		5																															
		4																															
		3																															
		2																															
Too COLD		1																															
		0																															
Thermometer reset	✓																																
Check fridge locked	✓																																
Check for expired stock	✓																																
Initial	RKM																																

If any temperature recorded sits on the border between blue and green or green and red repeat temperature monitoring in 30 minutes and document result.
Keep this record sheet as evidence for the annual Safe and Secure Medicines Audits.

BLUE ZONE ACTIONS: Any Temperature < 2°C

- **Inform the Nurse in Charge**
- **ACTION: QUARANTINE** affected medicines in another working medicines fridge in a clearly marked SEALED bag or container.
- **ADJUST** fridge temperature following manufacturers instructions
- **RESET** thermometer and inform **Pharmacy** for medicine assessment
- **DOCUMENT** actions & settings in the table below

IF STILL <2°C >1hr contact Estates for repair or replacement and inform Nurse in Charge, Pharmacy and complete a Datix form

RED ZONE ACTIONS: If MAX or CURRENT temperature >8°C

- **Inform Nurse in Charge**
- **ACTION:** Is the fridge plugged in? Is the fridge switched on? Is the door tightly shut?
- **If NO – CORRECT, RESET** the thermometer and RECHECK the fridge temperature in 30 minutes.
- **DOCUMENT** actions & settings in the table below.

IF STILL >8°C >30 minutes and NOT IMPROVING: QUARANTINE affected medicines in another working medicines fridge in a clearly marked SEALED bag or container. Inform Nurse in charge, Pharmacy, Estates

NOTE: Fridges that do not form a seal or are opened too frequently will not maintain their set temperature. Thermostat Settings are individual to the manufacturer. Read the instructions to check if dial is up or down to warm or cool, alter by 1 setting at a time, keep shut and re-check within 1 hour. Frequently too warm? Consider: Is the door shutting properly? Does the fridge need a service or replacement? Could a second fridge reduce the frequency it is accessed? Is the room too warm? Escalate concerns.

Date	Time	Action Taken	Who Reported To	Sign	Follow Up
Example	*10.00*	*Door not closed properly, closed at 11am. Reminder to staff to check door is shut put in the communications book.*	*Nurse in Charge informed*	*J.Cue*	*Max temperature 5C when rechecked at 1pm.*

Appendix 3: Specification for Medicines Refrigerators

Medicines refrigerators must comply with the following specification:

- Lockable,
- Automatic audible alarm when fridge goes out of range,
- Maximum minimum thermometer independent of mains power, and have
- Integral continuous temperature recording.

It should also be noted that medicines refrigerators must:

- Store only pharmaceutical products and
- Be large enough to hold stock and have sufficient space to allow air circulation.

Example of a suitable product:

www.labcold.com

Brand: Labcold

Model: Intellicold

Please Contact the Pharmacy Department for advice before purchasing a medicines refrigerator

Temperature Management for Medicines Storage (MP10) Standard Operating Procedure 1

The Monitoring and Recording of AMBIENT (Room) Temperatures

1.0 Procedure Statement

This procedure provides a standard set of instructions to be followed for the monitoring of ambient temperatures in rooms storing medication. Ambient temperatures will be monitored at the same time each day.- It is best practice to record ambient temperature at the hottest time of the day for each site e.g., early afternoon. This time may vary according to site characteristics.

Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicine storage temperatures are consistently monitored.

2.0 Accountabilities

The Trust Chief Executive is responsible for ensuring that medicines management within the Trust conforms to best practice at all times. This responsibility is delegated to the Clinical Director of Pharmacy, who is the medicines management lead for the Trust. This policy and associated procedures are guided by legislation, governmental directives, the General Pharmaceutical Council's (GPhC) guidance, and local policies and procedures agreed by the Trust's Medicines Management Group (MMG).

ALL STAFF are responsible for keeping up to date with the Medicines Policy and standard operating procedure (SOP) and complying with their requirements.

Nursing staff are responsible for the daily monitoring and recording of ambient temperatures.

Nursing staff are responsible for notifying Research Nurses when a clinical trial subject is admitted to the ward.

Research nurses are responsible for taking a copy of ward records to ensure appropriate trial records are maintained.

Pharmacy Staff are responsible for monitoring compliance with the SOP, and audit of ward and departmental compliance.

Estates Team are responsible for the maintenance of all ventilation and air conditioning equipment.

3.0 Procedure Detail and Actions

3.1 Daily monitoring, recording and escalating ambient temperatures

- A minimum, maximum and actual temperature thermometer must be available in all rooms storing stock medication, sited in an area recommended by a Medicines Management Technician**.**
- The Ambient (Room) Temperature Monitoring Record (MP10: Temperature Management for Medicines Storage – Appendix 10) should be kept within the room storing stock medication.
- A separate room thermometer and Ambient (Room) Temperature Monitoring Record should be used for each room storing stock medication.
- The Ambient (Room) Temperature Monitoring Record should be kept for TWO years prior to destruction.
- The ambient temperature must be maintained within the range 15ºC to 30ºC.
- The ambient temperature must be checked and recorded once daily, at approximately the same time of day - It is best practice to record ambient temperature at the hottest time of the day.
- The temperatures must be recorded on the Ambient (Room) Temperature Monitoring Record.
- **The following must be recorded:**
    - **Time the current temperature was recorded,**
    - **Actual current temperature,**
    - **Minimum temperature reached,**
    - **Maximum temperature reached,**
    - **Reset of the thermometer,**
    - **Name and signature of person recording the temperatures, and**
    - **Actions taken if the temperature is outside of the recommended range.**
- If the ambient temperature is recorded as 25ºC to 30ºC, action should be taken to reduce room temperature e.g., close window blinds, open windows or introduce mobile air conditioning units.
- If the ambient temperature is recorded as exceeding 30ºC for SEVEN readings across the month, this should be escalated to the Ward Manager and the Ward Based Pharmacy Team.
- **DO NOT** stop monitoring the area. Continue to monitor the area whilst awaiting advice from Pharmacy.
- Pharmacy will advise as to any remedial action that may need to be taken, which may include the reduction in the expiry date of the stock or

destruction of the stock, or reduction of stock holding held on the ward, or relocation of stock.

- If a reduction in expiry dates is to be completed, Pharmacy staff will complete this and reduce the expiry date of the affected stock or discard if appropriate.
- Ward stock will be topped up to minimum stock levels.
- Any medicine returns will be destroyed and not returned into stock.
- A risk assessment of the storage area is to be completed at the time of the event. Pharmacy can be contacted to provide advice on completing the risk assessment. Estates are to be contacted as they will be able to provide advice as to equipment that can be used to provide cooling to the area.

3.4 Pharmacy Responsibilities

- The ward-based pharmacy technicians will check that ambient temperatures are being recorded each week when performing the 'Weekly Ward Task list'.
- If ambient temperatures have not been recorded or correctly escalated, the technician must notify the Ward Manager and Ward Pharmacist.
- At month end the responsible person (pharmacist or clinical lead) must sign off each record, ensuring that appropriate action has been completed if the temperature was out of range.

4.0 Equipment Required

Rooms must be monitored with a calibrated digital maximum and minimum thermometer. The thermometer must have the ability to record actual, minimum and maximum temperatures.

Ambient (Room) Temperature Monitoring Record can be ordered from Clinical Illustration.

5.0 Training

All staff are required to read MP10: Temperature Management for Medicines Storage Policy in conjunction with this standard operating procedure. Clinical area managers must confirm staff understand the contents of the policy and procedure and are able to perform the required tasks.

6.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources?	Yes – No
2	Does the implementation of this document require additional revenue resources?	Yes – No
3	Does the implementation of this document require additional manpower?	Yes – No
4	Does the implementation of this document release any manpower costs through a change in practice?	Yes – No

5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff?	Yes – No
	Other comments	

7.0 Equality Impact Assessment

The proposed policy does not impact on the race equality duty and equality and diversity legislation.

8.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the procedure up to date. The standard operating procedures provide detail regarding the content within this policy. Any revisions to the standard operating procedures will be approved through the Trust's Medicines Management Group and ratified by the Trust Policy Group.

9.0 Communication and Training

Appendix 4 of Trust policy OP41 contains training needs analysis of healthcare staff in relation to this policy.

Ward and departmental managers are responsible for ensuring that all healthcare professionals involved in the use of medical products are trained to be competent to do so.

Divisional and departmental managers have a responsibility to ensure that copies of the Temperature Management for Medicines Storage Policy are available to their staff, and they must ensure that staff are fully aware of all the relevant procedure applicable to their ward/department/clinical area.

10.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Evaluation
Monthly data recorded on W Drive		Ward Storage Audit – Rolling programme of monitoring against regional checklist	Annual	Feedback to Ward Managers/ Departmental Leads
Daily records maintained by ward/clinic staff	Ward Based Pharmacy Technicians	Ward Based Weekly Tasklist	Weekly	Feedback to Ward Managers

11.0 References - Legal, professional or national guidelines

- Monitoring and recording ambient (room) and refrigerator temperatures - https://www.meht.nhs.uk/EasysiteWeb/getresource.axd?AssetID=20567&type=full&servicetype=Attachment
- Temperature Monitoring in Rooms Storing Stock Medication – https://www.covwarkpt.nhs.uk/download.cfm?doc=docm93jijm4n3613.pdf&ver=4931
- Temperature monitoring in clinic rooms where medicines are stored - http://www.oxfordhealthformulary.nhs.uk/docs/Temperature%20Monitoring%20in%20clinic%20rooms%20-%20Template%20SOP_June%202015.pdf?UNLID=70395469020193231009
- Temperature Management of Medicines: Storage and Transport - https://www.southernhealth.nhs.uk/_resources/assets/attachment/full/0/42469.pdf

Document Control

Procedure/ Guidelines number and version Version 1.0	**Title of Procedure/Guidelines** MP10; Temperature Management for Medicines Storage Policy Standard Operating Procedure 1: The Monitoring of and Recording AMBIENT (Room) Temperatures by the Multidisciplinary Team	**Status:** Final		**Author:** **Lead Medicines Information Pharmacist** **For Trust-wide Procedures and Guidelines Director Sponsor:** **Director of Pharmacy**
Version / Amendment History	Version	Date	Author	Reason
	1.0	Sept. 2023	Lead Medicines Information Pharmacist	Full Review of Overarching Policy and Appendices
Intended Recipients: All clinical staff				
Consultation Group / Role Titles and Date: Medication Safety Group (MSG) Medicines Management Group (MMG)				
Name and date of group where reviewed	Trust Policy Group – September 2023			
Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Management Committee – September 2023			
Date of Procedure/Guidelines issue	October 2023			
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	September 2026 every 3 years			

Training and Dissemination: All user bulletin Cascade via clinical leads	
To be read in conjunction with: MP01: Medicines Policy	
Initial Equality Impact Assessment: Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904 for Trust-wide documents or your line manager or Divisional Management office for Local documents.	
Contact for Review	Lead Medicines Information Pharmacist
Monitoring arrangements	MSG and MMG will monitor Policy, and report to Compliance Oversight Group when necessary.
Document summary/key issues covered This procedure provides a standard set of instructions to be followed for the daily monitoring of ambient temperatures in all rooms storing stock medication. Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicine storage temperatures are consistently monitored.	
Key words for intranet searching purposes	Ambient, Temperature, Monitoring, Thermometer

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Procedure/Guidelines number and version	**The Monitoring of and Recording AMBIENT (Room) Temperatures by the Multidisciplinary Team** **Version: 1.0**	
Reviewing Group	Medicines Management Group	**Date reviewed:** August 2023
Implementation lead: Paula Haydon: paula.haydon@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc.; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Procedure/Guidelines communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation Consider Business case development		
Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

The Royal Wolverhampton NHS Trust

Temperature Management for Medicines Storage (MP10) Standard Operating Procedure 2

The Monitoring and Recording of Fridge Temperatures

1.0 Procedure Statement

This procedure provides a standard set of instructions to be followed for the monitoring of fridge temperatures in refrigerators storing medication. Fridge temperatures must be monitored daily and at the same time each day.

Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicine storage temperatures are consistently monitored.

2.0 Accountabilities

The Trust Chief Executive is responsible for ensuring that medicines management within the Trust conforms to best practice at all times. This responsibility is delegated to the Clinical Director of Pharmacy, who is the medicines management lead for the Trust. This policy and associated procedures are guided by legislation, governmental directives, the General Pharmaceutical Council's (GPhC) guidance, and local policies and procedures agreed by the Trust's Medicines Management Group (MMG).

ALL STAFF are responsible for keeping up to date with the Medicines Policy and standard operating procedure (SOP), and compliance with its requirements.

Nursing staff are responsible for the daily monitoring and recording of ambient temperatures.

Nursing staff are responsible for notifying Research Nurses when a clinical trial subject is admitted to the ward.

Research nurses are responsible for taking a copy of ward records to ensure appropriate trial records are maintained.

Pharmacy staff are responsible for monitoring compliance with the SOP and for auditing ward and departmental compliance.

The Estates Team is responsible for the maintenance of all ventilation and air conditioning equipment.

3.0 Procedure Detail and Actions

3.1 Daily monitoring, recording and escalating medicines fridge temperatures

- The fridge must be a specialised refrigerator for the storage of pharmaceuticals or vaccines. Newly purchased fridges must have an integral data logger for the constant monitoring of the temperature range.
- The fridge thermometer must record current, maximum and minimum temperatures.

- The Medicines Fridge Temperature Monitoring Record (MP10: Temperature Management for Medicines Storage – Appendix 6) should be kept within the room storing stock medication.
- A separate Medicines Fridge Temperature Record must be used for each fridge storing medication.
- The Medicines Fridge Temperature Record should be kept for TWO years prior to destruction.
- The fridge temperature must be maintained within the range 2ºC to 8ºC.
- The temperature must be checked and recorded once daily, at approximately the same time of day.
- The following must be recorded.
    - **Time the current temperature was recorded.**
    - **Actual current temperature.**
    - **Minimum temperature reached.**
    - **Maximum temperature reached.**
    - **Reset of the thermometer**
    - **Name and signature of person recording the temperatures.**
    - **Action taken if the temperature is outside of the recommended range.**
- Temperatures recorded below 2ºC and above 8ºC must be acted upon immediately. Follow the Fridge Temperature Excursion Flowchart for guidance (MP10: Temperature Management for Medicines Storage – Appendix 13).
- **DO NOT** stop monitoring the fridge. Continue to monitor the fridge whilst awaiting advice from Pharmacy.
- Pharmacy will advise as to any remedial action that may need to be taken, which may include a reduction in the expiry date of the stock, destruction of the stock or reduction of stock holding held on the ward, or relocation of stock.
- Ward stock will be topped up to minimum stock levels.
- Any medicine returns will be destroyed and not returned into stock.
- A risk assessment of the storage area is to be completed at the time of the event. Pharmacy can be contacted to provide advice on completing the risk assessment. Estates are to be contacted as they will be able to provide advice as to equipment that can be used to provide cooling to the area.

3.4 Pharmacy Responsibilities

- The ward-based pharmacy technicians will check that fridge temperatures are being recorded each week when performing the ‘Weekly Ward Task list’.
- If fridge temperatures have not been recorded or correctly escalated the

technician must notify the Ward Manager and Ward Pharmacist.

- At month end, the responsible person (pharmacist or clinical lead) must sign off each record, ensuring that appropriate action has been completed if the temperature was out of range.

4.0 Equipment Required

Fridges must be monitored with a calibrated digital maximum and minimum thermometer. The thermometer must have the ability to record actual, minimum and maximum temperatures.

The Medicine Fridge Temperature Monitoring Record can be ordered from Clinical Illustration.

5.0 Training

All staff are required to read MP10: Temperature Management for Medicines Storage Policy in conjunction with this standard operating procedure. Clinical area managers must confirm staff understand the contents of the policy and procedure and are able to perform the required tasks.

6.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources?	Yes – No
2	Does the implementation of this document require additional revenue resources?	Yes – No
3	Does the implementation of this document require additional manpower?	Yes – No
4	Does the implementation of this document release any manpower costs through a change in practice?	Yes – No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff?	Yes – No
	Other comments	

7.0 Equality Impact Assessment

The proposed policy does not impact on the race equality duty and equality and diversity legislation.

8.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the procedure up to date. The standard operating procedures provide detail regarding the content within this policy. Any revisions to the standard operating procedures will be approved through the Trust's Medicines Management Group and ratified by the Policy Review Committee.

9.0 Communication and Training

Appendix 4 of Trust policy OP41 contains training needs analysis of healthcare staff

in relation to this policy.

Ward and departmental managers are responsible for ensuring that all healthcare professionals involved in the use of medical products are trained to be competent to do so.

Divisional and departmental managers have a responsibility to ensure that copies of the Temperature Management for Medicines Storage Policy are available to their staff, and they must ensure that staff are fully aware of all the relevant procedure applicable to their ward/department/clinical area.

10.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Evaluation
Monthly data recorded on W Drive		Ward Storage Audit – Rolling programme of monitoring against regional checklist	Annual	Feedback to Ward Managers/ Departmental Leads
Daily records maintained by ward/clinic staff	Ward Based Pharmacy Technicians	Ward Based Weekly Tasklist	Weekly	Feedback to Ward Managers

11.0 References - Legal, professional or national guidelines

- Monitoring and recording ambient (room) and refrigerator temperatures - https://www.meht.nhs.uk/EasysiteWeb/getresource.axd?AssetID=20567&type=full&servicetype=Attachment
- Temperature Monitoring in Rooms Storing Stock Medication – https://www.covwarkpt.nhs.uk/download.cfm?doc=docm93jijm4n3613.pdf&ver=4931
- Temperature monitoring in clinic rooms where medicines are stored - http://www.oxfordhealthformulary.nhs.uk/docs/Temperature%20Monitoring%20in%20clinic%20rooms%20-%20Template%20SOP_June%202015.pdf?UNLID=70395469020193231009
- Temperature Management of Medicines: Storage and Transport - https://www.southernhealth.nhs.uk/_resources/assets/attachment/full/0/42469.pdf

Document Control

Procedure/ Guidelines number and version Version 1.0	**Title of Procedure/Guidelines** MP10; Temperature Management for Medicines Storage Policy Standard Operating Procedure 1: The Monitoring of and Recording AMBIENT (Room) Temperatures by the Multidisciplinary Team	**Status:** Final		**Author:** **Lead Medicines Information Pharmacist** **For Trust-wide Procedures and Guidelines Director Sponsor:** **Director of Pharmacy**
Version / Amendment History	Version	Date	Author	Reason
	1.0	Sept. 2023	Lead Medicines Information Pharmacist	Full Review of Overarching Policy and Appendices
Intended Recipients: All clinical staff				
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Date of Procedure/Guidelines issue	October 2023			
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	September 2026 every 3 years			

Training and Dissemination: All user bulletin Cascade via clinical leads	
To be read in conjunction with: MP01: Medicines Policy	
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Contact for Review	Lead Medicines Information Pharmacist
Monitoring arrangements	MSG and MMG will monitor Policy, and report to Compliance Oversight Group when necessary.
Document summary/key issues covered This procedure provides a standard set of instructions to be followed for the daily monitoring of ambient temperatures in all rooms storing stock medication. Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicine storage temperatures are consistently monitored.	
Key words for intranet searching purposes	Ambient, Temperature, Monitoring, Thermometer

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Procedure/Guidelines number and version	**The Monitoring of and Recording AMBIENT (Room) Temperatures by the Multidisciplinary Team** **Version: 1.0**	
Reviewing Group	Medicines Management Group	**Date reviewed:** August 2023
Implementation lead: Paula Haydon: paula.haydon@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc.; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Procedure/Guidelines communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation Consider Business case development		
Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

Ambient (Room) Temperature Monitoring Record

Ward	
Room	
Year	
Month	

Refer to the following Medicines Policies for additional information:

MP10 – Medicine Cold Chain MP10 - Medicine Cold Chain Policy (xrwh.nhs.uk)

MP01 – Prescribing, Storage and Administration of Drugs MP01 - Prescribing, Storage and Administration of Drugs (xrwh.nhs.uk)

Standards for Ambient Temperature Monitoring

Refer to MP10: Temperature Management for Medicines Storage (insert web page link)

- Ambient temperature must be checked and recorded **once daily**
    - Clinical areas which are unmanned for extended periods e.g. weekends, and it is not possible to perform a temperature check must complete the record with a 'C' to indicate closed
- Record temperature at approximately the same time each day
- The **maximum** and **minimum** temperatures reached, plus the current temperature at the time of recording must be recorded
- The thermometer must be **reset daily**
- A separate thermometer must be used in each area being monitored

In the event of a temperature deviation:

- ############

Record **MIN & MAX** temperature with a '**X**' and **CURRENT** temperature with a '●'. If temperature outside the green range **TAKE ACTION** (see over)

Month:	Year:	Ward/Dept:	Room Name/No:

Date	E.g	Temperature 0C	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Time	1pm																																
T		>40oC																															
O		40																															
O		38																															
		36																															
H		34																															
O		32																															
T		30																															
Too WARM	MAX X	28																															
		26																															
OK		24																															
	CURRENT TEMP ●	22																															
		20																															
	MIN X	18																															
		16																															
		14																															
Initials	R.C																																

Keep this record sheet as evidence for the annual Safe and Secure Handling of Medicines Audits

If ANY temperature is above the GREEN zone TAKE ACTION (see overleaf)

25 - 29.9oC		30 - 34.9oC		35 - 40oC		>40oC	
1 Day	**>3 Consecutive Days**	**1 Day**	**>3 Consecutive Days**	**1 Day**	**>3 Consecutive Days**	**1 Day**	**>3 Consecutive Days**
Nurse Actions: Record temperature Inform Estates and Nurse in charge	**Nurse Actions:** Record Temperature Inform Estates, Nurse in charge and Matron	**Nurse Actions:** Record temperature Inform Estates and Nurse in charge	**Nurse Actions:** Record temperature Inform Estates, pharmacy team, Nurse in charge and Matron	**Nurse Actions:** Record temperature Inform Estates, pharmacy and Nurse in charge	**Nurse Actions:** Record temperature Inform Estates, pharmacy, Nurse in charge and Matron	**Nurse Actions:** Record temperature Inform Estates, pharmacy and Nurse in charge	**Nurse Actions:** Record temperature Inform Estates, pharmacy, Nurse in charge and Matron
			Pharmacy Actions: Reduce expiry by 1 month		**Pharmacy Actions: Reduce expiry by 2 months**		**Pharmacy Actions: Remove all medicines/Reissue**

Date	Time	Problem	Action Taken	Who Reported To	Sign	Follow Up
Example	*1pm*	*28oC sun shining in through windows*	*Fans turned on. Estates contacted.*	*Ward Manager*	*JKR*	*3pm 22oC*

Note - Estates: Has heat from direct sunlight been reduced? Have all non essential (for medicines storage) electrical devices been removed from the room? Has ventilation been checked and confirmed adequate / working? **Pharmacy:** Has risk to patients from medicines stored above recommended temperature been assessed? **Nurse:** Has the temperature been controlled adequately. Have you escalated the ongoing issues?

The Royal Wolverhampton NHS Trust

Temperature Management for Medicines Storage (MP10) Standard Operating Procedure 3

Actions to be Taken Following AMBIENT (Room) Temperature Deviations Above 30^0C

1.0 Procedure Statement

This procedure provides a standard set of instructions to be followed when medicine room temperatures rise above the recommended range of 30^0C.

Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicines which have been exposed to temperatures outside of the recommended range are dealt with consistently and appropriately.

The procedure also details the responses required from the Estates and Pharmacy departments in order to appropriately manage equipment and medicines in these circumstances.

The procedure ensures that the actions taken are evidence based, and the patient and financial risks are managed.

2.0 Accountabilities

The Trust Chief Executive is responsible for ensuring that medicines management within the Trust conforms to best practice at all times. This responsibility is delegated to the Clinical Director of Pharmacy, who is the medicines management lead for the Trust. This policy and associated procedures are guided by legislation, governmental directives, the General Pharmaceutical Council's (GPhC) guidance, and local policies and procedures agreed by the Trust's Medicines Management Group (MMG).

ALL STAFF are responsible for keeping up to date with the Medicines Policy and standard operating procedure (SOP), and compliance with its requirements.

Nursing staff are responsible for the daily monitoring and recording of ambient temperatures.

Nursing staff are responsible for notifying Research Nurses when a clinical trial subject is admitted to the ward.

Research nurses are responsible for taking a copy of ward records to ensure appropriate trial records are maintained.

Pharmacy Staff are responsible for monitoring compliance with the SOP and auditing ward and departmental compliance.

Medicines Information is responsible for appropriate information and guidance in the event a temperature sensitive medicine is exposed to temperatures above 30^0C.

The Estates Team is responsible for the maintenance of all ventilation and air conditioning equipment.

3.0 Procedure Detail and Actions

3.1 Documenting temperatures above 30°C

- Temperatures must be recorded on Trust approved paperwork only. The Ambient (Room) Temperature Monitoring Record (MP10: Temperature management for Medicines Storage - Appendix 10) is supplied as a booklet of 12. One record must be maintained for each room storing medicines.

- If the ambient temperature is between 25°C and 30°C action should be taken to reduce room temperature e.g., close window blinds, open windows or introduce mobile air conditioning units.
- If the ambient temperature is recorded as exceeding 30°C for SEVEN readings across the month, this should be escalated to the Ward Manager and the Ward Based Pharmacy Team.
- **DO NOT** stop monitoring the area. Continue to monitor the area whilst awaiting advice from Pharmacy.
- Pharmacy will advise as to any immediate remedial action that may need to be taken, this may include the reduction in the expiry date of the stock, destruction of the stock, reduction of stock holding held on the ward, or relocation of stock.
- If a reduction in expiry dates is to be completed, Pharmacy staff will complete this and reduce the expiry date of the affected stock or discard if appropriate.
- Ward stock will be topped up to minimum stock levels.
- Any medicine returns will be destroyed and not returned into stock.
- A risk assessment of the storage area is to be completed at the time of the event. Pharmacy can be contacted to provide advice on completing the risk assessment.
- Estates are to be contacted as they will be able to provide advice as to equipment that can be used to provide cooling to the area.

3.4 Pharmacy Responsibilities

- The ward-based pharmacy technicians will check that ambient temperatures are being recorded each week when performing the 'Weekly Ward Task list'.
- If ambient temperatures have not been recorded or correctly escalated the technician must notify the Ward Manager and Ward Pharmacist.
- At month end the responsible person (pharmacist or clinical lead) must sign off each record, ensuring that appropriate action has been completed if the temperature was out of range.

4.0 Equipment Required

Rooms must be monitored with a calibrated digital maximum and minimum

thermometer. The thermometer must have the ability to record actual, minimum and maximum temperatures.

The Ambient (Room) Temperature Monitoring Record (MP10: Temperature management for Medicines Storage - Appendix 10) can be ordered from Clinical Illustration.

5.0 Training

All staff are required to read MP01: Medicines Policy and MP10 Temperature Management for Medicines Storage in conjunction with this standard operating procedure. Clinical area managers must confirm staff understand the contents of the policy and procedure and are able to perform the required tasks.

6.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources?	Yes – No
2	Does the implementation of this document require additional revenue resources?	Yes – No
3	Does the implementation of this document require additional manpower?	Yes – No
4	Does the implementation of this document release any manpower costs through a change in practice?	Yes – No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff?	Yes – No
	Other comments	

7.0 Equality Impact Assessment

The proposed policy does not impact on the race equality duty and equality and diversity legislation.

8.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the procedure up to date. The standard operating procedures provide detail regarding the content within this policy. Any revisions to the standard operating procedures will be approved through the Trust's Medicines Management Group and ratified by the Policy Review Committee.

9.0 Communication and Training

Appendix 4 of Trust policy OP41 contains training needs analysis of healthcare staff in relation to this policy.

Ward and departmental managers are responsible for ensuring that all healthcare professionals involved in the use of medical products are trained to be competent to do so.

Divisional and departmental managers have a responsibility to ensure that copies of the Medicines Policy are available to their staff, and they must ensure that staff are fully aware of all the relevant procedure applicable to their ward/department/clinical area.

10.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Evaluation
Daily records maintained by ward/clinic staff	Ward Based Pharmacy Technicians	Ward Based Weekly Tasklist	Weekly	Feedback to Ward Managers

11.0 References - Legal, professional or national guidelines

- Monitoring and recording ambient (room) and refrigerator temperatures - https://www.meht.nhs.uk/EasysiteWeb/getresource.axd?AssetID=20567&type=full&servicetype=Attachment
- Temperature Monitoring in Rooms Storing Stock Medication – https://www.covwarkpt.nhs.uk/download.cfm?doc=docm93jijm4n3613.pdf&ver=4931
- Temperature monitoring in clinic rooms where medicines are stored - http://www.oxfordhealthformulary.nhs.uk/docs/Temperature%20Monitoring%20in%20clinic%20rooms%20-%20Template%20SOP_June%202015.pdf?UNLID=70395469020193231009
- Temperature Management of Medicines: Storage and Transport - https://www.southernhealth.nhs.uk/_resources/assets/attachment/full/0/42469.pdf

Document Control

Procedure/ Guidelines number and version Version 1.0	**Title of Procedure/Guidelines** Medicines Policy (MP01) Standard Operating Procedure 3: The Monitoring of and Recording AMBIENT (Room) Temperatures by the Multidisciplinary Team	**Status:** Final		**Author:** **Lead Medicines Information Pharmacist** **For Trust-wide Procedures and Guidelines Director Sponsor:** **Director of Pharmacy**
Version / Amendment History	Version	Date	Author	Reason
	1.0	Sept. 2023	Lead Medicines Information Pharmacist	Full Review of Overarching Policy and Appendices
Intended Recipients: All clinical staff				
Consultation Group / Role Titles and Date: Medication Safety Group (MSG) Medicines Management Group (MMG)				
Name and date of group where reviewed	Trust Policy Group – September 2023			
Name and date of final approval committee(if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Management Committee – September 2023			
Date of Procedure/Guidelines issue	October 2023			
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	September 2026 every 3 years			

Training and Dissemination: All user bulletin Cascade via clinical leads	
To be read in conjunction with: Medicines Cold Chain Policy (MP10)	
Initial Equality Impact Assessmen: Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904 for Trust-wide documents or your line manager or Divisional Management office for Local documents.	
Contact for Review	Lead Medicines Information Pharmacist
Monitoring arrangements	MSG and MMG will monitor Policy, and report to Compliance Oversight Group when necessary.
Document summary/key issues covered This procedure provides a standard set of instructions to be followed for the daily monitoring of ambient temperatures in all rooms storing stock medication. Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicine storage temperatures are consistently monitored.	
Key words for intranet searching purposes	Ambient, Temperature, Monitoring, Thermometer

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

Procedure/Guidelines number and version	**Fridge Temperature Monitoring by The Multidisciplinary Team Version: 1.0**	
Reviewing Group	Medicines Management Group	**Date reviewed:** August 2023
Implementation lead: Judith Morey Ext: 5136 judith.morey@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc.; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Procedure/Guidelines communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation Consider Business case development		
Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

The Royal Wolverhampton NHS Trust

Temperature Management for Medicines Storage (MP10) Standard Operating Procedure 4

Actions to be Taken when Medicine Fridge Temperatures Are Outside of the Recommended Range 2^0C to 8^0C

1.0 Procedure Statement

This procedure provides a standard set of instructions to be followed when medicine fridge temperatures fall outside of the recommended range of 2^0C to 8^0C.

Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicines which have been exposed to temperatures outside of the recommended range are dealt with consistently and appropriately.

The procedure also details the responses required from the Estates and Pharmacy departments in order to appropriately manage equipment and medicines in these circumstances.

The procedure ensures that the actions taken are evidence based, and the patient and financial risks are managed.

MANUFACTURERS ADVICE CHANGES CONTINUALLY THEREFORE PHARMACY SHOULD BE CONTACTED AFTER EVERY INCIDENT OF A FRIDGE TEMPERATURE OUTSIDE OF THE RECOMMENDED RANGE

2.0 Accountabilities

The Trust Chief Executive is responsible for ensuring that medicines management within the Trust conforms to best practice at all times. This responsibility is delegated to the Clinical Director of Pharmacy, who is the medicines management lead for the Trust. This policy and associated procedures are guided by legislation, governmental directives, General Pharmaceutical Council (GPhC) guidance, and local policies and procedures agreed by the Trust's Medicines Management Group (MMG).

All staff are responsible for keeping up to date with the Temperature Management for Medicines Storage Policy (MP10), associated standard operating procedures (SOPs), and compliance with the requirements.

In the event of a temperature below 2ºC or above 8ºC Ward Managers / Senior Sisters are responsible for the necessary immediate actions to rectify the temperature.

Nursing staff are responsible for contacting Medicines Information following every fridge temperature below 2ºC or above 8ºC.

Pharmacy Staff are responsible for monitoring compliance with the SOPs and auditing ward and departmental compliance.

Medicines Information is responsible for appropriate information and guidance in the

event of a reported temperature below 2ºC or above 8ºC.

Estates Team are responsible for the maintenance of all refrigerator equipment.

3.0 Procedure Detail and Actions

3.1 Documenting temperatures below 2ºC or above 8ºC

- Any temperature outside of the recommended range should be recorded on the back of the monitoring form (MP10: Temperature Management for Medicines Storage - Fridge Temperature Monitoring Record Appendix 6).
- The nurse undertaking the monitoring should ensure that all required actions and escalation have been documented.
- The record on the back of the monitoring form must be completed by the nurse with the following details.
    - Date and time the temperature outside of the recommended range has been identified.
    - Initial actions taken.
    - Who the deviation has been reported to, including pharmacy (if referral criteria have been met).
    - Signature of nurse completing the record.
    - Follow up (if needed) e.g., Estates contact including estates log number.

3.2 Quarantine of affected medicines

- All medicines located in a fridge which is subject to a temperature below 2ºC must be quarantined IMMEDIATELY in another working medicines fridge.
- Medicines stored in a fridge which is subject to a temperature above 8ºC, and which, despite appropriate interventions, is not improving, must be quarantined in another working medicines fridge.
- The medicines should be placed in a SEALED bag or container clearly marked with ‘DO NOT USE’.
- The medicines MUST NOT be used until pharmacy have approved the use.

Actions to be taken when the CURRENT fridge temperature is above the recommended upper level of 8ºC

CONSULT FRIDGE TEMPERATURE DEVIATION FLOW CHART (MP10: Temperature Management for Medicines Storage Policy - Appendix 13)

- **If the current temperature is out of range and is over 8ºC**
    - Check the fridge is plugged in and switched on.
    - Check the fridge door is tightly closed.
    - Check there is sufficient airflow around the contents of the

fridge.

- If any of the above is found:
  - Correct the issue,
  - **RESET** the thermometer,
  - Keep the fridge door closed,
  - **RECHECK** the fridge temperature in 30 minutes, and
  - **Record** any extra monitoring carried out.
- If the temperature is still above 8^0C and not improving inform the nurse in charge of the clinical area, pharmacy and estates.

****MOST INSTANCES OF HIGH FRIDGE TEMPERATURES WILL BE RESOLVED BY UNDERTAKING THE ABOVE ACTIONS AND RE-MEASURING AT 30 MINUTES AND 60 MINUTES****

- **If the <u>current temperature is in range</u> <u>but the MAXIMUM temperature is out of range and above 8ºC</u>**
  - Inform the Nurse in Charge.
  - Complete a fridge temperature excursion proforma (MP10: Temperature Management for Medicines Storage Policy - Appendix 14).
  - Contact Medicines Information for advice (Monday to Friday 9am to 5pm), Dispensary (Saturday and Sunday 9am to 5pm) or the on-call pharmacist via switchboard at all other times.

- **Actions to be taken when the fridge temperature, <u>CURRENT or MINIMUM, falls below the recommended lower level of 2ºC</u>**
  - Inform the Nurse in Charge.
  - Complete a fridge temperature excursion proforma (MP10: Temperature Management for Medicines Storage Policy Appendix 14).
  - Contact Medicines Information for advice (Monday to Friday 9am to 5pm), Dispensary (Saturday and Sunday 9am to 5pm) or the on-call pharmacist via switchboard at all other times.

3.3 Pharmacy Responsibilities

When notified of a fridge temperature outside of the recommended range it is the responsibility of the ward-based pharmacy team to ensure the following actions have been taken.

- All drugs in the fridge have been quarantined in another working drugs fridge and placed in a bag marked ‘DO NOT USE’ until it is established if they are suitable for use.
- Confirm that the fridge temperature proforma has been completed and take this

to the Medicines Information Team as soon as possible.

- Organise a supply of any medicines which are needed for patients on the ward. These medicines will need to be stored in the fridge of a neighbouring ward until the fridge anomaly is resolved.

4.0 Equipment Required

Fridges must be monitored with an integrated digital maximum and minimum thermometer **and** a data logger (SD Card or USB stick). In the absence of an integrated digital thermometer, temperatures should be recorded using a Trust approved digital thermometer and data logger as advised by the Pharmacy Department. The digital thermometer must have the ability to record actual, minimum and maximum temperatures.

The Medicines Fridge Temperature Monitoring Record (MP10: Temperature Management for Medicines Storage - Appendix 6) can be ordered from Clinical Illustration (CODE). The record is supplied as a booklet of 12. One record must be maintained for each fridge.

5.0 Training

All staff are required to read MP10: Temperature Management for Medicines Storage Policy in conjunction with this standard operating procedure. Clinical area managers must confirm staff understand the contents of the policy and procedure and are able to perform the required tasks.

6.0 Financial Risk Assessment

1	Does the implementation of this document require any additional Capital resources?	Yes – No
2	Does the implementation of this document require additional revenue resources?	Yes – No
3	Does the implementation of this document require additional manpower?	Yes – No
4	Does the implementation of this document release any manpower costs through a change in practice?	Yes – No
5	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programs or allocated training times for staff?	Yes – No
	Other comments	

7.0 Equality Impact Assessment

The proposed policy does not impact on the race equality duty and equality and diversity legislation.

8.0 Maintenance

The Clinical Director of Pharmacy is responsible for keeping the policy up to date. Any revisions to the policy will be reviewed by the Trust's Medicines Management Group before being submitted through the Trust's policy approval procedure. The attached standard operating procedures provide detail regarding the content within this policy. Any revisions to the standard operating procedures will be approved through the Trust's Medicines Management Group and ratified by the Policy Review Committee.

9.0 Communication and Training

Appendix 4 of Trust policy OP41 contains training needs analysis of healthcare staff in relation to this policy.

Ward and departmental managers are responsible for ensuring that all healthcare professionals involved in the use of refrigerated medical products are trained to be competent to do so.

Divisional and departmental managers have a responsibility to ensure that copies of the Medicine Cold Chain Policy are available to their staff, and they must ensure that staff are fully aware of all the relevant procedure applicable to their ward/department/clinical area.

10.0 Audit Process

Criterion	Lead	Monitoring method	Frequency	Evaluation
Monthly data recorded on W Drive Records of Fridge defrosting available		Ward Storage Audit – Rolling programme of monitoring against regional checklist	Annual	Feedback to Ward Managers/ Departmental Leads
Daily records maintained by ward/clinic staff	Ward Based Pharmacy Technicians	Ward Based Weekly Tasklist	Weekly	Feedback to Ward Managers

11.0 References - Legal, professional or national guidelines

https://www.cqc.org.uk/guidance-providers/adult-social-care/medicines-requiring-fridge-storage

https://assets.publishing.service.gov.uk/government/uploads/system//attachment_data/file/300304/Protocol_for_ordering__storing_and_handling_vaccines_March_2014.pdf

https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3

Document Control

Procedure/ Guidelines number and version Version 1.0	**Title of Procedure/Guidelines** Medicines Cold Chain Policy (MP10) Standard Operating Procedure 4: The Monitoring of Fridge Temperatures by the Multidisciplinary Team	**Status:** Final		**Author:** **Medication Safety Officer** **For Trust-wide Procedures and Guidelines Director Sponsor:** **Director of Pharmacy**
Version / Amendment History	Version	Date	Author	Reason
	1.0	Sept. 2023	Lead Medicines Information Pharmacist	Full Review of Overarching Policy and Appendices
Intended Recipients: All clinical staff				
Consultation Group / Role Titles and Date: Medication Safety Group (MSG) Medicines Management Group (MMG)				
Name and date of group where reviewed	Trust Policy Group – September 2023			
Name and date of final approval committee (if trust-wide document)/ Directorate or other locally approved committee (if local document)	Trust Management Committee – September 2023			
Date of Procedure/Guidelines issue	October 2023			
Review Date and Frequency (standard review frequency is 3 yearly unless otherwise indicated)	September 2026 every 3 years			

Training and Dissemination: All user bulletin Trust IT Screen Saver ePMA Message of the day Cascade via clinical leads	
To be read in conjunction with: Medicines Cold Chain Policy (MP10)	
Initial Equality Impact Assessment: Completed Yes / No Full Equality Impact assessment (as required): Completed Yes / No / NA If you require this document in an alternative format e.g., larger print please contact Policy Administrator 8904 for Trust-wide documents or your line manager or Divisional Management office for Local documents.	
Contact for Review	Medication Safety Officer
Monitoring arrangements	MSG and MMG will monitor Policy, and report to Compliance Oversight Group when necessary.
Document summary/key issues covered This procedure provides a standard set of instructions to be followed for the daily monitoring of medicine fridges in clinical areas. Adherence to the procedure will guarantee that patient safety is maintained by ensuring that medicine storage temperatures are consistently monitored.	
Key words for intranet searching purposes	Fridge, Temperature, Monitoring

IMPLEMENTATION PLAN

To be completed when submitted to the appropriate committee for consideration/approval

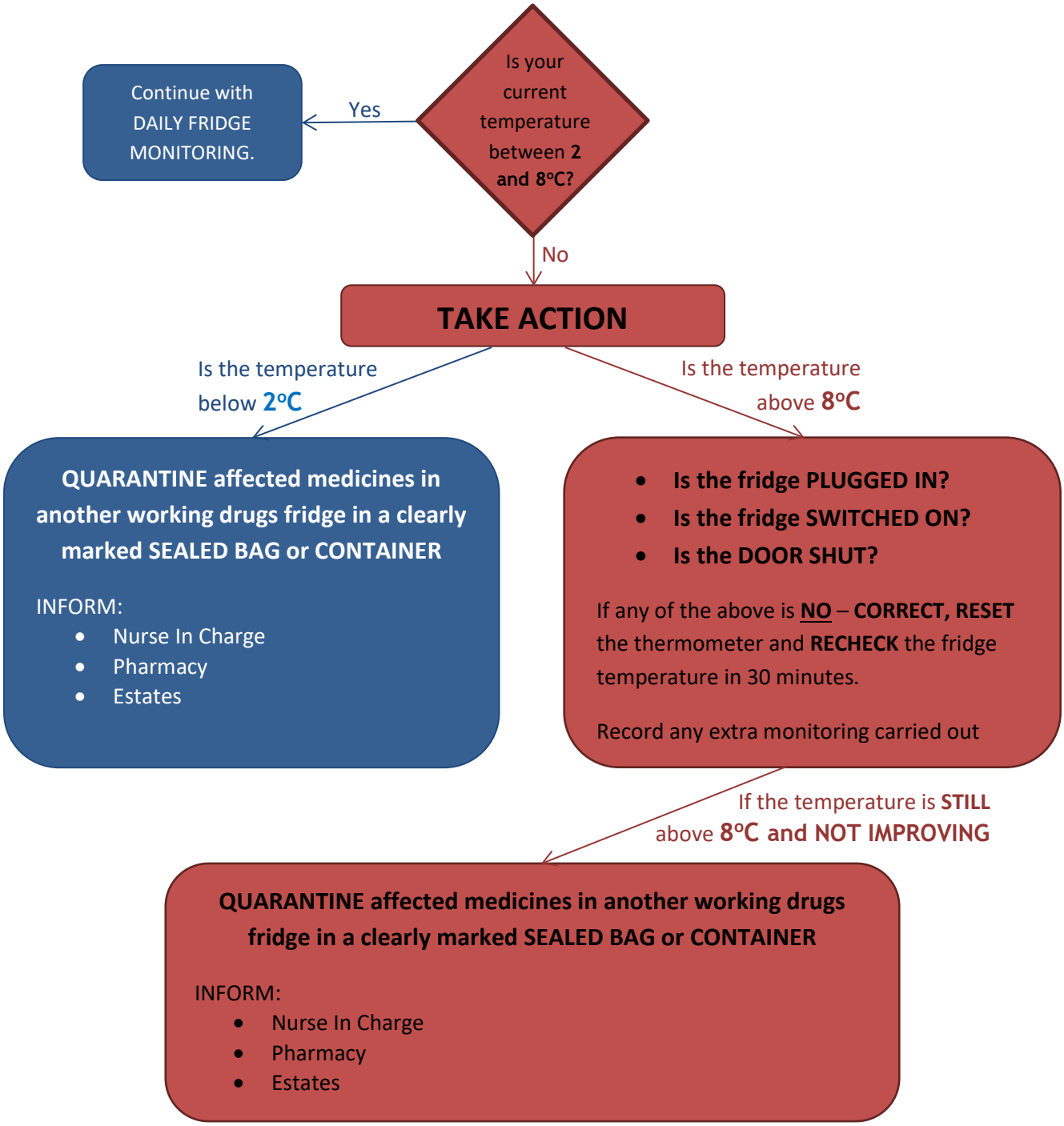
Procedure/Guidelines number and version	**Fridge Temperature Monitoring by The Multidisciplinary Team Version: 1.0**	
Reviewing Group	Medicines Management Group	**Date reviewed:** August 2023
Implementation lead: Paula Haydon Ext: 5795 paula.haydon@nhs.net		

Implementation Issue to be considered (add additional issues where necessary)	**Action Summary**	**Action lead / s (Timescale for completion)**
Strategy; **Consider** (if appropriate) 1. Development of a pocket guide of strategy aims for staff 2. Include responsibilities of staff in relation to strategy in pocket guide.		
Training; Consider 1. Mandatory training approval process 2. Completion of mandatory training form		
Development of Forms, leaflets etc.; Consider 1. Any forms developed for use and retention within the clinical record **MUST** be approved by Health Records Group prior to roll out. 2. Type, quantity required, where they will be kept / accessed/stored when completed		
Procedure/Guidelines communication; Consider 1. Key communication messages from the policy / procedure, who to and how?		
Financial cost implementation Consider Business case development		
Other specific issues / actions as required e.g. Risks of failure to implement, gaps or barriers to implementation		

The Royal Wolverhampton NHS
NHS Trust

THIS FRIDGE IS FOR THE STORAGE OF MEDICINES ONLY

LOOK AFTER IT AND IT WILL LOOK AFTER YOUR MEDICINES!



Contact Numbers for pharmacy:

MEDICINES INFORMATION ext. **85136** bleep **7271** (Monday – Friday 9am to 5pm)

DISPENSARY ext. **88079** (Saturday & Sunday 9am to 5pm)

ON-CALL PHARMACIST via switchboard (all other times)

Prepared by Medicines Information, Pharmacy Department
Ext. 5136 Bleep 7271

January 2018

Fridge Temperature Excursion Proforma

*****IMPORTANT NOTICE*****

Fridge temperature excursions are not a common occurrence and should not be treated as such. The Trust is incurring a high level of medication wastage due to fridge temperature excursions. All incidents regarding to temperature excursions should be treated seriously to prevent reoccurrence.

1. **Please complete all fields and return to rwh-tr.medicinesinformation@nhs.net (incomplete forms will be returned)**
2. **Please complete an DATIX incident form**
3. **If you believe your fridge/freezer is malfunctioning, please call Estates immediately**
4. **If you are unsure, MP10: Temperature Management for Medicines Storage provides guidance on how to monitor fridges**

Enquirer Details

Department	Contact Name	Contact Details

Details Of Temperature Excursion

N.B.: Please use your data logger information. If you do not have a datalogger, you need to look at the date & time of the last recorded temperature in range up until now, to calculate the 'worst-case scenario' duration of the fridge being out of range.

	Date	Time	Temperature		
			Min	Current	Max
Current reading					
Maximum/minimum readings when breach detected					
Last recorded readings (before the breach was detected)					

Have you quarantined the drugs now in a working fridge?

Have further supplies been ordered? If required, do you have an alternative fridge/freezer to store the product?

Urgency of response

Name (e.g. lorazepam), **Strength** (e.g. 4mg/mL) **and Form of drug** (e.g. injection)	**Brand Name** (e.g. Ativan) **and Manufacturer** (e.g. Pfizer)	**Batch Number & Expiry**

Manufacturers' advice changes continually therefore pharmacy should be contacted after every incident.

Appendix 11: Specification for Medicines Cool boxes

Validated medical grade cool boxes are available in a variety of sizes. It is important that the bag has a certificate of calibration demonstrating the ability to maintain cold temperature over an appropriate amount of time.

e.g. iBin Cold Chain Bag

Technical Report for Cold Chain Bag

Samples Submitted

A sample of insulated bag referenced 'B' Large (47cm x 31cm x 25cm), was submitted for testing using BS EN 12546-2:2000 Specification for insulated bags and boxes Clause 4.2 Insulation - Modified.

The modifications applied are as follows:

- The test has been conducted with the bag as received, the preconditioning specified in the standard has not been carried out.
- A thermocouple to be placed in the centre of the bag to measure the internal air temperature of sample.
- 4 x 140mm x 258mm freezer blocks (supplied) were placed into the bag, three in the base and one in the pocket provided in the lid.
- The freezer blocks had previously been placed into a freezer for >12 hours.
- The external temperature maximum 22°C, testing time 16 hours
- Internal temperature to try and achieve 2 - 8 °C for up to 6 hours

Test Results

Mean external temperature: 22°C		
Elapsed Time (hours)	Elapsed Time (minutes)	Temperature of Internal air (°C)
Start	Start	6.3
1	60	3.9
2	120	4.8
3	180	4.8
4	240	5.0
5	300	5.1
6	360	5.2
7	420	5.4
8	480	5.4
9	540	5.5
10	600	5.7
11	660	5.9
12	720	6.3
13	780	6.5
14	840	7.0
15	900	7.4
16	960	8.0