

Policy Document

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Storage, Prescription, Supply and Administration of Medicines

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7	April 2014	Inclusion of statements relating to the medicines optimisation agenda, change in job title of Clinical Director of Pharmacy and NHS Trust Development Authority compliance requirements relating to medicines; Inclusion of radiopharmaceuticals and investigational medicinal products included in definition of medicines. Updated roles and responsibilities to reflect current organisational structures and Trust Groups / Committees supporting medicines optimisation / management; Policy reformatted to include in Appendices all relevant standard operating procedures which have been approved and developed to support the implementation of MM03. F1 doctors should not prescribe oral methotrexate in line with Deanery guidance issued in 2013. Ratified at Quality and Safety Forum.
8	January 2019	Updates to: <ul style="list-style-type: none"> • Mandatory training arrangements • Additional SOPs – fridges and ambient temperature monitoring. • Additional guidance on covert medicines • Requirements for double checking for paediatrics • Exemption for double checking for anaesthetists in theatre. • Additional professions added to non-medical prescribers • Additional guidance on prescribing and administering insulin • Additional guidance on prescribing sodium valproate to girls and women. • Responsibility of Clinical Directors to support the management of medicines shortages • Nursing Associates and their role in relation to medicines • Changes in terms of Trust and health economy medicines related committees / groups • Inclusion of reference to NICE guidance and quality standards
9	November 2019	Ambient Temperature Monitoring Form added to Appendix D SOP
10	January 2021	COVID-19 Vaccination Programme addendum added to Appendix I

Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed [here](#)

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1. INTRODUCTION

Medicines optimisation is a patient centred approach to improving outcomes and supporting high quality patient care in relation to medicines. This encompasses: improving patient experience; reducing harm from medicines; ensuring medicines use is as safe as possible; ensuring evidence based use of medicines and embedding good practice(s).

The national medicines optimisation agenda was launched in 2013 and a good practice guidance for healthcare professionals was issued by the Royal Pharmaceutical Society.¹ It was endorsed by NHS England, Royal College of Nursing, the Royal College of General Practitioners and the Academy of Medical Royal Colleges. The National Institute for Health and Care Excellence has issued a guideline (NG5) and quality standard (QS120) on medicines optimisation.

Given that medicines remain the most common therapeutic intervention in healthcare, and that the Trust spends in excess of £70 Million per annum on medicines, it is essential that healthcare professionals, patients and the wider public work collaboratively together to get the best outcomes from medicines used and ensure value for money.

Medicines management is a part of the wider medicines optimisation agenda. It focuses more on the systems and processes involved (e.g. selection of medicines, procurement, prescription, administration, management and disposal of waste medicines, etc).

The Department of Health requires that NHS Trusts establish, document and maintain an effective and economical system to ensure and demonstrate that medicines are handled in a safe and secure manner.

This overarching Policy on medicines is an important and broad-reaching document which supports the implementation of the Trust's Medicines Optimisation Strategy and the safe medication agenda. This revised policy supports the Trust in achieving compliance with the requirements of NHS Improvement in relation to medicines optimisation and the Care Quality Commission standards for medicines.

This Policy is a multidisciplinary document that is intended to be comprehensive and as inclusive as possible. It supports professionals, encourages good practice and ensures that medicines are available and used when clinically required by patients. The format follows the process of medicines use within the organisation and the Policy Appendices contain guidance and approved standard operating procedures which have been developed corporately to support staff and the medicines optimisation agenda.

All staff involved with medicines management and optimisation should be familiar with other relevant Trust policies and associated standard operating procedures relating to medicines. These include:

MM01	Policy on Medicines Reconciliation
MM02	Policy for the Prescribing, Safe Handling, Use and Administration of Systemic Anti-Cancer Treatments.
MM04	Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines
MM05	Policy on the Supply and Administration of Medicines via Patient Group Directions
MM06	Policy for the Storage, Prescription, Administration and Supply of Controlled Drugs
MM07	Policy and Procedures on the Safe Handling, Use and Administration of Intrathecal Chemotherapy
MM10	Intravenous Sedation Policy for Adults
C05	Policy for the Discharge of Adult Patients
C15	Policy for the Use of Immunoglobulins
C28	Policy for the Management of Thrombo-prophylaxis
C57	Policy for the Prescription of Oxygen in Adults
G02	Research governance
EF 18	Operational Policy for Medical Gas Pipeline Systems

EF05 Trust Policy for Waste Disposal

An “Equality Impact Assessment” has been undertaken and no actual or potential discriminatory impact has been identified relating to this document.

2. POLICY STATEMENT

The overall aim of the policy is to improve the management of medicines within the organisation, enhance their safe use and ensure compliance with new legislation and national requirements including safety guidance.

The policy sets out the principles by which medicines are stored, prescribed, transported, supplied and administered within the Trust and makes it clear who is responsible for each role. In addition, the Trust will ensure that there are robust processes in place to identify, monitor and record medication related adverse incidents and their associated harm so that lessons can be learnt and cascaded through the organisation to prevent re-occurrence and / or reduce harm.

The Policy should: encourage the adoption of safe systems of work and therefore the protection of patients and staff by reducing the potential for error; dispelling confusion and provide clarity with concise and easily accessible guidance and safety tips as well as providing a framework for teaching, training, audit and future development.

The overarching Policy on the Storage, Prescription, Supply and Use of Medicines and accompanying standard operating procedures must be adhered to by all staff involved with any aspect of handing medicines. Wards and departments need to ensure that they have adequate and up-to-date standard operating procedures (SOPs) in place for any additional activities involving medicines not specified in this policy. All SOPs associated with activities involving medicines in wards and departments must be ratified by the Trust Safe Medicines Committee and reviewed at regular, agreed timescales.

The outcome of the policy should be that:

- The management of medicines within the Trust is improved and that medicines are stored appropriately in a safe and secure manner.
- The **right medicine** is available and should be given in the **right dose** to the **right patient** at the **right time** and by the **right route**.

3. SCOPE

This policy and associated procedures apply to all Trust staff and any external contractors, agency or locum staff involved in any aspect of the medicines management process within the Trust or on behalf of the Trust. The policy and associated SOPs must be followed at all times.

4. DEFINITIONS

Medicine:

Medicines are defined in the Medicines Act 1968 as “pharmaceutical products in dosage form for administration to human beings”. Medical gases, radio-pharmaceuticals, investigational medicinal products, vaccines and preparations of human blood are included in this definition. Pharmaceutical preparations such as medicated or interactive dressings, disinfectants, reagents and similar products are included and therefore covered by this policy.

Controlled Drug:

A Controlled Drug is defined as a preparation, which is subject to the requirements of the Misuse of Drugs Regulations 2001 (and subsequent amendments). Preparations specified in Schedule 2 and 3 of this regulation are distinguished in the British National Formulary (BNF) by the symbol CD. The current BNF includes a summary of the Misuse of Drugs Act together with drugs included in each schedule.

One Stop Dispensing (OSD): refers to the supply of inpatient medicines as a single 28-day supply labelled with directions for discharge.

Patient's own drugs (PODs): medication which a patient has brought into hospital on admission.

Prescriber applies to any practitioner legally authorised to prescribe under the Medicines Act 1968 or any subsequent amendments. Thus, this policy applies equally to both medical and non-medical practitioner prescribing. Authorised prescribers must be approved by the Trust and include registered medical staff and accredited nurse, pharmacist or other non-medical prescribers. Registered Non-medical Prescribers are authorised by the Deputy Chief Nurse and may prescribe as independent or supplementary prescribers according to their annotation on the register.

Appointed Practitioner in Charge is the senior registered practitioner appointed in overall charge of the ward or department or, where appropriate, a senior registered professional (i.e. Radiographer, ODP, Physiotherapist, Pharmacist, Chiropodist).

Assigned Practitioner in Charge:

The senior practitioner on-duty for the ward or department, who has been rostered as the professional in charge for that shift

Designated Practitioner:

A practitioner from a Health Care Group (approved by the Trust) is identified from the Appointed Practitioner in Charge as competent and appropriate to perform a specific function and the designation as such has been communicated to and accepted by the practitioner.

Patient Specific Direction:

The traditional written instruction, from a doctor, dentist, nurse or independent prescriber for medicines to be administered to a named patient. The majority of medicines are still supplied or administered using this process.

Supplementary Prescribing:

A voluntary prescribing relationship between the independent prescriber (Doctor or Dentist) and the supplementary prescriber, to implement an agreed patient specific clinical management plan, with the patients agreement.

Patient Group Direction (PGD):

A written instruction for the supply or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may not be (but can be) identified before presenting for treatment.

Nursing Associate

Nursing associate is a new role being introduced into the health and care workforce in England from 2019. The NMC has issued proficiency standards in relation to nursing associates including the procedural competencies required for administering medicines safely. Nursing associates cannot administer medicines under a patient group directive. The Deputy Chief Nurse, Senior Nurse Education and Workforce development and ACNs will ensure that relevant Trust SOPs are updated to reflect the competencies and roles that can be undertaken by nursing associates regarding the safe administration of medicines including checking of medicines.

5. ROLES AND RESPONSIBILITIES

5.1 The **Chief Executive** of the Trust has overall responsibility for the safe and secure handling of medicines as part of the Trust Assurance Framework.

5.2 Within the Trust and local health economy there are a number of committees to support and monitor the delivery of specific aspects of medicines management agenda. These include:

- Trust Safe Medication Group and associated Divisional Groups
- Trust and Health Economy N.I.C.E. Implementation and External Publication Group
- Trust Antimicrobial Stewardship Group
- Trust Patient Group Direction Meeting
- Trust Strategic and Local Chemotherapy Group
- Trust Thrombosis Committee
- Trust Medical Gases Pipeline and Cylinders Steering Group
- Sub-Regional Immunoglobulin Assessment Panel
- The Bedside Clinical Guidelines Partnership
- Health Economy New Medicines Committee
- Health Economy Area Prescribing Committee

5.3 Trust Board

The Trust is legally responsible, through the Trust Board, for the services it manages, including medicines management and optimisation. The Chief Executive and other corporate Trust Executive Directors are accountable for ensuring that the Trust has in place policies for the management of medicines that comply with the legal requirements and best practice guidelines. The Trust Board must allocate resources sufficient to meet the requirements of the Policy.

5.4 The Executive Medical Director is the Executive lead for medicines optimisation and is supported in this role by the **Clinical Director of Pharmacy and Medicines Optimisation, Deputy Medical Directors, Chair of Trust Safe Medication Group, the Chief Nurse and the Head of Quality, Safety and Compliance**. The Medical Director ensures through membership of the Trust Board, Executive Team and Committee that adequate corporate performance management arrangements are in place regarding the implementation of the Trust Medicines Optimisation Strategy. This includes the implementation of this policy.

5.5 Clinical Director of Pharmacy and Medicines Optimisation is responsible for:

- Establishing, monitoring and reporting on a system for assuring the safe and secure handling of medicines.
- The production and review of this policy.
- Ensuring the safe and effective management and procurement of medicines within the Pharmacy Directorate including external accreditations. This includes ensuring that adequate and up-to-date departmental standard operating procedures are in place for all relevant pharmaceutical activities.
- Ensuring that the pharmacy-lead audit programme is relating to the safe and secure storage of medicines are undertaken in a timely manner and appropriate feedback is provided to Directorates / Divisions.
- Ensuring implementation of all medicinal product recalls received from the Medicines and Healthcare Products Regulatory Agency (MHRA).

5.5.1 Deputy Chief Nurse is the identified Trust lead responsible for non-medical prescribing and patient group directions and will consider the implications of any changes in legalisation and workforce in these areas.

5.6 The Antimicrobial Stewardship Group is responsible for all aspects of medicines optimisation in relation to antimicrobial stewardship and prescribing. This is in accordance with the Trust Policy IC 24.

5.7 The Trust Thrombosis Committee is responsible for all aspects of medicines optimisation in relation to prescribing of venous thromboembolism prophylaxis and anticoagulants. This is in accordance with Trust Policy C28

- 5.8** The Trust **Medical Gases Pipeline and Cylinder Committee** is responsible for all aspects of medicines optimisation in relation to prescribing of piped and bottled medical gases. This is in accordance with Trust Policies C57 and EF18.
- 5.9** The Trust **N.I.C.E and External Publications Group** is responsible for reviewing N.I.C.E Implementation Impact Assessment proformas for Health Technology Appraisals including medicines. This includes mandatory implementation timeline, financials and service delivery implications and is in accordance with Trust Policy G14.
- 5.10** The **New Medicines Committee** is responsible for reviewing the evidence base, clinical and cost effectiveness of applications for new medicines to be included in the North Staffordshire Formulary.
- 5.11** The health economy **Area Prescribing Committee** is responsible for ratifying the recommendations of the New Medicines Committee and deciding on the colour category of formulary medicines.
- 5.12** The **Trust Patient Group Direction (PGDs) Group** is responsible for reviewing and ratifying PGDs to be used to supply or administer medicines to patients. This is in accordance with Trust Policy MM05.
- 5.13** The **Trust Immunoglobulin Panel** is responsible for all aspects of medicines optimisation relating to Immunoglobulin in accordance with Trust Policy C15
- 5.14** **Divisional Associate Directors** are responsible for ensuring that appropriate structures, mechanisms and governance arrangements exist within their Divisions to facilitate the effective and timely implementation of the Trust Medicines Optimisation Strategy, Medicines Management Policies, medicines related QIPP agenda and the safe medication agenda.
- 5.15** **Clinical Directors** are responsible for:
- Ensuring that a mechanism exists within their Directorate for providing feedback to all medical staff on relevant medicines management and optimisation issues and ensuring any required actions are taken. These specific responsibilities relate to:
 - Implementation of the Trust Medicines Optimisation strategy, all Trust related medicines policies and associated SOPs.
 - Professional conduct and clinical decision making, with regard to medicines management activities.
 - Implementation of key prescribing messages (including antimicrobial initiatives and Safety Alerts relating to medicines).
 - Ensuring training needs analysis and clinical competence assessment of all staff in relation to medicines management activities.
 - Clinical Directors will be supported in this by Consultant medical staff and Educational Supervisors.
 - Management of medicines related shortages and clinical input into suitable alternative medicines.
- 5.16** The **Associate Chief Nurses, Departmental Heads and Directorate Managers** are responsible for:
- Ensuring that a mechanism exists within their relevant Division / Directorate for providing feedback to all nursing / midwifery staff or allied health professionals (including non-medical prescribers) on relevant medicines management issues and ensuring any required actions are taken. These specific responsibilities relate to:
 - Implementation of the Trust Medicines Optimisation strategy, all Trust related medicines policies and associated SOPs.
 - Professional conduct and clinical decision making with regard to medicines

- Training needs analysis and clinical competence assessment of all staff in relation to medicines management activities.
- Ensuring that the Trust standard operating procedures relating to medicines are followed and identifying practice that may deviate from the SOPs. In these circumstances a risk assessment must take place and an appropriate SOP developed by the relevant area and ratified by the Trust Medication Safety Group.
- To be notified of all unresolved discrepancies relating to medicines on wards / clinical areas within Directorate / Division and initiation of appropriate investigations.
- To ensure that any observations/actions arising from any of the medicines related audits are actioned promptly.
- Escalate to Executive Medical Director and Clinical Director of Pharmacy and Medicines Optimisation for unresolved and serious incidents

The Associate Chief Nurses and Directorate Managers will be supported in this by the Matrons, Head of Midwifery and ward sisters / charge nurses.

5.17 All Consultants, Matrons, Ward sisters / charge nurses and registered healthcare professionals in charge of a department are responsible for the day to day implementation of this Policy. This includes ensuring that:

- All staff are aware of their role regarding the management of medicines and the implementation of this Policy.
- Staff receive the relevant mandatory medicines management training according to their role and are competent to implement this Policy.
- Staff are aware of and comply with standard operating procedures relating to this Policy.
- Records are kept as specified in this Policy
- Ensuring medicines related issues and incidents are reported via Datix® and investigated in a timely manner and escalated to the relevant professional head or ACN if unresolved or serious.
- All audits related to the safe and secure storage of medicines, controlled drugs audits, omitted doses audits or any other audits relevant to this policy are noted and actions implemented in a timely manner to address any concerns / deficiencies.

5.18 The Appointed Practitioner in Charge of a ward or department is specifically responsible for:

- Ensuring arrangements are in place for the safe and secure storage of medicines and controlled stationery (including when their ward is closed or relocated to another area).
- Ensuring that all staff handling medicines in their ward/department have received the relevant training for the medicines related SOPs relating to their area of practice.
- Ensuring that appropriate Trust and local standard operating procedures are followed by staff.
- Ensuring arrangements are in place for the correct monitoring of fridge and ambient temperature.

5.19 Prescribers carry their own responsibility and are professionally accountable for their judgement(s) in doing so. It is their responsibility to:

- Prescribe medicines for individual patients in accordance with this Policy and associated standard operating procedures (MM03–SOP-5 and MM03–SOP–6) ensuring that all prescriptions for medicines comply with legal requirements.
- Only prescribe medicines for persons who are registered patients of the Trust on Trust approved prescriptions.
- Ensure their prescribing complies with the North Joint Staffordshire Formulary and N.I.C.E Health Technology Appraisal Guidance – see appendix 3 Safe Prescribing of Medicines.
- Involving patients in decisions regarding the initiation and / or cessation of medicines including potential side effects and the intended outcomes of treatment.

5.20 Registered Pharmacists and Pharmacy Technicians work in accordance with

approved Pharmacy standard operating procedures and this includes:

- Checking and confirming the clinical suitability of the prescription prior to dispensing.
- Inspecting the prescriptions in the dispensary and on wards, annotating when necessary and contacting the prescriber in case of doubt. This is in accordance with the Pharmacy Directorate Clinical Pharmacy Framework and associated SOPs.
- Providing advice to nursing staff and individual practitioners on the safe use of medicines. This includes the safe and secure storage of medicines at ward / department level and promptly highlighting any concerns and / or deficiencies to senior ward/department staff and escalating to senior pharmacy staff.
- Procurement and supply of medicines according to this policy and national and local guidance.

5.21 Messengers / Porters / Drivers are responsible for:

- Ensuring the safe and secure delivery of the intact containers containing medicines between the pharmacy to the correct ward / department area.
- Keeping medicines secure during their journey through the organisation

5.22 Waste Control Manager and Dangerous Goods Advisor are responsible for:

- Providing specialist advice on the disposal of medicines within the Trust in accordance with relevant legislation and highlighting any concerns in the annual audit report.

5.23 Trust Security Management Team are responsible for:

- Providing specialist advice in relation to the safe and secure storage of medicines including participation in any relevant investigations regarding security concerns / breaches.
- Supporting ward/department leads in undertaking risk assessments for storage of medicines if the storage arrangements are unable to comply with this policy.

6. EDUCATION, TRAINING AND IMPLEMENTATION PLAN

Individual registered practitioners are responsible for ensuring that they have appropriate knowledge and experience to prescribe, supply or administer medicines competently in their area of practice. They need to comply with the registration requirements of their registering body and ensure that they keep their professional and clinical knowledge up-to-date. This should form part of their personal development plan and be reviewed at their annual performance and development review.

Consultants are responsible for ensuring that all medical officers in their teams are trained to be competent in all aspects of the prescribing of medicines, as specified in this policy. Nursing and departmental managers are responsible for ensuring that any non-medical prescribers working for them are similarly competent.

Mandatory / Induction Training

- Medicines Management forms part of the Trust Mandatory Training programme as per HR53 and is available through Trust E-learning courses.
- Medicines management training, delivered by a senior pharmacist, is included in the junior doctor's induction training day.
- Newly qualified nurses and nurses new to the Trust attend a preceptorship course where a workshop on medicines management is delivered.
- The FY1 doctors receive a dedicated prescribing workshop, delivered by a senior pharmacist, within the first 2 months of commencing employment at the Trust.

All training should be recorded in staff personal records and ideally within electronic staff record (ESR).

Additional Training

- Divisional and departmental managers have a responsibility to ensure that copies of the Trust Policy MM03 and associated SOPs are available to their staff, and they must ensure that their staff are fully aware of all relevant procedures applicable to their Ward / Clinical Area.
- All staff called upon to do so must be competent in the calculation of dosages associated with the administration of medicines.
- All practitioners are encouraged to utilise e-learning packages to support their continuing professional development. A number have been developed nationally to support the implementation of National Patient Safety Alerts relating to oral anticoagulants, insulin and injectable medicines
- Links with Keele Medical School, Keele Schools of Nursing and Pharmacy and the Foundation Medical School have been developed and will continue to be strengthened thus ensuring that adequate medicines management training is provided and reflects national and local safety initiatives.

Competence, Accountability and Responsibility of Practitioners

- Competence means that a designated practitioner has the background, underpinning knowledge and skill sufficient to carry out a role unsupervised. Competence is a broad concept and staff must be aware of their limitations in any given circumstance. It is the direct responsibility of each practitioner and the indirect responsibility of his / her manager / supervisor and his / her co-workers to ensure that he / she is, and remains, competent in all tasks they are called on to perform.
- Accountability will remain with the individual practitioner at all times. Accountability and responsibility for all actions cannot be shared or deferred to another person:
 - When two trained staff check medicines they hold equal responsibility for the correctness of the procedure.
 - When a student nurse (or other trainee) is involved the responsibility rests with the competent practitioner to ensure the correctness of the procedure.
- It is the responsibility for all staff to ensure that they act at all times in the best interest of the patient. Staff cannot be made to undertake tasks, including the storage, supply and prescription and administration of medicines, for which they are not competent or in circumstances where the individual is unsure of his / her actions.
- If a competent practitioner knows, or believes, the prescription to be in error or that the intended action is incorrect or inappropriate he / she must question the prescription with the prescribing doctor (or deputy) prior to dispensing or administration. If unresolved to the satisfaction of the competent practitioner further advice should be sought from either his / her immediate supervisor, the Consultant looking after the patient or the Pharmacy Directorate / on-call pharmacist. Documentation of the incident in the nursing / medical notes should be made and a Trust incident form completed on Datix®.

Plan of Implementation

The Trust Safe Medication Group, Divisional Safe Medication Groups, Quality, Safety and Compliance Department and the Pharmacy Directorate will work closely with the Divisions and Directorates to ensure that all staff involved with medicines management are aware of the policy.

7. MONITORING AND REVIEW ARRANGEMENTS

Internal Monitoring

There should be on-going monitoring of compliance with the Policy by the Clinical Directors and Specialty leads, CAN / Heads of Profession and the Clinical Director of Pharmacy and Medicines

Optimisation in all areas where medicines are prescribed, dispensed, transported, stored and/or administered.

An annual audit (minimum) regarding the safe and secure storage of medicines on wards and departments will be undertaken by the Pharmacy Directorate and any concerns and / or deficiencies identified will be highlighted to the ward/department manager so that they are addressed in a timely manner. In addition the Pharmacy team will periodically carry out checks on wards and departments to ensure safe and secure storage of medicines.

Areas of non-compliance should be identified and action taken to identify the causes of non-compliance and plan means of rectifying them. It may be appropriate to audit compliance across a Directorate if major problems are identified or a number of adverse incidents occur in one particular area.

The Trust Medication Safety Officer will review all reported medication incidents at least monthly and highlight any themes or incidents of concern to the Trust Safe Medication Group. Divisional Safe Medication Groups will be responsible for overseeing appropriate investigation and learning occurs from identified incidents and will report outcomes/progress at least quarterly to the Trust Safe Medication Groups. Feedback from Divisional Safe Medication Groups will also include: review of relevant audits to any aspects of medicines management and optimisation; approval of standard operating procedures; review of medicines related adverse incidents on Datix® to establish the outcomes with regard to harm, identify trends and, where appropriate, develop action plans to share learning from adverse incidents across the Trust.

In addition the Risk Management Panel will review the root case analysis of any medicines related adverse incident resulting in moderate harm or above and ensure that any relevant recommendations and actions are forwarded to the Clinical Director of Pharmacy and/or the Trust Medication Safety Officer.

External Inspections

The Care Quality Commission can review medicines management arrangements within acute Trusts and this includes the arrangements in place regarding the management of controlled drugs.

The Pharmacy Directorate holds a Medicines and Healthcare Products Regulatory Agency (MHRA) Manufacturer's "Specials" Licence on behalf of the pharmacy technical services and the radiopharmacy department (within the Imaging Directorate) at the RSUH site. A MHRA Wholesale Dealer's Licence is also held for the RSUH Pharmacy Store. The MHRA undertake regular Good Manufacturing Practice (GMP) and Good Distribution Practice inspections to support the on-going accreditation of these licences. These inspections are risk based assessments and the frequency of assessment will be determined by the MHRA.

In addition under EL 97 (52) the Farwell Audit will be undertaken within the Pharmacy Manufacturing Unit every 12-18 months.

The MHRA can also inspect the management of any clinical trials that are being undertaken with Trust (commercial or Trust sponsored studies). The timing of these inspections is determined by the MHRA. The inspection would be relating to named clinical trials and would look at all aspects of the trial according to Good Clinical Practice (GCP) and GMP guidelines. Feedback regarding compliance and an accompanying action plan will be noted at Trust Quality and Safety Forum.

The Pharmacy dispensaries at both the RSUH and County Hospital sites are registered with the General Pharmaceutical Council (GPhC). The GPhC carry out inspections at a frequency decided by the GPhC.

Review of Alerts and Supporting Policies

Monitoring of the implementation of NHS England Patient Safety Alerts occurs via the Trust Safe Medication Group. Any residual risks should be recorded on the relevant risk register.

The Bedside Clinical Guideline Partnership Guidelines (Medicine, Surgery and Paediatrics) are updated on an annual basis and all relevant prescribing guidelines are reviewed in light of the North Staffordshire formulary, national guidance (e.g. N.I.C.E.), safety initiatives (e.g. NPSA Safety Alerts) and relevant adverse incidents.

To support antimicrobial prescribing initiatives within the Trust the Pharmacy Directorate has undertaken regular audits and these will continue on a six monthly basis. Audit findings and action plans are sent directly to Clinical Directors for appropriate action within their Directorate.

The national and local medicines management and safety agenda influences the corporate and local audit programme which is reviewed on an annual basis.

Policy Review

The Clinical Director of Pharmacy and Medicines Optimisation is responsible for undertaking review of this document at least every 3 years or earlier if major change is necessary due to changing legislation / national medication safety initiatives.

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Monitoring Table

MM03 Policy for the Storage, Prescription, Supply and Administration of Medicines Monitoring Table					
Aspect of compliance or effectiveness being monitored	Monitoring method	Individual or department responsible for the monitoring	Frequency of the monitoring activity	Group/committee/ forum which will receive the findings/monitoring report	Committee/ individual responsible for ensuring that the actions are completed
Process for prescribing medicines	Regular review of adverse prescribing incidents	Divisional Safe Medication Groups, Pharmacy Directorate, Clinical Audit	Monthly	Trust Safe Medications Group	Trust Safe Medications Group
	Prescription Intervention monitoring		Annually		
	Audit of discharge		As		

University Hospitals of North Midlands NHS Trust
MM03 Storage, Prescription, Supply and Administration of Medicines

	prescriptions	Pharmacy	requested by Trust Safe Medication Group		
Process for ensuring the accuracy of all prescription charts	Pharmacists verify most prescription charts at least on admission and discharge in accordance with Clinical Pharmacy SOPs. Assurance of pharmacy verification undertaken as part of omitted doses audit	Wards Pharmacists		Trust Safe Medications Group	Trust Safe Medications Group
Process for ensuring safe and secure storage of medicines	Control Drug Audit Ward Storage Audits CEF assessment visits Storage checks	Pharmacy Department Quality nursing team Pharmacy	Six monthly Annually Annually quarterly	Divisional Safe Medications Group	Ward or Department Manager / Matron Trust Safe Medications Group
How medication errors are reported	Datix (Adverse Incidents / Complaints)	Divisional Governance and Quality Managers	As required	Divisional Safe Medications Group	Trust Safe Medications Group
How the organisation learns from medication errors	MSO reviews incidents and identifies themes/learning. Shared with relevant groups by attending training sessions and/or trust safety/learning alerts. Root Cause Analysis of moderate/serious harm	Divisional Governance and Quality Managers	As required	Divisional Safe Medications Group Trust Safe Medications Group	Trust Safe Medications Group Quality and Safety Forum
Organisation's expectations in relation to staff training, as identified in the training needs analysis	Attendance records for medicines management training courses	Directorate managers Medical staffing	See individual staff group training requirements	Divisional Governance groups	Divisional Governance groups

Standard Operating Procedure (SOP)

MM03-SOP-1

Storage and Safe Custody of Medicines and Controlled Stationary

January 2019



University Hospitals
of North Midlands
NHS Trust

APPENDIX A

The purpose of this SOP is to ensure the minimum standard and consistency of approach is maintained for the storage and safe custody of medicines and associated products.

This SOP links to Trust Policy MM03

This SOP applies to all members of Trust staff involved in medicines optimisation and the storage and safe custody of medicines at Trust. It must be followed at all times including out of hours and at weekends. This SOP does not cover the safe custody of controlled drugs. Please refer to Trust Controlled Drug Policy MM06 and associated SOPs for further information.

- **The appointed practitioner in charge of the department is responsible for:**
 - Ensuring there are systems in place for the safe storage of medicines and controlled stationary at all times in accordance with this procedure.
 - Keys to cupboards are kept securely in accordance with this SOP
 - Codes for coded lock access are not shared with anyone not permitted to gain access to medicines and changed at appropriate intervals.
 - Ad-hoc medicine storage checks to ensure that systems and standards continue to be maintained and implementing systems to address or improve deficiencies identified as a result.
 - Reporting any instances of upheld loss or theft of medicines or controlled stationary to the Clinical Director of Pharmacy/Trust Medication Safety Officer immediately.
- **Prescribers are responsible for:**
 - The safe custody of prescriptions and prescription pads issued to them for their individual use.
- **The Director of Pharmacy and Medicines Optimisation is responsible for:**
 - Ensuring that every ward / department at UHNM that holds medicines is subject to a safe and secure storage of medicines audit. This must be undertaken a minimum of annually and more regularly for departments with significant non-compliances on previous audits.
 - Reporting the Trust audit results to the Trust Safe Medication Group
- **The Divisional Safe Medication groups are responsible for:**
 - Discussing the outcomes of the ward storage audits and identifying required actions to improve where required.
 - Monitoring the progress of required actions to address deficiencies identified during the safe and secure storage of medicines audits.
- **All staff are responsible for:**
 - Adhering to this procedure to ensure that medicines are fit for purpose when administered or supplied
 - Reporting any instances of non-compliance to the practitioner in charge and rectifying immediately where possible
 - Reporting any incidents relating to the loss or theft of medicines or controlled stationary immediately to the practitioner in charge.
 - Reporting adverse events via the Datix® Risk Management System.

No.	Description of Procedural Steps
1	<p>Persons permitted access to medicines</p> <p>Registered practitioners whose role directly relates to the supply, storage, prescribing and administration of medicines have authorised access to medicines. This includes:</p> <ul style="list-style-type: none"> • Pharmacists • Pharmacy Technicians • Medical and non-medical prescribers • Nurses • Midwives • Operating Department Practitioners • Radiographers and X-Ray Technicians • Physiotherapists • Perfusionists <p>In addition to these roles, other non-registered staff involved in these duties may be given access as authorised by the appointed practitioner in charge of the ward or department. This includes:</p> <ul style="list-style-type: none"> • Pharmacy Support Workers (Assistant Technical Officers) • Nursing assistants and housekeepers designated by the appointed practitioner in charge.
2	<p>Items subject to storage requirements</p> <p>The following items are subject to safe / secure storage requirements at Trust:</p> <ul style="list-style-type: none"> • Medicines / pharmaceuticals including: <ul style="list-style-type: none"> ○ Ward stock ○ Discharge medication ○ Inpatient medication ○ Outpatient medication ○ Clinical trials ○ Patients own medication brought in from home ○ Medication provided for self-administration ○ Emergency / resuscitation medicines ○ Medicines no longer required – waste medicines or medicines waiting for return to pharmacy. • Fluids including: <ul style="list-style-type: none"> ○ Parenteral fluids ○ Sterile topical fluids (e.g. water for irrigation) ○ Dialysis solutions • Disinfectants, antiseptics and other cleaning products • Reagents • Medical gases • Flammable medicines • Controlled stationary: <ul style="list-style-type: none"> ○ Inpatient and supplementary prescription charts ○ Trust outpatient prescriptions and FP10 HPs ○ Controlled Drug requisition and record books. Refer to Trust CD Policy MM06 for further information.
3	<p>Medicines and controlled stationary security requirements</p> <p><u>General</u></p> <ul style="list-style-type: none"> • All staff must be vigilant to ensure that unauthorised persons do not gain access to medicines. Any suspicions or concerns regarding security must be escalated to the practitioner in charge of the department immediately. <p><u>Areas / cupboards / trolleys locked with a key</u></p> <ul style="list-style-type: none"> • All medicines storage cupboards must be locked with a key when not in use. If the ward/department has identified that there is a risk to patient care of delayed administration of medicines a risk assessment must be undertaken annually, approved by the matron for the area, the Trust security manager and the Trust Medication Safety Officer. • Medicine trolleys must be locked with a key when not in use – including during the medicines round when the nurse/midwife is not directly supervising it. When the medicines trolley is not in use it must be tethered to a wall or stored securely behind a locked door in the clinical room. • POD lockers must be locked if medicines are stored in them. If POD lockers are broken and cannot be locked this must be escalated immediately to the estates department for repair. Medicines must not be stored in the POD locker if the lock is not intact.

No.	Description of Procedural Steps
	<ul style="list-style-type: none"> • Cupboards / locations used for medicine storage must never be left unlocked / unsecure when not in use. • Ideally medicines storage locations will be sited in areas convenient for nursing staff, allowing adequate space and permitting surveillance to afford maximum security against unauthorised entry. <p><u>Coded lock / swipe access areas</u></p> <ul style="list-style-type: none"> • All clinical rooms where medicines /fluids are stored must be locked with a coded lock/swipe card controlled access. The door must always be kept locked, even when staff are in the room. • The code / swipe access must be given to approved personnel only. • Set codes must be individual to each area and not be a recognised code for other departments • Set codes must be unique to medicines/fluids storage on the ward/department and not be a recognised code for such areas as staff / tea rooms and bathroom facilities. • Codes must be changed a minimum of every 6 months. • Swipe access must be reviewed a minimum of every 6 months and if there is a suspicious incident involving staff. <p><u>Cupboards and Trolleys in Anaesthetic Rooms</u></p> <ul style="list-style-type: none"> • In line with the Royal College of Anaesthetists recommendations medicine cupboards and trolleys in anaesthetic rooms may remain unlocked for the duration that the theatre and anaesthetic room are in use to allow immediate access to critical medicines. This does not include the controlled drugs cupboard which must remain locked at all times. • When the theatre is not in use the cupboards and trolleys must be locked and the keys stored in the approved key storage cupboard.
4	<p>Medicines storage requirements</p> <p><u>Cupboards</u> When purchasing medicine storage cupboards ideally they should comply with the British Standards for Medicines Storage. They must be suitable for medicines storage with appropriate locks. Wards / departments must consult the Senior Directorate Pharmacist for advice before purchasing.</p> <p><u>Temperature requirements</u></p> <ul style="list-style-type: none"> • Areas designated for medicines storage must be maintained above 15°C and below 25°C. This ensures that the stability of the medicine is not compromised and that the shelf life of the medicine is unaffected. High temperatures increase the rate of chemical degradation and microbial spoilage of medicines. Low temperatures may cause extreme viscosity in some liquid medicines causing such issues as crystallisation and precipitation. Inappropriate freezing of medicines may break or cause a large increase in the droplet size of emulsions. • Medicines storage facilities must not be sited above or near radiators or other major sources of heat or above sinks where they may be subject to higher than average humidity. • Fridge and ambient temperatures must be monitored at least daily - see SOP for fridge/ambient temperature monitoring. <p><u>General storage requirements</u></p> <ul style="list-style-type: none"> • The area must be well maintained – i.e. clean, free from litter, dust and pests and cupboards etc must be in a good state of repair. • The area must have adequate lighting to avoid errors through inability to read labels effectively. • There must be adequate bench space to allow the preparation of intravenous medicines and doses of controlled drugs. The bench must be clean and free from clutter. • Medicines must be stored in the original container in which they were issued/dispensed from Pharmacy. Loose ampoules must not be left outside of the original box. Strips of tablets/capsules must be kept in the original box they were dispensed in. It is not acceptable to have loose strips of tablets capsules in cupboards/trolleys/POD lockers. The only time it is permissible to have a loose strip of tablets/capsules in a medicines trolley is when a ward has had to borrow a critical medicine from another ward outside Pharmacy opening hours to avoid missing a dose. • Medicines cupboards must only contain medicines as defined under the Medicines Act 1968. • Adequate precautions should be taken against spillage or breakage and cross contamination. There must be local spillage standard operating procedures available for staff to consult. • The storage of food, drink or medication for staff personal use in these areas is prohibited. • There must be a system in place to ensure that stock is rotated and regular checks to ensure that the system is operating effectively. Products that are beyond their expiry date should be separated from usable stock and returned to pharmacy for destruction.

No.	Description of Procedural Steps
	<ul style="list-style-type: none"> Medicines/boxes of fluids should not be stored on the floor. They must be stored on appropriate shelving/cupboards or stacked on a plinth. Where possible different strengths of the same product which visually look similar or products with similar packaging should not be stored directly next to each other. <p><u>Specific storage instructions</u> Particular attention should be paid to medicines requiring specialist storage conditions such as:</p> <ul style="list-style-type: none"> Refrigeration or freezing. See Trust SOP: Monitoring of medicine refrigerator temperature. Protection from light – some products specify that they must be protected from light. These products must be kept in the packaging designed to protect them from light. Medicines with hazardous properties such as flammable medicines. Refer to hazard warning symbols on specific medicines and adhere to the manufacturer's storage instructions. Flammable products – please refer to trust fire safety officer for advice on storage of flammable products.
5	<p>Keys to Medicines Cupboards</p> <ul style="list-style-type: none"> Medicine cupboard keys must be of the type that cannot be easily duplicated without appropriate authorisation. The keys must be kept by the practitioner in charge of the department and only given to approved personnel. The practitioner in charge must know who is in possession of the keys at all times. Authorised personnel are: <ul style="list-style-type: none"> Nurses Midwives Operating Department Practitioners. Pharmacists Pharmacy Technicians Pharmacy support workers Healthcare assistants/housekeepers specifically nominated to undertake topping up/putting away medicines. N.B. Refer to Trust CD Policy MM06 for CD key requirements. CD keys must not be kept on the same ring as the general keys to the medicine cupboards. CD keys must be held on the person of the practitioner in charge. Spare keys must be held securely by the Divisional Office responsible for the clinical area. Arrangements for access must be made locally. Departments that have limited opening hours must make local arrangements to ensure the security of keys and departments containing medicines. Refer to the Pharmacy Department for advice where necessary. <p><u>Loss of keys</u> The loss or misplacing of keys must be reported:</p> <ul style="list-style-type: none"> In hours: To the Matron, Professional Head of Nursing and a member of the Pharmacy Senior Management Team. Weekends during pharmacy opening hours: Directorate Nursing Lead on duty and a Senior Pharmacist in the dispensary. Out of hours: The site manager / on-call divisional manager for advice. If the loss of keys results in serious security breach or a potential compromise to patient care the on-call Pharmacist must be informed who will escalate to a senior member of pharmacy staff as necessary. Via the Datix® Risk Management Program under 'medication' with the security box ticked 'yes'.
6	<p>Receipt of medication</p> <p><u>Ward / Department stock medication</u></p> <ul style="list-style-type: none"> Expiry dates must be checked Medicines must be stock rotated when they are put away to ensure that medication with the shortest expiry date is at the front of the cupboard to prevent waste and out of date products in cupboards. <p><u>Non-stock medication labelled for individual patient use</u></p> <ul style="list-style-type: none"> Must be checked against the prescription and stored in the POD locker. <p><u>Patients own drugs brought in from home</u></p> <ul style="list-style-type: none"> See Trust Medicines Reconciliation Policy MM01. Must be checked for suitability and placed into the relevant patient's own drugs (POD) locker unless

No.	Description of Procedural Steps
	<p>subject to specific storage requirements e.g. CDs, items requiring refrigeration.</p> <ul style="list-style-type: none"> • N.B. Before putting the medication into the locker check: <ul style="list-style-type: none"> ○ The patient's name is correct on the dispensing label. There have been instances when patients have brought old medication or medication that does not belong to them / was never intended for them. ○ The medication has been dispensed within the last 6 months and has not exceeded the expiry date. <p><u>Transfer of medication</u> See section 9 of this SOP.</p> <p><u>Discharge medication</u></p> <ul style="list-style-type: none"> • Must be received by a registered practitioner (nurse / midwife) who must: <ul style="list-style-type: none"> ○ Check all medicines against the discharge prescription to confirm that all details are correct. ○ Report any discrepancies to the Pharmacy Department immediately via the ward pharmacy team if present or by telephoning the Pharmacy Dispensary and asking for a lead member of staff. • Lock the discharge medicines in a medicine cupboard until required. • Identify items subject to special storage requirements and store appropriately until required.
7	<p>Standards for medicines refrigerators/freezers</p> <p>See SOP MM03-SOP-2 For details</p> <p>All medicines marked 'store in a refrigerator', 'store below 15°C' or 'store between 2-8°C' must be stored in a refrigerator designed for medicine storage. Before purchasing a new refrigerator wards / departments must check with Medicines Safety team to establish the most appropriate refrigerator specifications for the needs of the ward/department.</p> <p>Installing and relocation of refrigerators and freezers</p> <ul style="list-style-type: none"> • Once the refrigerator or freezer has been positioned correctly the refrigerant contained within the unit must be allowed to resettle / rebalance before use. It is recommended that the unit be left to settle for 24 hours before use. • New devices need to be PAT tested by the Estates team before being switched on. • Devices must be PAT tested annually. <p><u>Trust Medicines refrigerator requirements</u></p> <ul style="list-style-type: none"> • See Trust SOP: Monitoring of medicine refrigerator temperature. • Must maintain an air temperature of 2-8°C with the minimum of intervention. • Must <u>not</u> have a freezer compartment. Refrigerators with freezer compartments often have cold spots near the freezer compartment which may damage the medicines. • Must not be sited in an environment where extremes of temperature (less than 10°C or greater than 32°C) will affect their performance • Must be lockable • Must allow sufficient space to be maintained between the good and the internal surfaces to allow adequate air flow. If air flow is insufficient this can cause a deviation of the temperature. • New refrigerators must have built in digital displays of maximum and minimum temperatures and an alarm facility for temperature deviations. Ideally new refrigerators should have fan assisted cooling. • For old refrigerators a maximum / minimum thermometer should be kept in the refrigerator • Daily recordings of refrigerator temperature must be made and kept for two years. See Trust SOP: Monitoring of medicine refrigerator temperature for the Trust approved record form. • Current temperature • Maximum temperature over the previous 24 hours • Minimum temperature over the previous 24 hours • It is prudent to ensure that the electricity supply to the refrigerator cannot be turned off inadvertently. • Food, nutritional products or pathology specimens are not permitted to be stored in the medicines refrigerator or freezer. • Designated wards storing intrathecal chemotherapy products must have a separate dedicated refrigerator for this purpose. Refer to Trust Policy MM07 for further details. • Adequate records of repair, maintenance and calibration activities must be retained for a minimum of one year as a scanned or hard copy. • Refrigerators require ventilation for efficient operation. It is important that air can circulate to all external points around each refrigerator unit, in particular at the back and / or above each refrigerator.

No.	Description of Procedural Steps
	<p>Medication requiring freezer storage</p> <ul style="list-style-type: none"> • A freezer designed for medicines storage must be used. • Must maintain a temperature of below -18°C <p>Refrigerator / freezer temperature excursions Refer to Trust SOP Monitoring of medicine refrigerator temperature for required actions.</p> <p>Breakdown of a refrigerator / freezer or prolonged temperature excursion</p> <ul style="list-style-type: none"> • Immediate action must be taken to protect the integrity of the medicines. • All stock must be moved to an alternative storage location promptly. These must be clearly marked as 'quarantined' ideally in a bag or box labelled with 'quarantined', the originating ward and the date. These must be segregated from any other medicines in the refrigerator and details noted as to how long the items have been outside of the recommended temperature range. • Advice must be sought from the Pharmacy Medicines Information Department regarding the suitability of the medicines based on the above information. • Wards / departments to contact the Pharmacy Department if storage of large amounts of stock is required and / or when replacement stock is required. • Complete an adverse incident report on the Datix® system.
8	<p>Controlled stationary storage requirements</p> <ul style="list-style-type: none"> • A pro-security culture is mandatory for the security of prescription forms at Trust with support from the NHS Security Management Service. • FP10HPs should be stored in a controlled drug cupboard or a cupboard with the same security as a controlled drugs cupboard. Records should be kept of receipt and issuing of FP10HPs and any loss should be notified to the Trust Medication Safety Officer/Clinical Director of Pharmacy as soon as possible. • Other prescription stationary – in-patient chart, outpatient prescriptions, other types of prescriptions must be kept in a locked, secure cupboard/drawer/room. • Incidents relating to the loss or theft of prescription stationary must be escalated to the Director of Pharmacy or Pharmacy Senior Management Team immediately and via the Datix® Risk Management Program. This will facilitate: <ul style="list-style-type: none"> ○ The urgent investigation of losses / theft. ○ Counter fraud initiatives in conjunction with Staffordshire Police and primary care where required. ○ Appropriate alerting cascade to all local pharmacies where required. ○
9	<p>Arrangement of Stock</p> <ul style="list-style-type: none"> • Oral medication should be stored separately. Tablets and capsules must be stored in alphabetical order maintained in a tidy and organised manner to ensure that stock can be located safely and easily. Medicines should be stored in the original container it was supplied from Any similar looking packaging or similar sounding medicines should be separated and clearly labelled e.g. Sando K and Sando Phos. Liquid medicines and oral powders should be stored ideally in a separate cupboard but alternatively a separate shelf would be acceptable. • Medicines intended for injection should be stored in a separate cupboard, in alphabetical order. Ampoules/vials must always be stored in the original packaging in which they were supplied. It is not acceptable to store loose ampoules/vials as this poses a risk of incorrect selection or medicines going out of date. • Medicines for inhalation must be stored in a separate cupboard/separate shelf • Topical preparations must always be stored in a separate cupboard. • Fluids <ul style="list-style-type: none"> ○ Should be stored in the original boxes in which they were supplied ○ Should be stored on shelves or in a cupboard. If the fluid boxes need to be stacked they must be stored on a plinth off the floor. ○ Different fluids must be separated from each other and labelled. ○ Potassium containing fluids must be separated from non-potassium containing fluids. • Epidurals/Local anaesthetics must be separated from other injectable medication. Ideally these items should be in a separate cupboard but a separate shelf is acceptable provided it is not a cupboard for other injectable medicines.
10	<p>Transfer of medication / patient movement</p>





No.	Description of Procedural Steps
	<p>Refer to Trust Policies C24 and C21: Policy for the Handover, transfer and escort arrangements of adult patients between wards and departments and procedure for the Transfer / Discharge of Children.</p> <p>If the patient is transferred to another ward within the Trust it is the responsibility of the practitioner in charge of the care of the patient at the time of the transfer to transfer all patient specific medication to the next ward / department. This includes:</p> <ul style="list-style-type: none"> ○ Patients own drugs ○ All currently prescribed medication supplied by Trust labelled for the individual patient – labelled for either inpatient use or for discharge. ○ Refrigerated items including TPN. ○ Patients own controlled drugs. Refer to Trust CD Policy MM06. <p><u>General stipulations</u></p> <ul style="list-style-type: none"> • Transfer of medicines is mandatory at Trust as it is essential to avoid missed doses of critical and other medicines. Refer to NPSA Missed Doses Alert. • Transfer of medicines is also essential to reduce medicine waste and waste of resources. • Consideration must be given to the security of the medication during transfer. If a practitioner or healthcare is escorting the patient during transfer they should, where possible, remain in possession of the medication and hand it to the nurse receiving the patient on the next ward. • In situations where there is no nursing / healthcare escort the transfer of medication should be written in handover nursing / other documentation so that the practitioner receiving the patient on the next ward also receives the medication.
11	<p>Closure of a ward / department</p> <p><u>General principles</u></p> <ul style="list-style-type: none"> • Local assessment by the senior nursing team (or corresponding departmental leads) is required to safeguard and prevent unauthorised access to medicines. • Building contractors / other unauthorised persons are not permitted unsupervised access to medicines. <p><u>Opening a ward</u></p> <p>If the decision is taken to open a new ward:</p> <ul style="list-style-type: none"> • During pharmacy opening hours: Contact the Principal Pharmacist for Clinical Services. • Outside of pharmacy opening hours: Contact the on-call Pharmacist. <p>Ideally this should be with a minimum notice period of 24 hours. Consideration must be given to adequate security and storage of medicines.</p> <p><u>Temporary closure</u></p> <ul style="list-style-type: none"> • When a department closes for less than seven days and the location is closed to access the stock medicines may stay on the department provided there is adequate security to prevent unauthorised access. • If there is not adequate security or the department is not closed to access the medicines must be moved to an alternative secure location such as an alternative secure patient care area or the Pharmacy Department. • The Pharmacy Department must be included in plans for temporary closure so that staff can be allocated to support the closure and transfer of medicines. <p><u>Permanent closure</u></p> <ul style="list-style-type: none"> • When a department is closed for a period of longer than seven days all medicines must be returned to the Pharmacy Department. • It is the responsibility of the practitioner in charge of the department / the Matron to coordinate this with the Pharmacy Department with a sufficient notice period. The Pharmacy Department must be informed of the decision to close departments straight away in order to assist with medicines transfer. • It is the responsibility of the closing department to package the medicines appropriately with requested support from the pharmacy team. • Under no circumstances should any medicines be left in a department that has been permanently closed. This is the responsibility of the practitioner in charge of the department and the Matron.
12	<p>Audit</p> <ul style="list-style-type: none"> • The Pharmacy Department will audit every ward and department a minimum of every 12 months in conjunction with the appointed practitioner in charge of the department where possible. This audit will take

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No.	Description of Procedural Steps
	<p>place on an ad-hoc basis where possible.</p> <ul style="list-style-type: none"><li data-bbox="188 253 1516 315">• The Pharmacy Department will communicate good practice and identified deficiencies to individual areas and advise where appropriate how improvements can be made.<li data-bbox="188 320 1516 405">• The Pharmacy Department will communicate audit results to the Trust and Divisional Safe Medication Groups. The Divisional Safe Medication Groups will monitor the progress of actions resulting from the audit.



Summary of Medicine Storage Regulations

- All medicine storage locations must be approved by the Trust Security Manager and the Clinical Director of Pharmacy or Medicines Safety Officer
- Ideally medicines storage locations will be sited in areas convenient for nursing staff, allowing adequate space and permitting surveillance to afford maximum security against unauthorised entry
- Medicines storage facilities must not be sited above or near radiators or other major sources of heat or above sinks where they may be subject to higher than average humidity.




Storage Description	Approved items	Further information	Photograph
Medicines cupboard	<ul style="list-style-type: none"> • Internal preparations (e.g. tablets, capsules, liquids). • Injectable medicines (not epidurals). • Not to be used for CDs or medicines requiring specialist storage such as flammables and items requiring refrigeration. 	<ul style="list-style-type: none"> • This may take the form of one large or several small cupboards. • Generally sited in a clean utility room to which there is no public access • Must only contain medicines as defined under the Medicines Act 1968. • Medicines must be segregated appropriately. • Must be locked when not in use unless a current risk assessment in place 	
POD (patient own drugs) Lockers	<ul style="list-style-type: none"> • All patients own drugs for a single patient can be stored in the locker at the side of a patients bed 	<ul style="list-style-type: none"> • individual patient lockers designed for the storage of patients own medication and medication intended for self-administration. • Each cupboard has an individual and a master key. • Installed on the wall near the bed or attached to the bedside lockers. 	
Medicines trolley	<ul style="list-style-type: none"> • As above. • Tablets/capsules must be stored in the original container in which they are dispensed. There should be no loose strips in the trolley other than on the occasion a critical medicine has been borrowed from another ward to avoid a missed dose. • For current 'in-use' medicines only: <ul style="list-style-type: none"> • Any stock medicines no longer required must be returned to the appropriate ward medicines storage cupboards • Any non-stock items no longer required must be returned to Pharmacy Stores. 	<ul style="list-style-type: none"> • Must be locked when not in use. • They must be either tethered to a wall or stored in a locked room when not in use. • Must not be left unattended during the drugs round. If not possible the trolley must be locked. 	

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<p>External medicines cupboard</p>	<p>Medicines for external use:</p> <ul style="list-style-type: none"> ○ Lotions, creams, ointments ○ Pharmaceutical bath and shower products ○ Vaginal and rectal preparations 	<ul style="list-style-type: none"> • Medicines for external use must be stored separately from medicines for internal use. • Due to limited storage facilities some areas do not have space for a medicine cupboard designated for external medicines. In such cases, internal and external medicines must be clearly segregated and stored on different shelves in order to minimise the risk of incorrect product selection. 	
<p>Epidural injections and local anaesthetics</p>	<ul style="list-style-type: none"> • Epidurals must be stored in a cupboard or fridge solely for the purpose of storing epidurals. • Reference NPSA Safety Alert 21. 	<ul style="list-style-type: none"> • Epidurals must never be stored with any other injectable product. • This also applies to Controlled Drug epidurals. 	
<p>CD epidural injections and infusions</p>	<ul style="list-style-type: none"> • CD epidurals must be stored in a CD cupboard designated and labelled for CD epidurals only. • If a separate cupboard is not practical epidural infusions must be clearly separated and labelled in yellow baskets 	<ul style="list-style-type: none"> • See Trust CD Policy MM06 for further details and 	
<p>Controlled Drug (CD) cupboard</p>	<ul style="list-style-type: none"> • This must be used to store drugs controlled under the Misuse of Drugs Acts 1971 and associated regulations. • This includes Schedule 1 and 2 controlled drugs and any other CDs requiring safe custody such as Temazepam and Phenobarbitone / Phenobarbital. • Trust also store Midazolam and concentrated Potassium in the CD cupboard. 	<ul style="list-style-type: none"> • See Trust CD Policy MM06 for further details • CD cupboards must be: <ul style="list-style-type: none"> ○ Reserved solely for CDs / concentrated potassium. ○ Secured to a brick or concrete wall • New cupboards must be dedicated CD cupboards (not a cupboard within a cupboard). • Locks must not be common to any other lock in the hospital. • These specifications also apply to CDs requiring refrigeration. 	
<p>Concentrated Potassium cupboard (N.B. may be stored in CD cupboard if no concentrated Potassium cupboard available)</p>	<ul style="list-style-type: none"> • 10% (1gram potassium in 10mls) • 15% (1.5gms potassium in 10mls) • 20% (1gram potassium in 5mls) • Solutions of potassium hydrogen phosphate and potassium di-hydrogen phosphate in ampoules and vials (e.g. Addiphos). 	<ul style="list-style-type: none"> • Restricted use only. Pharmacy hold a list of wards approved to stock concentrated potassium. • Areas approved to hold concentrated potassium will be required to complete an annual proforma and risk assessment to justify reasons for continued use and reduce risks. • Reference NPSA Potassium Safety Alert 	<p style="color: red;">Intravenous potassium can be fatal if given inappropriately</p>

<p>Separate storage for fluids containing potassium</p>	<ul style="list-style-type: none"> Any infusion fluids containing potassium chloride 	<ul style="list-style-type: none"> Potassium containing infusion fluids must be stored separately from other infusion fluids. The shelves / drawers in which they are stored must be clearly labelled. The storage should be organised in such a way to avoid the inadvertent selection of a potassium containing fluid when not prescribed. Reference NPSA Potassium Safety Alert 	<p>Intravenous potassium can be fatal if given inappropriately</p>
<p>Fluid storage: 1) Open shelving in a lockable room.</p>	<ul style="list-style-type: none"> Parenteral fluids Sterile topical fluids (e.g. water for irrigation) Dialysis solutions 	<ul style="list-style-type: none"> Ideally fluids should be stored in the original box they are supplied in. Shelving should be labelled according to the fluids stored there Potassium containing fluids should be clearly separated. If bags of fluids need to be decanted from the original boxes into appropriately labelled trays/baskets. Extreme care must be taken to ensure that stock is rotated appropriately and expiry dates must be checked. N.B. Potassium containing fluids must be stored separately from other fluids. 	
<p>Medicines refrigerator</p>	<ul style="list-style-type: none"> Medicines requiring refrigeration are usually marked 'Store in a refrigerator', 'Store between 2-8°C' or 'Store below 25°C'. The range for a medicines refrigerator at Trust is between 2-8°C. Total Parenteral Nutrition (TPN). Must be temperature monitored daily. Must not be used to store any other item other than medicines. Must not be used to store nutritional products (kitchen fridge only). 	<ul style="list-style-type: none"> Must be a fridge designed for medicines storage only. Must be locked when not in use Segregation principles apply See refrigerator temperature monitoring information in Trust SOP: Monitoring of medicine refrigerator temperature. 	
<p>Flammable cupboard</p>	<p>Medicines pharmacy products with flammable properties</p>		

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<p>Medicines no longer required</p>	<ul style="list-style-type: none"> Medicines to be disposed of / waste medicines. Medicines waiting to be returned to pharmacy for credit inside pharmacy returns kits. 	<p>Follow Medicines Returns Procedure</p> <ul style="list-style-type: none"> Must be stored in a locked / secure area. Green tote boxes containing medicines must be sealed at both ends before handing the items over to a porter. 	
<p>Resuscitation and emergency drugs Incl: Resus boxes for adults, paediatrics and neonates. Anaphylaxis packs</p>	<ul style="list-style-type: none"> Drugs required immediately for clinical emergencies such as cardiac arrest or anaphylaxis. These medicines are pre-packed in tamper evident packaging to facilitate storage outside secure rooms. 	<ul style="list-style-type: none"> See Trust Resuscitation Policy C09. Resuscitation boxes must be kept in a location that is readily accessible in an emergency but where surveillance will prevent unauthorised access. All staff must be aware of the designated location of resuscitation boxes and emergency medication. Contents of the box are agreed by the Trust Resuscitation Committee. Resuscitation boxes and trolleys must be checked daily for suitability by nursing staff. Pharmacy staff are responsible for refilling and issuing resuscitation boxes as requested. 	
<p>Discharge medication</p>	<ul style="list-style-type: none"> Store in a locked cupboard Ensure that items requiring specialist storage such as controlled drugs or items requiring refrigeration are separated and stored appropriately. 		
<p>Medical gases</p>	<ul style="list-style-type: none"> Must be stored in a locked secure room. Must be stored upright in a vertical position. Must be secured in order to avoid toppling. Refer to the specific data sheet for safe handling instructions. 		
<p>Controlled Stationary</p>	<ul style="list-style-type: none"> FP10HPs should be stored in a controlled drug cupboard or a cupboard with the same security as a controlled drugs cupboard. 	<p>Records should be kept of receipt and issuing of FP10HPs and any loss should be notified to the Trust Medication Safety Officer/Clinical Director of</p>	

University Hospitals of North Midlands NHS Trust
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	<ul style="list-style-type: none">All other documents used to prescribe medicines must be stored in a safe and secure location where only approved staff have access	Pharmacy as soon as possible.	
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Related Documents

Trust Policies:

- MM02:** Policy for the Prescribing, Safe handling and Storage, Supply and Administration of Cytotoxic Agents
- MM03:** Policy for the Storage, Prescription, Supply and Administration of Medicines.
- MM06:** Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs
- C24:** Handover / Transfer and escort arrangements of adult patients between wards and departments.
- C21:** Procedure for the transfer / discharge of children.

Trust SOPs

- MM06-SOP-1 Storage and safe custody of Controlled Drugs
- MM03-SOP-2 Trust Procedure for Fridge Monitoring

Standard Operating Procedure (SOP)

MM03-SOP-2

Procedure for the return of pharmacy products and intravenous fluids from wards / departments to Pharmacy / Supplies and the re-use of pharmacy products on the wards.

January 2019



University Hospitals
of North Midlands
NHS Trust

APPENDIX B

The purpose of this SOP is to ensure the safe custody of pharmacy products and intravenous fluids is maintained at all times at UHNM with specific reference to the return of such products for re-use at UHNM or disposal.

This SOP links to Trust Policy MM03

This SOP applies to all UHNM staff and relevant Sodexo staff involved in the return of all pharmacy goods and intravenous fluids. This includes:

- Healthcare practitioners such as nurses, midwives, operating department practitioners
- Pharmacy staff (excluding administration staff)
- Hospital transportation staff
- Sodexo/ Portering staff

This SOP does not cover any process involving Schedule 1, 2 or 3 Controlled Drugs (as classified under the Misuse of Drugs Act 1971). Refer to UHNM MM06 Policy for the Prescribing, Storage, Administration of Controlled Drug for further instructions on all aspects of Controlled Drugs management at UHNM.

Corporate Services

Corporate Services are responsible for:

- Ensuring availability of appropriate UHNM Trust policies and procedures (see related documents) for Sodexo staff.
- Ensuring that the Yard Marshall is trained in the content of this SOP.

Yard Marshall

The Service Yard Marshalls are responsible for:

- Coordinating pharmacy and IV fluids goods in and out of the service yards in a secure manner
- Conducting daily checks to ensure that all pharmacy and IV fluids are securely stored
- Escalating non-compliance of this SOP to the relevant area (e.g Sodexo / Transport).

Pharmacy Clinical Director / Pharmacy Clinical Governance team

The Pharmacy Clinical Governance Team are responsible for:

- Advising on issues with medicines security / adverse incidents where applicable
- Providing professional input / advising where appropriate and required

Pharmacists and Pharmacy Technicians

- Providing general professional input / advising where appropriate and required regarding the return of pharmacy goods.

Supplies and Procurement Team

The Supplies and Procurement Team are responsible for

- Providing advice on the supply and return of intravenous fluids supplied by their service where required.

Practitioners in charge of wards/departments/Sodexo Portering Manager/Transport Manager:

These roles are responsible for:

- Ensuring that staff in their area of responsibility receive sufficient training and are competent to return pharmacy items/intravenous fluids in accordance with this SOP as part of the induction process / ongoing training as applicable.
- Records are kept as specified in this SOP.



- Investigating and rectifying any incidents of non-compliance with the SOP.
- Informing the Pharmacy Clinical Governance Team of any serious breaches of security or other incidents during the returns process and ensuring that a Datix® has been completed if this occurs.

Ward staff/Sodexo staff/Hospital Transport staff:

These roles are responsible for:

- Meeting minimum standards outlined in this SOP and ensuring compliance.
- Alerting their Manager to non-compliance with the standards
- Assisting with audit as requested
- Reflecting on and reviewing own practice after feedback, e.g. adverse incidents.

No.	Description of Procedural Steps	
1	<p>Items that can be returned to Pharmacy</p> <ul style="list-style-type: none"> • Out of Date Medicines • PODs no longer required for a patient • Excess medicines no longer required on the ward 	
2	<p>Designated Quarantine container</p> <ul style="list-style-type: none"> • Each ward / department must identify an appropriate secure location to store medicines that are no longer required on the ward. • This should be either a green Pharmacy tote box that can be kept in the secure clinical room or an approved Pharmacy waste bin. • In some wards/departments the Pharmacy waste bin can be secured to a wall and kept locked at all times to ensure only designated staff can access the contents. • The green Pharmacy tote bin must be kept in a secure area at all times and sealed with red Pharmacy return seals by the nursing staff before the porters transport them to Pharmacy. The boxes must never be left unattended in an area with access for patients/public. • The secure Pharmacy waste bins can only be emptied by a member of the Pharmacy staff. 	
3	<p>Out of Date Medicines and PODs</p> <ul style="list-style-type: none"> • When a medicine is identified as out of date or no longer fit for purpose it can be placed into the quarantine container for removal to Pharmacy for destruction. 	
4	<p>Excess Medicines no longer required on the ward/department</p> <p>Goods received back into pharmacy or the supplies department will be assessed for suitability for re-use. Credit will only be given for goods which meet the following criteria:</p> <ul style="list-style-type: none"> • Have a remaining shelf life of at least six months excluding high cost items which will be re-used within UHNM if the opportunity arises. • Have been issued from the UHNM Pharmacy Department / Supplies Department and is an agreed item for return (no feeds / part packs). • Have been stored securely as per the Medicines Management Policy instructions (MM03). • Have been stored in a manner that meet general storage requirements outlined in MM03 and any storage requirements specific to the individual product such as refrigeration. • Are not damaged/defaced/sticky 	

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> • Have a patient information leaflet/technical information leaflet where applicable • Are in complete packs (i.e. no items missing such as tablets popped out or opened syrups). Note: Mixing packs of medication at ward level is unsafe practice and is prohibited. • Are accompanied by a completed returns note. • Are in the original pack. <p>Note:</p> <ul style="list-style-type: none"> • Any items returned to Pharmacy or Supplies that are not deemed suitable for re-use will be disposed of. Patient's Own Drugs (PODs) issued from non-UHNM sources such as community chemists or other hospitals are not suitable for re-use and will be disposed of as per Pharmacy SOP PHA002 Waste Management (For pharmacy staff only). This includes PODs issued by UHNM that have left the UHNM Trust e.g were supplied on a previous admission. • Pharmacy products / intravenous fluids are not accepted for return on weekends / Bank Holidays unless special permission has been obtained from pharmacy / supplies. <p>The ward designated waste lead must separate items for return to supplies from items for return to pharmacy to avoid confusion.</p> <p>For packaging these items suitable for credit see below</p>	
5	<p>Pharmacy Fridge / Freezer items requiring credit</p> <p>Fridge items that can be re-used must be returned either:</p> <ul style="list-style-type: none"> • Via the ward pharmacist / medicines management technician • By telephoning pharmacy stores who can advise on arranging collection with appropriate refrigerated transport packaging in order to maintain the required temperature and therefore drug stability. 	
6	<p>Packing items for return</p>	
7	<p><u>6.1 Pharmacy items requiring credit to the ward</u></p> <p>Please note: Pharmacy do not accept anaesthetics (e.g sevoflurane / isoflurane) back for disposal. Contact the Trust Waste Manager for further advice on disposal if required.</p> <p>All boxes, such as green pharmacy tote boxes, containing cytotoxic medication to be returned to pharmacy must be labelled 'Contains cytotoxic products'. This indicates that the box contains products that are potentially hazardous in case of spills /damage during transit.</p> <p>Ward staff must ensure that items being returned for re-use are returned in the pharmacy returns kit (see picture) with appropriate paperwork completed. Suitable items include:</p> <ul style="list-style-type: none"> • UHNM labelled items <ul style="list-style-type: none"> ○Unused inpatient items 	

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> ○ Unused discharge medication ● One Stop Dispensing items (items labelled with directions for specific patient's in anticipation of discharge) ● UHNM supplied unlabelled ward stock items. <p>Ward staff must</p> <ol style="list-style-type: none"> i. Place the items with completed returns note inside the returns kit bag inside a green pharmacy box. Returns kits are available from pharmacy stores. They should be ordered via the stock list with the usual weekly order. ii. Seal both ends of the green tote box with a red tamper evident seal. The seals are sent up inside the green pharmacy boxes with the orders. Red pharmacy seals may also be requested from pharmacy stores and will be delivered at the latest, on the next working day. iii. Pharmacy fluids must also be returned via a sealed pharmacy green box to avoid incorrect return to Supplies. 	
8	<p><u>6.2 Pharmacy items requiring disposal</u></p> <ol style="list-style-type: none"> i. Ward staff must place the items (including fridge / freezer items) into the green pharmacy box. ii. Seal both ends of the green tote box with a red tamper evident seal. The seals are sent up inside the green pharmacy boxes with the orders. Red pharmacy seals may also be requested from pharmacy stores and will be delivered at the latest, on the next working day. iii. Nutritional feeds / supplements for destruction must not be returned to pharmacy (this included anything that has been opened). Liquid products may be discharged to sluice and powders may be disposed of via the domestic waste stream. This includes products such as procal shot / ensure / osmolite. iv. Anaesthetics (e.g Isoflurane / Sevoflurane must not be returned to pharmacy. Please contact the Trust Waste Manager for further advice if required. v. All boxes, such as green pharmacy tote boxes, containing cytotoxic medication to be returned to pharmacy must be labelled 'Contains cytotoxic products'. This indicates that the box contains products that are potentially hazardous in case of spills / damage during transit. 	
9	<p><u>6.3 Intravenous fluids for return requiring credit</u></p> <p>No intravenous fluids will be re-used by Supplies at the current time. This will be reviewed and may change. It is essential that wards order efficiently to avoid overstocking as all intravenous fluids returned to Supplies will be disposed of on receipt and thus credit will not be given.</p>	
10		
	<p>Completing a returns note</p> <p>Ward staff must complete a returns note for all pharmacy products that are being returned to pharmacy for credit. If there is returns note available with the returned pharmacy products the goods will be disposed of and the ward will not be credited.</p> <ol style="list-style-type: none"> i. For pharmacy returns a returns note is in the returns kit. The white top copy, once completed, must be sent to pharmacy with the goods for return inside the pharmacy returns kit. It may be attached to larger items that will not fit in the returns kit bag. The pink copy may be retained on the ward for reference. ii. For Supplies returns see Supplies IV Returns note at: <p>Record the following on either returns note:</p>	

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> • Ward number • Description • Quantity being returned. • Assurance that the item has been stored correctly according to the manufacturers specifications. This information is usually found on the outer container, in the patient information leaflet or in the summary of product characteristics (SPC). If missing up to date copies can often be found on the electronic medicines compendium www.medicines.org.uk • Assurance is given that the item has been stored securely at UHNM according to the Trust Policy MM03. • Name and designation of ward staff approving the item for return (must be a registered healthcare practitioner [e.g nurse] or a pharmacy Assistant Technical Officer.) <p>Please note: If the returns note is incomplete the item will likely be disposed of and the ward will not receive financial credit from the returned items.</p>	
	<p>Collection of pharmacy items for return/ intravenous fluids for delivery to holding area / pharmacy / supplies</p> <p>Please note that pharmacy products / intravenous fluids are not accepted for return on weekends / Bank Holidays unless special permission has been obtained from pharmacy / supplies.</p> <ol style="list-style-type: none"> i. Porters are only permitted to collect pharmacy items that are returned in a sealed box. Please note: Intravenous fluids are bulky products that cannot be sealed at the current time and may be collected by Sodexo porters. ii. Porters must attend the ward as per porter run and ask the nurse in charge if there are any items for return as they will likely be stored in an area that is not accessible by porters. iii. Refer any unsealed boxes to the healthcare practitioner in charge (nurse / midwife / ODP / member of pharmacy staff / other). It is not the responsibility of the porter to seal the boxes. iv. Transport the returned items to either the locked holding area in Service yard 3 in Lyme Building (NSPD) or directly to pharmacy if during working hours. v. Medicines / intravenous fluids must be locked into the secure area immediately on arrival. vi. If the holding area is full for any reason liaise with the porter manager who will liaise with transport for swift collection. <p>It is <i>not</i> permissible for porters to leave any medicines / returns / intravenous fluids unattended at any time during transit or holding.</p>	
	<p>Collection by Hospital Transport Team from holding area to be delivered to pharmacy / supplies</p> <p>As section 8 it is essential that safe custody of medicines including intravenous fluids is maintained at all times.</p> <ol style="list-style-type: none"> i. Hospital Transport must collect the items from the holding area and return pharmacy products to pharmacy stores and intravenous fluids to supplies. ii. When transport staff have collected the items the service tunnel holding area must be locked. <p>It is <i>not</i> permissible for porters to leave any medicines / returns / intravenous fluids unattended at any time during transit or holding.</p>	
	<p>Escalation of medicine related issues</p> <p>If at any time a member of UHNM staff identifies an issue with the</p>	

No.	Description of Procedural Steps
	<p>safety or security of medicines they must:</p> <ul style="list-style-type: none"> • Alert their line manager immediately. • Complete an electronic adverse incident report form (Datix®). <p>The line manager must:</p> <ul style="list-style-type: none"> • Resolve the situation straight away where possible (i.e. secure any items left out / return to the appropriate department straight away). • Report serious breaches with continuing risk to the safety / security of the medication/patient to the Pharmacy Clinical Governance Team / Divisional Pharmacist. If it is a member of nursing staff they must also report to the Professional Head of Nursing. • Ensure that a Datix® has been completed.

Glossary

Appointed Practitioner in Charge: The senior practitioner appointed in overall charge of the ward or department (e.g ward sister / charge nurse, operating department practitioner).

Assigned Practitioner in Charge: The senior practitioner on-duty for the ward or department who has been rostered as the professional in charge for that shift.

CD: Controlled Drug – a preparation subject to the requirements of the Misuse of drugs Regulations 2001.

Datix®: Electronic adverse incident reporting form / system used by UHNM

Expiry date: the date after which a medicine should not be used. The expiry date of each product is recorded on the product packaging.

OSD: One Stop Dispensing

PIL: Patient Information Leaflet (supplied with most pharmaceutical products)

PODs: Patient's Own Drugs

Shelf-life: the time between the manufacture of a medicinal product and its expiry date.

SOP: Standard operating procedure

SPC: Summary of Product Characteristics

UHNM: University Hospitals of North Midlands

Related Documents

MM03: UHNM Policy for the Storage, Prescription, Supply and Administration of Medicines.

MM02: UHNM Policy for the Prescription, Safe Handling, Use and Administration of Cytotoxic Agents and Drugs affecting Immune Response.

MM06: UHNM Policy for the Prescribing, Storage, Administration of Controlled Drugs.

MP2: Procedure for the safe custody of pharmacy products and intravenous fluids during transportation and delivery across UHNM

PHA002: Pharmacy SOP Waste Management (For pharmacy staff only).

Standard Operating Procedure (SOP)

MM03-SOP-3

The Monitoring of Medicine Refrigerator

Temperatures

January 2019



University Hospitals
of North Midlands
NHS Trust

APPENDIX C

The purpose of this SOP is to



1. To ensure that the safety of patients is preserved if they are administered medicines that are required to be stored in a fridge.
2. To ensure that all fridges required for the storage of medication are used and monitored in accordance with Trust policy MM03 and the legal/licenced requirements for storage of medicines requiring refrigeration are met to prevent patients coming to harm as a result of incorrect storage.
3. To ensure that refrigerated medicines are stored within the correct temperature range 2°C to 8°C

This SOP links to Trust Policy MM03


This SOP applies to the storage of all refrigerated medicines in approved medication fridges within the trust. It applies to all staff involved in the administration, ordering, receipt or management of refrigerated medicines, and excludes fridges in areas that have approved electronic temperature monitoring systems e.g. Pharmacy


- It is the responsibility of the ward /department manager to ensure that all fridges used to store medicines within their ward/department comply with the Trust and legal requirements of a medicines fridge as detailed in this SOP. This includes having an assurance that the medicines are stored at a temperature between 2°C to 8°C.
- It is the ward or departmental manager's responsibility to ensure that EVERY fridge storing medicines is monitored on a daily basis for actual, maximum and minimum temperatures. This task may be delegated to appropriately trained, nominated individuals but the ward/departmental manager is responsible and must assure themselves that temperature monitoring has taken place at least every 24 hours.
- The person delegated to monitor the fridges has a responsibility to carry out the monitoring of the fridge in line with this SOP and ensuring that they escalate to the person in charge of the ward if the temperature is noted as being above 8oC or below 2 oC.
- The person in charge of shift is responsible for overseeing that fridge monitoring has taken place and that appropriate action is taken if a temperature is recorded as below 2°C for minimum temperature or above 8°C for maximum temperature. This must be documented on the monitoring form and signed by the nurse in charge (Appendix 1)
- If a fridge is noted to be outside of range 2 oC to 8 oC without an explanation (e.g. temperature increase as door open for short period) it is the responsibility of the nurse in charge to escalate to the ward pharmacist Monday – Friday or the senior pharmacist on duty in the dispensary during Pharmacy opening hours.

No.	Description of Procedural Steps	
1	<p>General Maintenance:</p> <p>All medicine refrigerators must be used solely for the purpose of storing medicines.</p> <p>All fridges used for the storage of medicines must be approved and designed for this purpose.</p> <p>Every fridge needs to be locked when not in use or be in a clinical area that has an approved risk</p>	<p>Epidural medications and chemotherapy products require an individual fridge specifically for the storage of these medications in accordance with NPSA alert 21 and Trust policy MM07 respectively.</p> <p>Locks may be integral to the fridge or external pad locks can be used.</p>

No.	Description of Procedural Steps	
	assessment in place with regard to locking medicine cupboards e.g. critical care	
2	All plugs used for fridges must be permanently protected from accidental switch off. In addition the fridge must be able to be switched off for the purpose of defrosting if required.	It is essential that the electricity supply to the fridge is not lost inadvertently. It is essential that the ward manager has control over the ability to defrost a fridge if required.
3	Each area may have a different make/model of fridge. All fridges must have the correct manual for staff to refer to for correct recording of actual, minimum and maximum temperature readings and ability to reset thermometer.	Most manufacturers have online manuals if originals are lost. If manual for correct use of thermometer not available a new external thermometer is needed. If the fridge is too old to obtain a maintenance manual then the viability of the fridge should be looked at and a new fridge may need to be purchased. Refer to Trust Medication Safety Officer for advice Tel:74538
4	<p>Maintenance of the fridge and good housekeeping will help keep the fridge within acceptable range of 2°C - 8°C.</p> <ul style="list-style-type: none"> Do not let ice build-up at the back of the fridge. Refer to fridge manual for instructions. Stock must be stored appropriately to ensure adequate circulation of air flow around the fridge. If ice is continually accumulating at back of fridge the viability of the fridge must be questioned and no medicines should be stored in the fridge. Any medicines found to be next to an ice block in a fridge must be destroyed. A Datix should be completed. 	 <p>Pharmacy and Estates should be contacted regarding the viability of the fridge before any further medicines are placed in the fridge.</p>
5	<p><u>Arrangement of Stock</u></p> <p>Do not overstock items. Plastic bags and cardboard trays reduce cold air circulation.</p> <p>If fridges are overstocked then it makes stock rotation difficult.</p>	
6	<p><u>Temperature Monitoring</u></p> <p>Each medicine refrigerator must have their own trust approved daily temperature monitoring form-</p>	<p>Use hyperlink below for access to trust approved fridge monitoring form</p> <p>http://uhns/clinicians/support-</p>

No.	Description of Procedural Steps																						
	<p>(see appendix 1 attached for example)</p> <p>Where there is more than one medicine fridge in an area each fridge will need to be identified so that they can be linked to the allocated monitoring form.</p>	<p>services/pharmacy/medicines-management</p> <p>under documents</p>																					
7	<p>Each fridge requires a thermometer that is able to</p> <ul style="list-style-type: none"> ➤ Record the actual temperature at time of reading ➤ Record the minimum drop in temperature since thermometer last reset ➤ Record the maximum spike in temperature since thermometer last reset ➤ Be reset 	<p>For the monitoring of 24 hour ranges then thermometer needs the function of a ‘reset’ button for continual accurate monitoring.</p> <p>The thermometer may be integral to the fridge or an external unit with probe inside the fridge. The Trust Supplies department has the approved list of medicine fridges and thermometers.</p>																					
8	<p>If using an external thermometer with probe the probe must be placed securely in the middle of the fridge</p>	<p>To provide even temperature monitoring the external probe should be placed in the middle shelf half way back and securely wrapped around the shelf.</p>																					
9	<p>Complete the data at the top of the daily temperature monitoring form.</p> <p>A new chart is required each month.</p> <p>Fridge monitoring charts are required to be kept for a minimum of 2 years and these must be available for review (scanned or hard copy) when requested for audit or inspection. They must be stored in a designated folder for easy access and reference</p>	<p style="text-align: center;">DAILY MEDICINES REFRIGERATOR TEMPERATURE MONITORING FORM</p> <p>Ward / Department: _____</p> <p>Fridge location: _____</p> <p>MONTH/YEAR: _____</p>																					
10	<p>The dates of the month are already on the form so each row represents one day. Every day the time, actual, minimal and maximum temperature must be recorded then reset according to manufacturer’s instructions.</p> <p>Where a ward or dept. is closed over the weekend or bank holidays this needs to be recorded on the corresponding row of the monitoring form.</p>	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2">Date</th> <th rowspan="2">Time</th> <th colspan="3">Temperature °C</th> <th rowspan="2">Reset</th> </tr> <tr> <th>Actual</th> <th>Minimum</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>1st</td> <td>0920</td> <td>2.4</td> <td>2.3</td> <td>2.6</td> <td>yes</td> </tr> <tr> <td>2nd</td> <td>ward</td> <td>closed</td> <td>for</td> <td>weekend</td> <td>N/A</td> </tr> </tbody> </table>	Date	Time	Temperature °C			Reset	Actual	Minimum	Maximum	1 st	0920	2.4	2.3	2.6	yes	2 nd	ward	closed	for	weekend	N/A
Date	Time	Temperature °C			Reset																		
		Actual	Minimum	Maximum																			
1 st	0920	2.4	2.3	2.6	yes																		
2 nd	ward	closed	for	weekend	N/A																		
11	<p>Each entry requires the name, clearly written of the person recording the readings (this person may be a registered or unregistered practitioner) but must be deemed competent and have knowledge of this MSOP before doing so.</p>	<table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Readings recorded by:</td> </tr> <tr> <td style="padding: 5px; text-align: center;">A.N Other</td> </tr> </table>	Readings recorded by:	A.N Other																			
Readings recorded by:																							
A.N Other																							
12	<p><u>Out of Range :</u></p> <p>If the temperature readings are out of range then this must be reported to the nurse in charge of the shift or the clinical person in charge for the department to take immediate action. The following action must be undertaken:</p>	<p>It is imperative that daily recordings are taken so the length of time that medicines could potentially be out of range may be assessed.</p> <p>It is essential that patients do not miss doses of critical medicines due to a fridge temperature being out of range. If a patient requires a medicine that would have been in the fridge a dose can be obtained from Pharmacy during</p>																					

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> • Look for what may be an obvious reason for the temperature deviation e.g. door left open, power accidentally switched off, over stocked and resolve. • If all previous readings have been within range, reset the thermometer and take another reading an hour later. • If the readings are still out of range, quarantine the medicines contained in the fridge in a sealed bag and label “do not use until further notice due to fridge temperature out of range” sign and date. It may be appropriate to place the quarantined medicines in an alternative fridge until advice from Pharmacy available. • Contact the Pharmacy department during working hours within 12 hours. The Pharmacy department is open 7 days a week and enquiries should be addressed to the pharmacist in charge of the dispensary at the time. The Pharmacy department will advise on the appropriateness of using the medicines. • Contact Estates to review the fridge to establish if it can be repaired. DO NOT store medicines in a fridge that is not reliably maintaining temperature within range 2°C and 8°C. 	<p>Pharmacy opening hours or borrow from an appropriate ward outside Pharmacy opening hours and critical medicines list on-line on Trust Intranet.</p>
13	<p><u>Buying New Equipment</u></p> <p>Before buying a new medication fridge or thermometer please refer to the trust Recommended Product List on Web-basket or contact Standardisation of Products in Supplies</p> <p>Ensure that the fridge is of a suitable size to hold the required medicines for a ward or department and fits the space available on the ward. For advice please contact your ward/department pharmacist lead.</p>	

No.	Description of Procedural Steps	
14	<p>Recommended external thermometer. Standardising equipment used will help staff familiarise themselves and improve accuracy and compliance with SOP.</p> <p>See below for instructions on how to use advised thermometer</p>	 <p>The image shows a white digital thermometer with a LCD screen. The screen displays '4.8°C' in large digits, with '4.0°C' and '5.6°C' below it. The text 'Min/Max Alarm Thermometer' is printed on the device. Below the screen are three blue buttons labeled 'Min-Reset', 'Mode', and 'Max-Reset'. There are also small red indicators 'Lo' and 'Hi' below the buttons. A service tag is attached to the left side of the device.</p>

Appendix 1

SampleOnly

DAILY MEDICINES REFRIGERATOR TEMPERATURE MONITORING FORM

Ward / Department:

Ward 999

Fridge location/ID: Labcold 152 - clinical room

MONTH/YEAR: July 2015

Temperature Range = 2 - 8°C – record minimum, maximum and actual temperature daily

Date	Time	Temperature °C			Min/Max reading reset	Readings recorded by: Please PRINT	If out of range who reported to and time reported-what actions taken?
		Actual	Minimum	Maximum			
1 st	0900	2.4°C	2.2°C	5.6°C	reset	A Nurse	
2 nd	0850	3.4°C	2.4°C	6.7°C	reset	B Nurse	GOOD PRACTICE
3 rd	1026	5.6°	3.5°C	5.7°C	reset	B Hope	
4 th	0630	2.2°C	2.2°C	4.1°C	reset	H Wales	
5 th							
6 th	0830	0.6°	0.6°	24°	Reset by CH	C Nurse	Estates contacted immediately. Ward Manger made aware. Temp rechecked. Drugs isolated and moved to ward 998 fridge whilst awaiting estates to check.
7 th	0915	4.6°	3.6°	5.5°C	reset	C Nurse	Drugs returned to fridge after estates checked
8 th							
9 th	1000	5.2°C	2°C	8°C		A N Other	This may indicated that the staff member who is recording this doesn't understand the SOP
10 th	0900	4.2°C	2°C	8°C		A N Other	correctly and/or is recording the incorrect information.
11 th	1430	4.2°C	2°C	8°C		A N Other	It would be unusual for the readings to be so consistent over three days.
12 th							
13 th							
14 th							
15 th	0915	5.4	0.3	5.4			Three days the fridge has been out of range.
16 th	1033	1.4	0.3	5.4			No one has escalated this or documented actions.
17 th	1400	2.1	0.3	5.4			Thermometer not reset so no one can determine if the medications has been out of range or is it
18 th							User error. This may result in medications being
19 th							destroyed at great financial cost to the ward
20 th							
21 st							
22 nd							
23 rd							
24 th							
25 th							
26 th							
27 th							
28 th							
29 th							
30 th							
31 st							

Appendix 2

DAILY MEDICINES REFRIGERATOR TEMPERATURE MONITORING FORM

Ward / Department:

Fridge location/ID:

MONTH/YEAR:

Temperature Range = 2 - 8°C – record minimum, maximum and actual temperature daily

Date	Time	Temperature °C			Min/Max reading reset	Readings recorded by: Please PRINT	If out of range who reported to and time reported-what actions taken?
		Actual	Minimum	Maximum			
1 st							
2 nd							
3 rd							
4 th							
5 th							
6 th							
7 th							
8 th							
9 th							
10 th							
11 th							
12 th							
13 th							
14 th							
15 th							
16 th							
17 th							
18 th							
19 th							
20 th							
21 st							
22 nd							
23 rd							
24 th							
25 th							
26 th							
27 th							
28 th							
29 th							
30 th							
31 st							

**PHARMACY FRIDGES – LABCOLD PURCHASED THROUGH
SUPPLYCHAIN** (prices correct June 15)

Appendix 3



SUPPLYCHAIN PRODUCT CODE: KDU152

SUPPLIER PRODUCT CODE: RLDF0110

COST PRICE: £409.18

LEAD TIME: 5 DAYS

DESCRIPTION: Refrigeration pharmacy 36 litres lock temp display solid door gross capacity 535Hx450Wx485D



SUPPLYCHAIN PRODUCT CODE: KDU153

SUPPLIER PRODUCT CODE: RLDF0210

COST PRICE: £492.69

LEAD TIME: 5 DAYS

DESCRIPTION: Refrigeration pharmacy 66 litres lock temp display solid door gross capacity 720Hx450Wx485D



SUPPLYCHAIN PRODUCT CODE: KDU155

SUPPLIER PRODUCT CODE: RLDF0510

COST PRICE: £642.99

LEAD TIME: 5 DAYS

DESCRIPTION: Refrigeration pharmacy 150 litres lock temp display solid door 820Hx600Wx610D



SUPPLYCHAIN PRODUCT CODE: KDU157

SUPPLIER PRODUCT CODE: RLDF1010

COST PRICE: £833.39

LEAD TIME: 5 DAYS

DESCRIPTION: Refrigeration pharmacy 300 litres lock temp display solid door 1500Hx600Wx660D



SUPPLYCHAIN PRODUCT CODE: KDU158

SUPPLIER PRODUCT CODE: RDDF1510

COST PRICE: £1544.85

LEAD TIME: 5 DAYS

DESCRIPTION: Refrigeration pharmacy Refrigeration pharmacy 430 litres lock temp display solid door 1860Hx600Wx700D

Appendix 4
Fridge manuals- click on hyperlink for access

Recommended fridge

Instruction manuals for fridges already in use

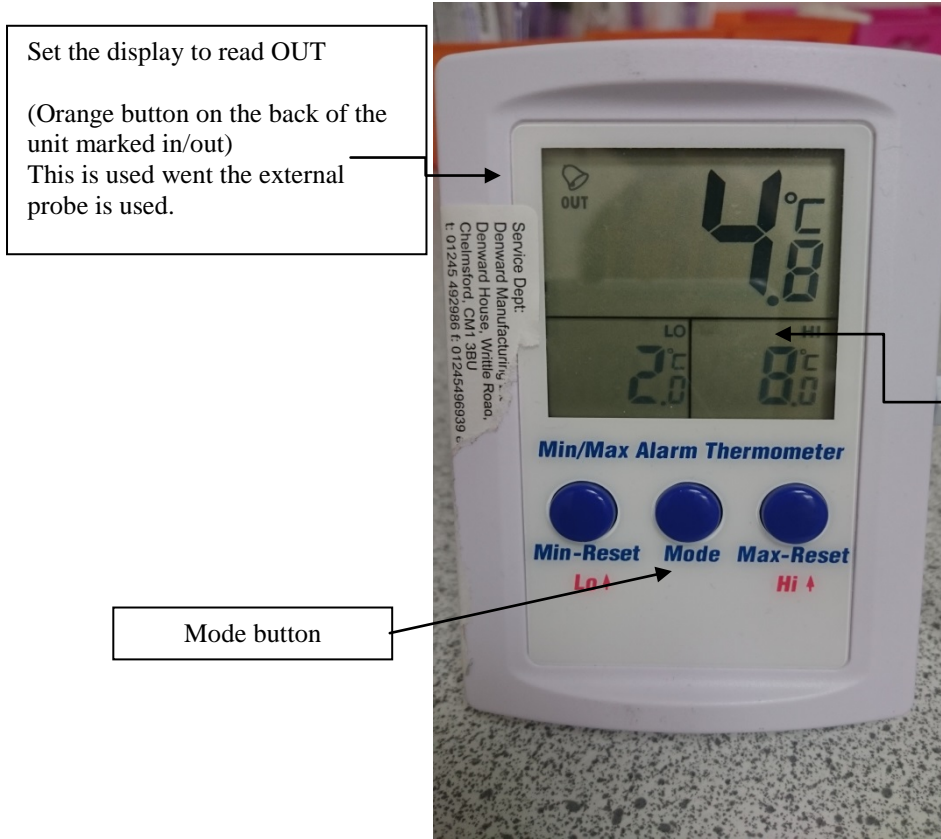
<p><u>Labcold fridge</u></p> <p>See page 8 for recording actual min/max temperatures and how to reset</p>	<p>Follow hyperlink for access to the intranet</p> <p>http://uhns/clinicians/support-services/pharmacy/medicines-management/</p>
<p>LEC fridge</p>	<p>Follow hyperlink for access to the intranet</p> <p>http://uhns/clinicians/support-services/pharmacy/medicines-management/</p>

Appendix 5

Recommended external thermometer	<p>Calibrated Max/Min In/Out Thermometer (TMM111C)</p> <p>Or follow hyperlink for access to the intranet http://uhns/clinicians/support-services/pharmacy/medicines-management/</p>
----------------------------------	--

Denward Digital Thermometer

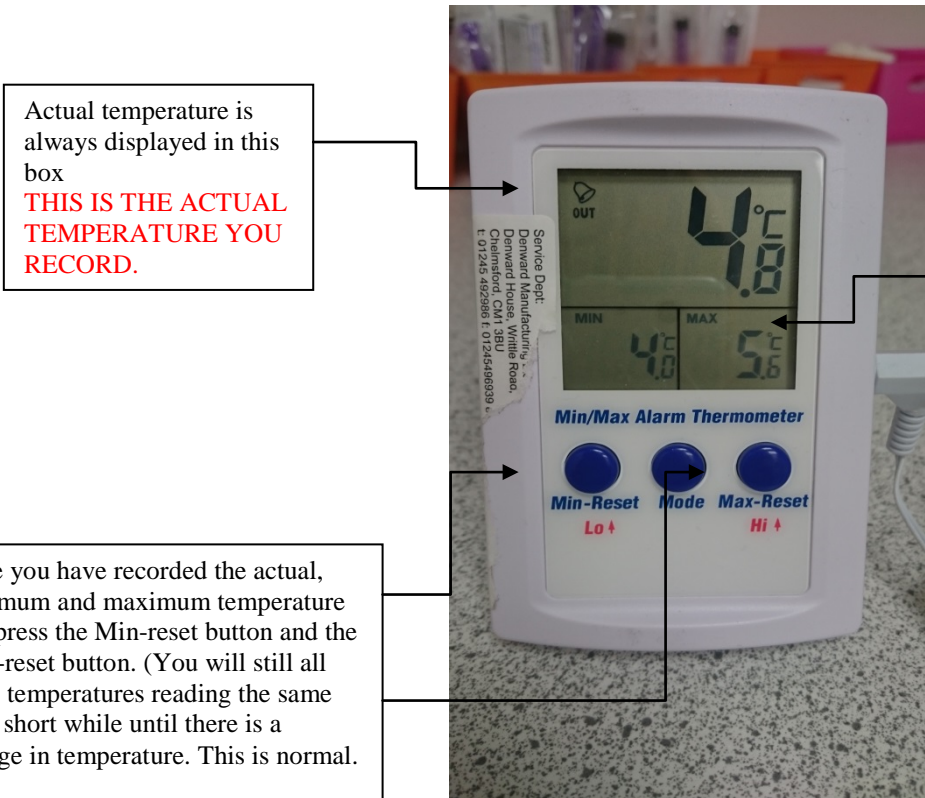
Setting up the thermometer



Set the display to read OUT
(Orange button on the back of the unit marked in/out)
This is used when the external probe is used.

Mode button

By pressing the mode button you will get two different displays. First display will show LO and HI in the top right of bottom boxes. You can set the alarm to 2°C & 8°C by pressing the min/max buttons until the correct number appears. **THESE ARE NOT THE READING YOU NEED TO DOCUMENT.**



Actual temperature is always displayed in this box
THIS IS THE ACTUAL TEMPERATURE YOU RECORD.

By pressing the mode button again you will change the display to MIN & MAX. In the top left of bottom boxes These are the reading you need to monitor the MINIMUM dip in temperature and MAXIMUM spike in temperature. **THESE ARE THE TEMPERATURES YOU NEED TO DOCUMENT EVERY 24 HOURS**

Once you have recorded the actual, minimum and maximum temperature you press the Min-reset button and the Max-reset button. (You will still all three temperatures reading the same for a short while until there is a change in temperature. This is normal.)

Standard Operating Procedure (SOP)

MM03-SOP-4

Ambient Room Temperature Monitoring for Medicines and Reagents

January 2019



University Hospitals
of North Midlands
NHS Trust


APPENDIX D


The purpose of this SOP is to provide monitoring and assurance that areas designated for medicines storage, outside of the main pharmacy dispensary, are maintained at temperatures above 15°C and below 25°C to ensure that the integrity, stability and shelf life of a product is unaffected.

This SOP links to Trust Policy MM03

This SOP applies to the storage of all medicines and reagents stored in clinics and clean utility rooms. It applies to all staff involved in the administration, ordering receipt or management of medicines or reagents. This SOP excludes areas under the direct control of pharmacy e.g. main dispensary, manufacturing room etc. and excludes refrigerated medicines.

Part A

No.	Description of Procedural Steps	
1	Medicines and reagents must be stored in cupboards that are used solely for the storage of such products.	
2	Each ward, clinical area/department must have their own Trust approved ambient room thermometer located in the room medicines and reagents are stored. The thermometer must be kept out of direct sunlight and away from direct sources of heat such as wall heaters, radiators or warming devices and away from drafts.	
3	Each ambient room thermometer must be able to : <ul style="list-style-type: none"> ✓ Display the actual temperature at the time of reading. ✓ Display the minimum temperature over the last 24 hours (or since the last recording where areas may be closed over the weekend). ✓ Display the maximum temperature (or since the last recording where areas may be closed over the weekend). ✓ Be reset 	
4	Each ward, clinical area/department must have their own Trust approved ambient room daily temperature monitoring form.	See appendix 1 attached for example.
5	Complete the data at the top of the daily temperature monitoring form.	

No.	Description of Procedural Steps																												
	<p>A new chart is required each month.</p> <p>Ambient room temperature monitoring forms are required to be kept for a minimum of two years and these must be available or review (scanned or hardcopy) when requested for audit or inspection.</p>																												
6	<p>The dates of the month are already on the form, therefore, each row represents one day.</p> <p>Every day the time, actual, minimum and maximum temperature must be recorded and the thermometer MUST be reset according to the manufacturer's instructions.</p> <p>Where a ward, clinical area/department is closed over the weekend, bank holidays or refurbishment this needs to be recorded on the corresponding row of the monitoring form.</p> <p>If a ward moves to another geographical location the ambient room temperature logs must be left behind for the attention of the incoming Ward Manager/Departmental Lead.</p>	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2">Date</th> <th rowspan="2">Time</th> <th colspan="3">Temperature °C</th> <th rowspan="2">Min/Max reading reset</th> </tr> <tr> <th>Actual</th> <th>Minimum</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>1st</td> <td>09.15</td> <td>21</td> <td>17</td> <td>24</td> <td>yes</td> </tr> <tr> <td>2nd</td> <td>ward</td> <td>closed</td> <td>for</td> <td>weekend</td> <td>N/A</td> </tr> <tr> <td>3rd</td> <td>ward</td> <td>closed</td> <td>for</td> <td>weekend</td> <td>N/A</td> </tr> </tbody> </table>	Date	Time	Temperature °C			Min/Max reading reset	Actual	Minimum	Maximum	1 st	09.15	21	17	24	yes	2 nd	ward	closed	for	weekend	N/A	3 rd	ward	closed	for	weekend	N/A
Date	Time	Temperature °C			Min/Max reading reset																								
		Actual	Minimum	Maximum																									
1 st	09.15	21	17	24	yes																								
2 nd	ward	closed	for	weekend	N/A																								
3 rd	ward	closed	for	weekend	N/A																								
7	<p>Each entry requires the name, clearly written of the person recording the readings (this person may be a registered or unregistered practitioner) but must be deemed by competent and have knowledge of this MSOP before doing so.</p>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: auto;"> <p>Readings recorded by: Please PRINT</p> </div>																											
8	<p><u>Out of Range:</u></p> <p>If the temperature readings are out of range this MUST be reported to the nurse in charge of the shift or the clinical person in charge for the department to review and take immediate action. The following action must be taken:</p> <ol style="list-style-type: none"> 1. Look for what may be an obvious reason for the temperature deviation e.g. the thermometer has been placed on, or too close to a source of heat, direct sunlight, an open window or draft. 2. If all previous temperatures have been within range reset the thermometer and take another reading an hour later. 3. Consider a battery change. 4. Look at previous results for trends and contact estates if there are sustained periods of excessive high and low temperatures being recorded. 5. If the readings are still out of range 	 <div style="border: 1px solid black; padding: 10px; margin-top: 10px; text-align: center;"> <p>The readings shown above are out of range.</p> <p>The range should be above 15°C or below 25°C.</p> </div>																											

No.	Description of Procedural Steps	
	after resetting contact: <ul style="list-style-type: none"> • Matron to discuss and if advised by Matron contact- • Estates to log a job for review of the air conditioning/heat setting as appropriate. 	
9	<u>Power Source</u> The Denward Thermometer is operated by a battery 1.5 volt AAA with a life of 5000 hours.	Batteries should be disposed of in battery recycling bins which are available around the site.
10	<u>Trouble Shooting</u> 1. Reset the thermometer and re-read results. 2. Change the batteries.* 3. Ensure the instrument is not in a high frequency radio field i.e. near a mobile phone as this can affect performance. 4. Contact the ward pharmacy team for advice	*Change the batteries immediately when readings become erratic or the display clarity fails. The batteries are located under the battery cover at the rear of the instrument. Link to the thermometer return form: http://www.pharmacy-equipment.co.uk/temperature-monitoring-1/thermometers/max-min-in-out-thermometer .
11	<u>Buying New Equipment</u> Before buying a new ambient room thermometer please refer to the Trust recommended Product List on Web-basket or contact Standardisation of Products in Supplies	Supplier: Denward Manufactures code: TMM111C FRIDGE THERMOMETER Contract Code: FXPA18 Cost £31.19.
12	Please see appendix 2 for the instructions for recording and resetting temperatures on the Denward Thermometer.	

**DAILY AMBIENT (ROOM) TEMPERATURE MONITORING FORM FOR
 MEDICINE STORAGE AREAS**

Ward / Department:

MONTH	YEAR:20
-------	---------

Date	Time	Temperature °C			Min/Max reading reset	Readings recorded by: Please PRINT	Action
		Actual	Minimum	Maximum			
1 st							
2 nd							
3 rd							
4 th							
5 th							
6 th							
7 th							
8 th							
9 th							
10 th							
11 th							
12 th							
13 th							
14 th							
15 th							
16 th							
17 th							
18 th							
19 th							
20 th							
21 st							
22 nd							
23 rd							
24 th							
25 th							
26 th							
27 th							
28 th							
29 th							
30 th							
31 st							

Safe Prescribing of Medicines – General Principles

To be used in conjunction with MM03 – SOP 5 Trust SOP for Prescribing of Medicines to Outpatients and MM03 – SOP 6 Trust SOP for Prescription of Medicines to Inpatients.

Roles and Responsibilities

Prescribers must be familiar with the guidance/regulations specified in the General Medical Council's "Good Practice in Prescribing and Managing Medicines and Devices", April 2013, relevant Nursing and Midwifery Council standards or Professional Standards specified by the General Pharmaceutical Council (GPHC).

1. Prescribers are responsible for all prescriptions they sign and for decisions and actions when prescribing or administering medicines and devices. Prescribers must be prepared to explain and justify decisions and actions when prescribing medicines. It is good practice to document any decisions/actions related to prescribing in the patient's medical notes.
2. Prescribers must ensure that when initiating any new medicine that they counsel the patient about the medicine and ensure that where appropriate patients are aware of the purpose of the medicine, any potential side effects and any effects that may occur as a result of interaction with concomitant medicines.
3. Prescribers must recognise and work within the limits of their competence and knowledge and must keep their knowledge and skills up to date. This includes being aware of, and taking appropriate action with, any national or UHNM safety alerts regarding medicines.
4. It is the responsibility of the prescriber to ensure that the prescription can be interpreted accurately, safely and in a timely manner. Prescribers will be challenged by nursing/pharmacy staff if there is any doubt about the intention of the prescriber.
5. Prescribers may write prescriptions only for persons who are registered patients of the Trust.

Professionals Permitted to Prescribe

Professionals who may prescribe medicines, defined by The Human Medicines Regulations 2012, are:

Medical doctor

Dentist

Nurse supplementary or independent prescriber

Pharmacist independent prescriber

Physiotherapist independent prescriber

Optometrist independent prescriber

Therapeutic radiographer independent prescriber

Supplementary prescriber – pharmacist, midwife, nurse, chiropodist, dietician, physiotherapist, radiographer, optometrist.

All professionals authorised to prescribe at the Trust are verified by:

Medical Staffing department confirms the registration status of all medical doctors and dentists employed by the Trust before issuing a Trust ID card.

Any locum doctors are recruited through approved locum agencies who confirm registration status before issuing with the locum agency ID card.

A register of all non-medical prescribers at the Trust is available on the Trust intranet. The verification of registration is the responsibility of the Deputy Chief Nurse who is the Trust Non-medical Prescribing Lead.

Prescribing Medicines

All medicines must be prescribed in accordance with MSOP11: Trust SOP for Prescribing of Medicines to Outpatients (appendix D) and MSOP12: Trust SOP for Prescription of Medicines to Inpatients (appendix E)

- All medicines administered at the Trust must be prescribed by an authorised prescriber who must be carrying an appropriate ID card.
- All medicines must be prescribed on Trust approved prescriptions. N.B. all prescription (paper or electronic) documents used for prescribing medicines within the Trust and any pre-printed labels used on in-patient prescription charts must be approved by the Trust Safe Medication Group prior to use.
- Electronic prescription of medicines must be through appropriately validated systems that have been approved by Trust Safe Medicines Committee and Pharmacy Directorate. Staff must be appropriately trained to utilise the system before being permitted to prescribe. An appropriate governance framework must be in place along with contingency plans for action in the event of a system failure.

Specific Considerations

Antimicrobial Prescribing

All prescribing of antimicrobials must be in accordance with the Antimicrobial Guidelines available on the UHNM Intranet ([link](#)). The guidelines are updated annually by the Antimicrobial Stewardship Committee. If an antimicrobial is required outside of the guidelines this can only be on the advice of a Consultant Microbiologists or Consultants in Infectious Diseases or in accordance with specific antimicrobial sensitivity data. The advice must be documented on the prescription chart.

Intravenous Potassium

The Intravenous administration of solutions containing potassium to correct hypokalaemia is associated with a significant risk of cardiac toxicity. The Trust Bedside Clinical Guidelines must be followed with regard to choice of treatment and route. The prescription and administration of solutions containing concentrated potassium is restricted to those areas where appropriate additional safeguards are in place – refer to Trust SOP for the Supply, Storage, Prescription and Administration of Potassium Chloride Concentrate and other strong potassium solutions .

Medication for Children

- Prescribing for children requires additional considerations. Misinterpretation of paediatric dosage guidelines can lead to errors being made. The recommended children's formulary at the Trust is the current edition of the Children's British National Formulary. Additional recommended information sources include: The Trust Bedside Clinical Guidelines Partnership Paediatric and Neonatal guidelines; the Northern Neonatal Formulary and other local guidelines – confirm with HH.
- When prescribing for paediatric in-patients or day case patients, prescribers must use the Trust Paediatric prescription chart, Paediatric CAU chart or approved electronic prescribing system.

Oxygen Therapy

Oxygen is legally classed as a medicine and must be prescribed on an approved prescription chart before it can be administered. The In-patient Adult and Paediatric prescription charts have an allocated, pre-printed space for prescribing oxygen. Refer to C57 Policy for the Prescription of Oxygen in Adults for further guidance.

In an emergency situation in which an adult patient requires increased oxygen via an ambu bag/re-breathing circuit/face mask, a registered practitioner may administer oxygen at up to 10-15 litres a minute until the emergency medical team give further instructions on arrival and oxygen can be prescribed.

Controlled Drugs

Please refer to Policy MM06 on the storage, prescription, supply and administration of controlled drugs for details regarding the in-patient and out-patient prescription of medicines.

Unlicensed Medicines and Off-Label Medicines

Please refer to MM04 Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines

Cytotoxic Medicines

Please refer to Policy MM02 on the storage, prescription, supply and administration of cytotoxic chemotherapy.

Intravenous Immunoglobulin

In line with the DH demand management programme and commissioning arrangements for intravenous immunoglobulin Policy C15 must be followed.

Dietary Products

Most dietary products are considered to be 'borderline substances' and should be prescribed on the in-patient prescription chart or approved supplementary prescription chart in accordance with local standard operating procedures and guidance:

- Oral nutritional supplements – can be written on the prescription chart by a registered dietician or an authorised prescriber. The entry on the chart must detail:
 - The product to be used, the amount required and the time of administration;
 - Signature and printed name of the practitioner with the date.
- Enteral tube feeds – must be prescribed by an authorised prescriber on the written advice of a registered dietician. The entry on the chart must detail:
 - The route – this must be clearly stated e.g. PEG; NG
 - The product to be used.
 - The dietician's enteral regime chart should ideally be attached to the prescription
 - Signature and printed name of the practitioner with the date.
- Dietary supplements can interact with some medicines therefore the use of a dietary product should always be recorded on the inpatient prescription chart. Prescribers should review the prescription of dietary products with advice from the dietician / pharmacist.
- Patients must only be supplied with dietary products to take home if these have been discussed and / or recommended by a dietician and are prescribed on the discharge prescription. Seven days supply is provided and clear recommendations for future use must be communicated to the primary care prescriber.

Discharge (TTO) Prescriptions

- See Trust Policy C05 Discharge of Patients
- An electronic discharge summary must be completed for all inpatients and day case patients on leaving hospital including weekend leave. The electronic discharge summary can act as the discharge prescription, alternatively the appropriate section of the in-patient prescription chart can be completed.
- It is critical that the medicines prescribed on the electronic discharge summary are an accurate record of the medicines that the patient is receiving at discharge, including any instructions to the GP with regard to continuing therapy or monitoring. It is the responsibility of the practitioner

signing the discharge summary to ensure the accuracy of the prescription before it is sent to the G.P.

- To ensure that there is no delay in the discharge of the patient, the ward nursing and medical staff must ensure that all medicines to be taken after discharge are prescribed promptly in advance. Ideally this should be 24 hours prior to discharge and discharge prescriptions should be sent to the Pharmacy dispensaries as early in the day as possible.
- Ideally discharge prescriptions, must receive a clinical check from a pharmacist before being given to the patient to prevent errors in prescribing/transcribing continuing into Primary Care.
- Where possible the Trust will ensure that patients have a minimum of 14 days supply of regular medication. For specialist, hospital only medicines or medicines that have a fixed duration e.g. antibiotics) sufficient medication will be supplied to complete the course.

Prescribing for Outpatients and Patients Attending A&E

See MM03 SOP 5 Trust SOP for Prescribing for Outpatients

The care of a patient attending an outpatient department or clinic is shared by the hospital doctor and general practitioner (GP). The hospital doctor who recommends a change in treatment is responsible for ensuring that a prompt, clear and appropriate communication is sent to the GP regarding any recommendations made relating to the initiation of drug therapy or changes to existing drug treatments that have been made in the out-patient setting or need to be made by the GP. The GP must be given sufficient information on therapies that he / she would not normally be familiar.

The GP refers a patient to a hospital consultant for an opinion and in the majority of cases will act upon the advice given. However, a specific drug recommended may be modified by the GP.

The GP retains overall responsibility for the patient including the prescribing of regular medicines, with the exception of hospital only drugs. Legal responsibility for prescribing lies with the medical practitioner who signs the prescription.

Medicines for out-patients should only be prescribed to meet a patient's immediate needs up to the point at which the clinic letter reaches the GP. If the patient does not have an immediate clinical need the request to prescribe a medicine should be included within the clinic letter, and the clinic letter marked as urgent for typing. Where there is likely to be a delay in the clinic letter reaching the GP a 'Dear Dr' letter (available in clinics and on the intranet) can be given to the patient. Please make the patient aware that it will take the GP at least 2 working days to issue prescriptions for any new medicines from the time the patient presents the request at the surgery. Examples of medicines that would usually be expected to be prescribed for dispensing within the hospital are:

- The patient requires treatment that in the doctor's clinical opinion should be commenced immediately. For example: initiation of antibiotic therapy; regular medication that requires an immediate dose adjustment (within 2 weeks); A&E patient requiring immediate analgesia; patient requires a "stat" dose of medicine.
- The patient requires a medicine that is not available outside the hospital. For example, clinical trial supply; hospital-only medicine; unlicensed medicine.
- The patient requires a medicine or complex treatment regime for which safe and effective prescribing depends on knowledge or experience unlikely to be possessed by the GP. For example, oral chemotherapy.
- The patient requires treatment of a disease with a drug where it has been agreed that the hospital clinician is responsible. For example, management of multiple sclerosis with disease modifying treatments; management of renal associated anaemia with erythropoietins; hepatitis C infection with interferon alpha and ribavarin.

The vast majority of out-patient and A&E prescriptions are dispensed at the RSUH site by the outsourced Pharmacy, Lloyds and at County Hospital at the Hospital Pharmacy Department. Prescriptions requiring medicines within a clinical trial and other agreed specialist medicines are dispensed at the Trust Pharmacy Dispensary at either RSUH or County Hospital.

N.B. The GMC advises that FY1 doctors are not permitted to prescribe for outpatients as these prescriptions are generally not dispensed within the Trust Pharmacy Department and therefore the prescribing would not be considered supervised.

Verbal Orders

- Verbal orders are **not** legal or valid prescriptions.
- In an emergency life threatening situation some medicines may be administered without a prescription – See Procedure for administration of medicines.
- The Trust does not permit the administration of a medicine against a verbal order unless it is a life threatening situation. In this exceptional case the following must occur:
 - Two people (one of which must be a qualified person who will administer the medicine) must witness the conversation. If the phone available does not allow for two people to listen at the same time, the prescriber must repeat the order to the second witness.
 - The order must be documented in the patient's notes giving details of:
 - The reason for the verbal order
 - The name and job title of the Doctor giving the order.
 - The name of the medicine, form, route and dose.
 - Signature of two witnesses
 - Date

North Staffordshire Joint Formulary, N.I.C.E. Health Technology Appraisals and the Bedside Clinical Guidelines

Formulary

The Trust, in conjunction with North Staffordshire CCG, Stoke-on-Trent CCG and North Staffordshire Combined Healthcare NHS Trust, has developed a Health Economy North Staffordshire Formulary. Prescribing within the Trust must comply with this formulary.

The main aim of the formulary is to promote safe, effective and economic prescribing in both general practice and secondary care. Use of the joint formulary will help to ensure seamless prescribing for patients between Primary and Secondary Care.

The formulary can be accessed via the Trust Intranet Site → Clinical Section → North Staffordshire Joint Formulary.

General Practitioners (GPs) must **not** be asked to prescribe products which have not been approved for use within the hospital. Local prescribing patterns are monitored by Trust and the CCGs and action will be taken by the Medical Director and Clinical Directors in the event of complaints from CCGs.

An application for a product to be included in the formulary may be made on the proforma obtained from the North Staffordshire Joint Formulary intranet site. All applications are reviewed by the Health Economy New Medicines Committee and ratified by the Area Prescribing Committee. The Consultant making the application must attend the relevant meeting of the New Medicines Committee to present the case for the drug.

It is recognised that all patients are individuals and there will be some situations where prescribing outside the formulary may be necessary.

Trust consultants may initiate a non-formulary medicine only with the agreement of their Clinical Director. The form, Supply Request for a Non-Formulary Medicine, must be completed by the consultant and countersigned by their Clinical Director (or designated deputy). The completed form

must then be attached to the patients prescription chart before it is sent to the Pharmacy dispensary. Pharmacy are not authorised to supply a non-formulary medicine without this form. Forms are available on both the Pharmacy and North Staffordshire Joint Formulary Sections of the Trust intranet. Patients admitted to hospital on a non-formulary medicine(s) may continue to be prescribed medicines without completion of a form.

When a non-formulary medicine has been initiated during an in-patient episode, the discharge letter should clearly indicate to the GP the reasons for this choice.

Medicines included in the Joint Formulary are categorised according to a traffic light system:

RED	Medicines that can only be prescribed within Secondary Care.
AMBER	<p>Amber medicines are further divided into 2 types:</p> <ul style="list-style-type: none"> • AMBER 1: Medicines which can be prescribed within Secondary Care, but are only considered suitable for prescribing in Primary Care under an approved shared-care agreement or Rationale for initiation, continuation and discontinuation (RIC_aD) • AMBER 2: Medicines which can be prescribed within Secondary Care, but are only suitable for prescribing in Primary Care after specialist referral. There is no need for approved shared care guidelines for medicines in this category.
GREEN	Medicines which can be prescribed in either Primary or Secondary Care.
GREY:	<p>These medicines have been reviewed by the New medicines Committee and the Area Prescribing Committee and found not to be suitable for inclusion in the Joint Formulary. The reason they are not included in the formulary may be:</p> <ul style="list-style-type: none"> • Inadequate or weak evidence for efficacy. • No clearly defined local need. • Lack of long term safety data. • No perceived benefit over established formulary alternatives. • Prescribers can consider these medicines where formulary alternatives are unsuitable, ineffective and not tolerated.

N.I.C.E. Health Technology Appraisals (HTAs) for Medicines

Local implementation plans (including costing template) of all N.I.C.E. HTAs for medicines must be reviewed by the Trust N.I.C.E. Implementation Group and incorporated automatically into the joint formulary within 3 months of the TA being published. Prescribing must be in accordance with the recommendations made by N.I.C.E. (unless otherwise agreed) and usage will be audited.

Bedside Clinical Guidelines

The Bedside Clinical Guidelines Partnership produce a number of local clinical guidelines for medicine, surgery, paediatrics and neonatal medicine which are updated annually. The guidelines are advisory, not mandatory. They provide an aide memoire for all staff concerned in the management of patients within these specialties. The guidelines provide prescribing information and advice on a range of conditions (including antimicrobial guidelines) and specific advice on some medicines (e.g. injectable medicines, warfarin). These guidelines should be utilised where possible by all prescribers.

Conditions for which over the counter items should not routinely be prescribed

As part of the Medicines Value Programme, NHS England in conjunction with NHS Clinical Commissioners has issued CCG guidance on conditions for which over the counter items should not be routinely be prescribed in primary care <https://www.england.nhs.uk/publication/conditions-for-which-over-the-counter-items-should-not-routinely-be-prescribed-in-primary-care-guidance-for-ccgs/>
The 6 CCG's in Staffordshire have incorporated this guidance into a CCG policy.

The aim of the guidance is that by reducing spend on treating conditions that are self-limiting or which lend themselves to self-care, or on items for which there is little evidence of clinical effectiveness, these resources can be used for other priority areas that have greater impact for patients, support improvements in services and deliver long-term sustainability of the NHS.

Under this policy, the CCGs advise that GPs and other prescribers follow the recommendations for each condition or item listed within the NHS England guidance, giving due regard to the general exceptions also listed.

At UHNM we support this NHS guidance and advise that prescribers working in A&E and out-patient clinics familiarise themselves with the conditions and items listed in the guidance and consider whether advising patients on the purchase of over the counter medicines and other remedies and providing written information to patients or advice could be appropriate taking into account the individual patient circumstances.

Standard Operating Procedure (SOP)

MM03-SOP-5

Prescription of Medicines to Outpatients

January 2019



University Hospitals
of North Midlands
NHS Trust

APPENDIX F

The purpose of this SOP is to ensure that all prescribing of medicines at Trust is in accordance with legislation and Trust policies and supports safe and effective Medicines Optimisation for patients at Trust.

This SOP applies to all prescribers at Trust when prescribing medicines for patients attending outpatient clinics and A&E at the Trust site. FY1 doctors are not permitted to prescribe for outpatients. This SOP must be followed at all times when medicines are prescribed for outpatients. All staff who prescribe medicines are responsible for ensuring knowledge and compliance with these procedures and Trust Bedside Clinical Partnership Guidelines must be followed where in place. All prescribers must be aware of their responsibilities as described in MM03.

Medicines form an important part of modern healthcare and a significant number of patients attending A&E or outpatient clinics will receive a prescription. Medicines are increasingly complex and it is essential that prescribing is undertaken by clinicians who have the knowledge and skills to achieve optimal effectiveness and minimise risk.

Professionals who may prescribe medicines, defined by The Human Medicines Regulations 2012, are:

1. Medical doctor
2. Dentist
3. Nurse supplementary or independent prescriber
4. Pharmacist independent prescriber
5. Physiotherapist independent prescriber
6. Optometrist independent prescriber
7. Therapeutic radiographer independent prescriber
8. Supplementary prescriber – pharmacist, midwife, nurse, chiropodist, dietician, physiotherapist, radiographer, optometrist.

All prescribers follow guidance and legislation provided by their professional bodies and the Trust. This SOP is intended to form a framework for prescribing and should be used in conjunction with relevant guidelines in the Trust Bedside Partnership Guidelines and other guidelines approved for use within TRUST – see TRUST Intranet – Clinicians - Guidelines.

Part A:

No.	Description of Procedural Steps	
	General Out-patient Prescribing	
1	<ul style="list-style-type: none"> • Medication for out-patients and patients attending A&E that must be prescribed by a Trust prescriber must be prescribed on the Trust out-patient prescription form or approved electronic prescribing system. This prescription must be taken to the Lloyds Outpatient Pharmacy at the RSUH site or the Trust Pharmacy Dispensary at County Hospital. NB The prescriber must advise the patient that this prescription cannot be dispensed outside Trust. • FP10HP prescriptions must not be used during Pharmacy opening hours. However in exceptional circumstances if a medicine is required urgently outside Pharmacy opening hours e.g. A&E patients where a pre-labelled TTO pack unavailable, an FP10HP may be used. • FY1 doctors are not permitted to prescribe for outpatients. • Prescribers must print clearly in indelible ink. Illegible, incorrect or incomplete prescriptions will be returned to the prescriber for amendment and may delay a patient receiving medication. N.B. Fountain/ink/gel pens are not acceptable as they 	The formulary can be accessed via the TRUST Intranet Site → Clinical Section → North

No.	Description of Procedural Steps					
	<p>are not indelible when wet.</p> <ul style="list-style-type: none"> An outpatient prescription given to a patient for supply from the hospital pharmacy is valid for 6 months from the date of issue unless it is for a controlled drug which is only valid for 28 days. Formulary - Prescribing within the Trust must comply with the North Staffordshire Health Economy formulary. General Practitioners (GPs) must <u>not</u> be asked to prescribe products which have not been approved for use within the hospital. 	Staffordshire Joint Formulary.				
2	<p>Details that must be recorded on all prescriptions:</p> <ul style="list-style-type: none"> Patient's full name Patient's unit number / NHS number Patient's date of birth or age Clinic or Department Responsible consultant Known or suspected medicine allergies or sensitivities, Signature of the prescriber. (N.B. for approved electronic prescribing systems an electronic signature is acceptable) Date on which each prescription is written. Weight: The weight in kilograms of children under 16 years must be recorded 					
3	<p>Detailed Guidance for Prescribing for Outpatients</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; padding: 5px;">Name and form of the medicine</td> <td style="padding: 5px;"> <ul style="list-style-type: none"> Care must be taken not to prescribe the wrong medicine – medicine names that sound or look alike can easily be confused. The British Approved Name (new BAN) of the medicine, as recommended in the BNF should be clearly written and not abbreviated. The generic name of the medicine must always be used as community pharmacies (including the Lloyds Outpatient Pharmacy) cannot substitute a generic brand. However where different proprietary brands of a medicine are known to have differing bioavailabilities or release characteristics which are clinically significant the brand name may also be indicated e.g. modified release theophylline, lithium and mesalazine. Prescribers must not use abbreviations e.g. ISMN, FeSO₄, NaCl. The form of the medicine should be specified if relevant, e.g. 'liquid' for patients who cannot swallow tablets. If a specific device is required it must be clearly specified (e.g. Accuhaler, Novopen®). This is particularly important with inhalation devices and insulins. </td> </tr> <tr> <td style="width: 20%; padding: 5px;">Dose</td> <td style="padding: 5px;"> <ul style="list-style-type: none"> Inappropriate abbreviations can be misunderstood resulting in serious prescription errors. Only approved abbreviations are permitted: <p style="margin-left: 40px;">kg – kilograms mg – milligrams ml – millilitres</p> <ul style="list-style-type: none"> The words microgram or nanogram should be written in full. They should not be abbreviated to mcg or ng. The word unit (for example, for insulin) should always be written in full and never be abbreviated to U or IU. The word litre must be written in full. The dose must be expressed in metric units avoiding decimal points wherever possible, e.g. 1mg not 1.0mg. If fractions less than one are unavoidable, they should be preceded by '0' and not just a decimal point, e.g. 0.5mL not .5mL. </td> </tr> </table>	Name and form of the medicine	<ul style="list-style-type: none"> Care must be taken not to prescribe the wrong medicine – medicine names that sound or look alike can easily be confused. The British Approved Name (new BAN) of the medicine, as recommended in the BNF should be clearly written and not abbreviated. The generic name of the medicine must always be used as community pharmacies (including the Lloyds Outpatient Pharmacy) cannot substitute a generic brand. However where different proprietary brands of a medicine are known to have differing bioavailabilities or release characteristics which are clinically significant the brand name may also be indicated e.g. modified release theophylline, lithium and mesalazine. Prescribers must not use abbreviations e.g. ISMN, FeSO₄, NaCl. The form of the medicine should be specified if relevant, e.g. 'liquid' for patients who cannot swallow tablets. If a specific device is required it must be clearly specified (e.g. Accuhaler, Novopen®). This is particularly important with inhalation devices and insulins. 	Dose	<ul style="list-style-type: none"> Inappropriate abbreviations can be misunderstood resulting in serious prescription errors. Only approved abbreviations are permitted: <p style="margin-left: 40px;">kg – kilograms mg – milligrams ml – millilitres</p> <ul style="list-style-type: none"> The words microgram or nanogram should be written in full. They should not be abbreviated to mcg or ng. The word unit (for example, for insulin) should always be written in full and never be abbreviated to U or IU. The word litre must be written in full. The dose must be expressed in metric units avoiding decimal points wherever possible, e.g. 1mg not 1.0mg. If fractions less than one are unavoidable, they should be preceded by '0' and not just a decimal point, e.g. 0.5mL not .5mL. 	
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No.	Description of Procedural Steps	
	Route of administration	<ul style="list-style-type: none"> Inappropriate abbreviations can be misunderstood resulting in serious prescription errors. Only the following abbreviations are permitted to describe route of administration: <ul style="list-style-type: none"> IV - Intravenous ID - Intradermal SC - Subcutaneous PR - Per rectum PV - Per vagina PO - Per mouth IM - Intramuscular Neb - by nebuliser Top - Topical NG - Nasogastric NJ - nasojej JEJ - via jejunostomy tube PEG - via percutaneous endoscopic gastrostomy tube Other routes of administration should be written out in full, e.g. Intrathecal, Epidural, Left Eye, Right Ear, Sublingual and Buccal.
	Frequency	<ul style="list-style-type: none"> Directions should preferably be in English without abbreviation but it is recognised that Latin abbreviations as listed in the back of the BNF can be used. Maximum doses in 24 hours must be specified where relevant on all PRN prescriptions. The following are examples: <ul style="list-style-type: none"> Mane – in the morning Nocte / night – at night OD – once a day BD – twice a day TDS – three times a day QDS – four times a day Stat – give once only PC – after food PRN – as required (indication and interval must be stated)
	Controlled Drugs	Prescriptions for Controlled Drugs must comply with the Handwriting requirements as specified in the Misuse of Drugs Act 1971. It is illegal for a pharmacist to dispense a prescription for a controlled drug if it is incorrectly written so all incorrect prescriptions will be returned to the prescriber for correction prior to dispensing. This will cause unnecessary inconvenience for the patient. Detailed guidance can be found in the current BNF in the first section under Guidance on Prescribing, Controlled Drugs and drug dependence.
4	Complex Medication Regimes <ul style="list-style-type: none"> If the prescribed medicines have complicated dosing regimens (e.g. reducing doses), prescribers should write specific directions on the prescription to ensure that the patient has the correct information to comply with the intended prescription. 	
5	Patients' Records <ul style="list-style-type: none"> A record of the prescribed medication, including the dose and duration, should be entered in the patient's medical notes. The letter to the G.P. must include information on all medicines prescribed. 	

No.	Description of Procedural Steps	
6	<p>Prescribing Antimicrobials</p> <ul style="list-style-type: none"> All antimicrobials must be prescribed in line with the current TRUST Antimicrobial Guidelines and Trust Antimicrobial Policy available on the intranet. 	
7	<p>Prescribing Anticoagulant Therapy Prescribers must be aware of all anticoagulants that the patient may be taking as it is possible that patients may be prescribed more than one anticoagulant and it is a clinical decision with regard to the on-going need/appropriateness of each anticoagulant. Prescribers must be mindful of the new oral and parenteral anticoagulants that patients may be prescribed. For a full list consult the most recent BNF. Prescribers should follow the TRUST Bedside Partnership Guidelines with regard to choice of anticoagulant, dose and duration. It is the responsibility of the prescriber to ensure that appropriate monitoring is in place and there is a robust plan to review clinical need.</p> <p>i. Warfarin</p> <ul style="list-style-type: none"> All staff expected to prescribe anticoagulants must be trained and competent to do so. There is a specialist nurse led anticoagulant service available seven days a week. These practitioners have access to the DAWN electronic dose module and ideally all patients requiring warfarin should be referred to the Anticoagulant clinic to be dosed and monitored by the specialist team. The nomogram for prescribing warfarin in TRUST prescribing guidelines must be followed at all times. If, for clinical reasons, the guidelines cannot be followed the reason must be clearly documented in the patient's notes. All prescribers and pharmacists should be aware of medicines which interact with warfarin and hence affect the INR. Further information is available in the current BNF and from Pharmacy Medicines Information. All patients newly commenced on warfarin must be issued with an anticoagulant booklet (either from the pharmacy or clinic) and be counselled so that they can manage their medication safely. All patients commenced on warfarin must have the dosage clearly documented in their anticoagulant booklet and have a follow up appointment arranged. <p>ii. Dalteparin</p> <ul style="list-style-type: none"> .If dalteparin is required for administration in the patient's home, the dose and duration of treatment must be specified. The prescriber must ensure that the patient has been assessed as competent to self-administer dalteparin or that there is provision for the medicine to be administered. Arrangements must be in place for adequate monitoring and review of treatment. <p>iii. New Anticoagulants</p> <ul style="list-style-type: none"> New parenteral anticoagulants include argatroban and fondaparinux. New oral anticoagulants (NOACS/DOACS) include dabigatran, apixaban, rivaroxaban, edoxaban. These medicines can only be prescribed in accordance with clear guidance available within UHNM Guidelines. Prescribers must be extra vigilant when prescribing these anticoagulants to ensure that other anticoagulants are NOT inappropriately prescribed concomitantly. If patients are commenced on new anticoagulants as an out-patient, the GP letter <u>must</u> state the indication for the anticoagulant, the duration of treatment and required monitoring. The patient must be counselled as for warfarin above. The patient must be given a patient information leaflet and informed to present it every time they consult with a healthcare professional for advice or treatment (e.g. G.P., community pharmacist 	<p>Warfarin, heparin and related anticoagulants are frequently involved in serious medication errors and the NPSA issued a Patient Safety Alert relating to oral anticoagulants in 2007. Most patients are treated safely with anticoagulants, however, if therapy is not monitored properly, or the patient's clinical condition or concurrent drug therapy changes, over- or under-anticoagulation can result with potentially fatal consequences. Safe anticoagulation is a multidisciplinary process involving healthcare professionals in both secondary and primary care</p>

No.	Description of Procedural Steps	
8	<p>Prescribing of Oral Methotrexate</p> <p>The following safe prescribing checklist has been developed to minimise the potential for error:</p> <ul style="list-style-type: none"> • Information on the risks and benefits of oral methotrexate should be given to the patient by the prescriber initiating treatment. F1 doctors should not prescribe oral methotrexate in line with guidance from the Deanery and F2 doctors should <u>not</u> initiate treatment with methotrexate. N.B. for patients prescribed oral methotrexate for a malignant condition please see MM02 with regards to those authorised to prescribe • Confirmation of the patient's understanding and consent should be sought, baseline tests conducted, monitoring schedule explained and patient-held monitoring booklet issued. • The prescriber is responsible for ensuring that the correct dosage (in mgs) and frequency is recorded on the prescription (in-patient, discharge or out-patient) and monitoring booklet. • Methotrexate is usually taken as a weekly dose on the same day each week. The prescriber must ensure that all prescriptions for methotrexate clearly state the day of the week that the dose is to be taken (e.g. 15mg to be taken weekly on a MONDAY). • Methotrexate is available as 2.5mg and 10mg tablets. Only the 2.5mg tablet strength is stocked by the pharmacy at UHNM, but the 10mg strength is used in the Primary Care / community pharmacy setting. The prescriber must never assume the strength of the tablet being taken by patients admitted to TRUST on methotrexate. This should always be checked before methotrexate is prescribed, dispensed or administered. • All prescribers and pharmacists should be aware of medicines which interact with methotrexate, and the prescription and coadministration of medicines which may induce methotrexate toxicity should be avoided. Further information is available in the current BNF and from Pharmacy Medicines Information. • Before a patient leaves the clinic it must be ensured that the patient is clear regarding their dose, frequency and strength of tablets. 	<p>Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, very occasionally problems with taking the medication can cause serious harm and even death. As a result of this the NPSA issued a Patient Safety Alert entitled 'Reducing the harm caused by oral methotrexate' in 2006 which targeted the use of once weekly oral methotrexate in rheumatology, dermatology and other clinical areas (e.g. gastroenterology). The Safety Alert does not apply to the use of methotrexate when used as chemotherapy for patients with malignant disease.</p>
9	<p>Medicines That Require Extra Vigilance</p> <ul style="list-style-type: none"> • Cancer treatments – follow MM02 and local SOPs • Clinical Trials – Follow local SOPs • Certain medicines have a narrow therapeutic range for them to be effective and not cause toxicity. It is therefore important that appropriate monitoring of effectiveness, blood tests and other relevant parameters is in place for patients prescribed these medicines. Examples of medicines requiring specific monitoring are: <ul style="list-style-type: none"> ○ Immunosuppressant drugs ○ Lithium (oral) • Information on monitoring of these medicines can be found in the current edition of the BNF and The Bedside Clinical Guidelines Partnership Medical and Surgical Guidelines. • It is the responsibility of the prescriber to ensure that communication to the G.P. includes all medicines prescribed, dose regime, monitoring arrangements. • Insulin <p>Extreme care must be taken when prescribing insulin to ensure that patients get the correct insulin for their clinical needs, the correct strength and the correct device. There are now a number of insulins available in higher strengths and it is</p>	

No.	Description of Procedural Steps	
	<p>critical that the correct strength is prescribed to avoid a serious adverse incident. The introduction of biosimilar insulins has also introduced the risk of an adverse incident if a patient is inadvertently switched from one brand to another. Prescribers must ensure that they prescribe the dose clearly and specify units in full – ensure no opportunity for ambiguity as this can lead to serious error. Anyone prescribing insulin must:</p> <ul style="list-style-type: none"> • Prescribe by brand • Prescribe the strength of the preparation required – should be 100units per ml in most cases. In rare cases there may be a requirement for 200 units/ml, 300 units/ml or 500 units/ml. • Prescribe the device required • Prescribe the dose clearly in units • Ensure that the patient/carer understands clearly what insulin to administer at what time of day and the number of units to administer. <p>New insulin prescriptions – if patients are commenced on new insulin the patient should be issued with a patient information leaflet and an Insulin passport card specific to the brand and device prescribed. (NPSA/2011/PSA003). Ensure that the patient/carer fully understands the number of units to administer and document the number of dose units in the patient's record.</p> <ul style="list-style-type: none"> • Sodium Valproate <p>Sodium valproate/valproic acid can result in harm to the foetus if taken during pregnancy. Any girl/woman of child bearing potential (usually between 12 and 55) must be counselled on the risks of getting pregnant while on sodium valproate. The pregnancy prevention consent form must be signed by the doctor and the patient (or carer) and placed in the notes. This must be reviewed at least annually. The patient must be given the patient information booklet at the same time as the prescription.</p>	
10	<p>Prescribing for patients who may be Pregnant or Breastfeeding</p> <ul style="list-style-type: none"> • Extra vigilance is required for patients who may be pregnant or breastfeeding. It is essential that the prescriber considers the impact of the medicine on the foetus/baby. Contact Medicines Information for further information on 74537. 	

Standard Operating Procedure (SOP)

MM03-SOP-6

Prescription of Medicines to Inpatients where electronic prescribing is not used

January 2019



University Hospitals
of North Midlands
NHS Trust

APPENDIX G

The purpose of this SOP is to ensure that all prescribing of medicines at Trust is in accordance with legislation and Trust policies and supports safe and effective Medicines Optimisation for patients at Trust.

This SOP applies to all prescribers at Trust when prescribing medicines for inpatients at Trust. It does not apply to medicines prescribed via an electronic prescribing system. All staff who prescribe medicines are responsible for ensuring knowledge and compliance with these procedures and Trust Bedside Clinical Partnership Guidelines must be followed where in place. All prescribers must be aware of their responsibilities as described in MM03. This SOP does not cover intrathecal chemotherapy. Please refer to Trust Policy MM07: Policy and Procedure for the Safe Handling, Use and Administration of Intrathecal Chemotherapy. For Prescribing of chemotherapy please also refer to MM02.

This SOP links to Trust Policy MM03

Medicines form an important part of modern healthcare and almost all in-patients will receive at least one prescribed medicine during their in-patient stay. Medicines are increasingly complex and it is essential that prescribing is undertaken by clinicians who have the knowledge and skills to achieve optimal effectiveness and minimise risk.

Professionals who may prescribe medicines, defined by The Human Medicines Regulations 2012, are:

1. Medical doctor
2. Dentist
3. Nurse supplementary or independent prescriber
4. Pharmacist independent prescriber
5. Physiotherapist independent prescriber
6. Optometrist independent prescriber
7. Therapeutic radiographer independent prescriber
8. Supplementary prescriber – pharmacist, midwife, nurse, chiroprapist, dietician, physiotherapist, radiographer, optometrist.

All prescribers follow guidance and legislation provided by their professional bodies and the Trust. This SOP is intended to form a framework for prescribing and should be used in conjunction with relevant guidelines in the Trust Bedside Clinical Partnership Guidelines and other guidelines approved for use within UHNM – see Trust Intranet – Clinicians - Guidelines.

No.	Description of Procedural Steps	
	General In – patient Prescribing	
1	<ul style="list-style-type: none"> • All medicines that are administered to patients at Trust must be prescribed on a UHNM approved prescription and administration chart if an approved electronic prescription system is not available. This is a legal document that provides a permanent record of medicines prescribed and administered to a patient and forms part of the patient's medical records. There may be more than one current prescription and administration record card in use at any one time for any one patient. Where all the regular prescription spaces are filled, a second chart may be used which should be tagged to the first chart and both charts labelled as 1 of 2 or 2 of 2 on the front of the chart. Other supplementary prescription charts may also be in use at the same time and this should be indicated on the front of the main prescription chart (e.g. insulin). Other documents permitted for prescribing are anaesthetic charts in theatre and endoscopy/bronchoscopy. • Prescribers must print clearly in indelible ink. Illegible, incorrect or incomplete prescriptions will be returned to the prescriber for amendment and may delay a patient receiving medication. N.B. Fountain/ink/gel pens are not acceptable as they are not 	UHNM approved prescription charts include: <ul style="list-style-type: none"> - TRUST Adult prescription chart - TRUST Paediatric prescription chart - TRUST Paediatric CAU prescription

No.	Description of Procedural Steps							
	<p>indelible when wet.</p> <ul style="list-style-type: none"> Formulary - Prescribing within the Trust must comply with the North Staffordshire Health Economy formulary http://Trust/clinicians/clinical-guidance/clinical-guidelines/north-staffordshire-joint-formulary 	<ul style="list-style-type: none"> - TRUST Maternity prescription - TRUST Cardiology Day Case prescription - TRUST Diabetic charts - TRUST heparin prescription chart 						
2	<p>Details that must be recorded on all prescription charts:</p> <ul style="list-style-type: none"> Patient's full name Patient's unit number / NHS number Patient's date of birth or age Ward name or number or department – it is essential that this is amended if the patient is transferred from one ward to another. Responsible consultant Known or suspected medicine allergies or sensitivities, details of the reaction (e.g. anaphylaxis, rash) and the entry must be signed and dated. Complete the prescriber details on the front of the chart for each individual prescriber Date on which each prescription is written. Indication if patient is pregnant or breastfeeding Weight: <ul style="list-style-type: none"> The weight in kilograms of children under 16 years must be recorded in the front of the prescription chart. Weight in kilograms should be recorded on all charts regardless of age where the dosage of medication is related to weight e.g. therapeutic dalteparin. 							
3	<p>Detailed Guidance for the Use of the Inpatient Prescription and Administration Chart</p> <p>The prescription chart should be completed according to the following general notes:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #cccccc;">Section</th> <th style="background-color: #cccccc;">Prescribing guide</th> </tr> </thead> <tbody> <tr> <td style="width: 15%;">Date</td> <td> <ul style="list-style-type: none"> Indicates the date treatment commenced in this inpatient episode. It is <u>not</u> the date the prescription is re-written. </td> </tr> <tr> <td style="width: 15%;">Name and form of the medicine</td> <td> <ul style="list-style-type: none"> Care must be taken not to ensure that the correct medicine is prescribed – medicine names that sound or look alike can easily be confused. The British Approved Name (new BAN) of the medicine, as recommended in the BNF should be clearly written and not abbreviated. Where different proprietary brands of a medicine are known to have differing bioavailabilities or release characteristics which are clinically significant the brand name may also be indicated e.g. modified release theophylline, lithium and mesalazine, insulin. If a medicine is a combination of two or more medicines then a generic combination name may be used. When a brand name is used Pharmacy Services will supply the most appropriate product meeting the description given and annotate the prescription appropriately. Prescribers must not use abbreviations e.g. ISMN, FeSO₄, NaCl. The form of the medicine should be specified if relevant, e.g. 'liquid' for patients who cannot swallow tablets. If a device is required for the administration of a medicine it must be clearly specified (e.g. Accuhaler, Novopen®). This is particularly important with inhalation devices and insulins. </td> </tr> </tbody> </table>	Section	Prescribing guide	Date	<ul style="list-style-type: none"> Indicates the date treatment commenced in this inpatient episode. It is <u>not</u> the date the prescription is re-written. 	Name and form of the medicine	<ul style="list-style-type: none"> Care must be taken not to ensure that the correct medicine is prescribed – medicine names that sound or look alike can easily be confused. The British Approved Name (new BAN) of the medicine, as recommended in the BNF should be clearly written and not abbreviated. Where different proprietary brands of a medicine are known to have differing bioavailabilities or release characteristics which are clinically significant the brand name may also be indicated e.g. modified release theophylline, lithium and mesalazine, insulin. If a medicine is a combination of two or more medicines then a generic combination name may be used. When a brand name is used Pharmacy Services will supply the most appropriate product meeting the description given and annotate the prescription appropriately. Prescribers must not use abbreviations e.g. ISMN, FeSO₄, NaCl. The form of the medicine should be specified if relevant, e.g. 'liquid' for patients who cannot swallow tablets. If a device is required for the administration of a medicine it must be clearly specified (e.g. Accuhaler, Novopen®). This is particularly important with inhalation devices and insulins. 	
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No.	Description of Procedural Steps	
Dose	<ul style="list-style-type: none"> • Inappropriate abbreviations can be misunderstood resulting in serious prescription errors. Only approved abbreviations are permitted: <ul style="list-style-type: none"> kg – kilograms g - grams mg – milligrams ml – millilitres • The words microgram or nanogram should be written in full. They should not be abbreviated to mcg or ng. • The word unit (for example, for insulin) should always be written in full and never be abbreviated to U or IU. • The word litre must be written in full. • The dose must be expressed in metric units avoiding decimal points wherever possible, e.g. 1mg not 1.0mg. If fractions less than one are unavoidable, they should be preceded by '0' and not just a decimal point, e.g. 0.5mL not .5mL. 	
Route of administration	<ul style="list-style-type: none"> • Inappropriate abbreviations can be misunderstood resulting in serious prescription errors. Only the following abbreviations are permitted to describe route of administration: <ul style="list-style-type: none"> IV - Intravenous ID - Intradermal SC - Subcutaneous PR - Per rectum PV - Per vagina PO - Per mouth IM - Intramuscular Neb - by nebuliser Top - Topical NG - Nasogastric NJ - nasojej JEJ - via jejunostomy tube PEG - via percutaneous endoscopic gastrostomy tube • Other routes of administration should be written out in full, e.g. Intrathecal, Epidural, Left Eye, Right Ear, Sublingual and Buccal. • Only one route of administration can be specified for each prescribed medicine. It is not acceptable to prescribe more than one route on the same prescription as the bioavailability may be different e.g. PO/IV is not permitted. The medicine should be prescribed by the most appropriate route for the patient and medicine at the time of the prescription and if the route subsequently needs to be changed then the prescription should be cancelled and a new prescription written for the different route. 	
Times of administration	<ul style="list-style-type: none"> • The time at which each dose is to be administered should be marked in the appropriate line of the inpatient prescription chart. If the pre-printed administration times on the chart are not appropriate for a particular medicine, they may be crossed out and more suitable times entered. There must be no ambiguity, and the instructions for the nursing staff must be clear. • Directions should preferably be in English without abbreviation but it is recognised that Latin abbreviations as listed in the back of the BNF can be used. The following are examples: <ul style="list-style-type: none"> Mane – in the morning Nocte / night – at night OD – once a day BD – twice a day TDS – three times a day QDS – four times a day 	

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	<p style="text-align: center;">Stat – give once only PC – after food PRN – as required see 1d below X – entered in a specific date / time box indicates to omit the dose.</p> <hr/> <p>Signature</p> <ul style="list-style-type: none"> Each prescription must be authorised by the signature of a registered prescriber. Where the prescriber is non-medical an indication of their prescribing authority should be made after their name. N.B. Each prescriber must sign the front of the chart and print their name indicating their status and contact details to ensure that they can be identified and contacted if required. 	
4	<p>Cancellation of Treatment</p> <ul style="list-style-type: none"> If a prescription is to be discontinued a stop date must be entered into the “stop” section of the chart, a line must be put through the entire entry and it must be dated and signed by the practitioner who cancels the prescription. When a ‘stop date’ or ‘for x days’ direction is used in anticipation of a treatment course, unless otherwise indicated, this indicates that a 12.00 midnight on the date specified the prescription must be discontinued and no further doses are to be administered. If treatment is planned to stop part way through the day (e.g. antibiotics) the subsequent administration boxes must be blocked off with a cross. If stopping treatment temporarily, the individual doses should be omitted by the prescriber putting a cross in the administration square and initialling. 	
5	<p>‘As Required’ Medicines</p> <ul style="list-style-type: none"> The ‘As Required’ section must only be used for those medicines to be given at the practitioner’s discretion according to the needs of the patient. The indication should be stated e.g. “for nausea” or “for breakthrough pain”. The minimum interval between doses must be clearly specified by the prescriber. The maximum number of doses in 24 hours must be specified. The ‘As Required medicines’ prescription must be regularly reviewed by the prescriber to determine clinical need. Medicines originally prescribed ‘as required’, but which are needed regularly as indicated by the administration record and regular clinical need, must be reviewed and rewritten in the regular prescription section and cancelled from the “As Required Drugs” section unless additional doses are intended. Care must be taken not to duplicate medicines being taken regularly and thus overdose the patient. Combination analgesics frequently contain paracetamol, which may already be prescribed in the regular section of the prescription chart. Some “As Required Drugs” may be administered according to Patient Group Directions (PGDs). Administration of these medicines must be recorded as ‘PGD – ref: x’ where ‘x’ refers to the approved PGD number. See MM05 	
6	<p>Once Only (STAT) Medicines</p> <ul style="list-style-type: none"> Medicines that are intended to be given as a single dose once only must be prescribed in the ‘once only’ section on the front of the chart. The only exception is antibiotics used for prophylaxis which must be prescribed on the once only section of the antimicrobial section of the chart. 	
7	<p>Prescribing Antimicrobials</p> <ul style="list-style-type: none"> All antimicrobials must be prescribed in line with the current UHNM antimicrobial guidelines available on the intranet. Antimicrobials must be prescribed on the antimicrobial section of the prescription chart. An indication for the antimicrobial must always be specified in the appropriate box. The duration of the antimicrobial treatment must be specified and reviewed after 72 hours. The design of the prescription chart means that a maximum of seven days can be administered after which if the antimicrobial is to be continued it must be prescribed 	

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	<p>again in the next available space in the antimicrobial section.</p> <ul style="list-style-type: none"> N.B. When prescribing GENTAMICIN prescribers MUST follow the TRUST guidelines with regard to dose, frequency and monitoring. Gentamicin must be prescribed in the pre-printed gentamicin section of the antimicrobial page. 	
8	<p>Prescribing Anticoagulant Therapy Prescribers must be aware of all anticoagulants that the patient may be taking as it is possible that patients may be prescribed more than one anticoagulant and it is a clinical decision with regard to the on-going need/appropriateness of each anticoagulant. Prescribers must be mindful of the new oral and parenteral anticoagulants that patients may be prescribed. For a full list consult the most recent BNF. Prescribers should follow the TRUST Bedside Clinical Partnership Guidelines with regard to choice of anticoagulant, dose and duration. It is the responsibility of the prescriber to monitor the patient closely and review clinical need.</p> <p>iv. Warfarin</p> <ul style="list-style-type: none"> All staff expected to prescribe anticoagulants must be trained and competent to do so. There is a specialist nurse led anticoagulant service available seven days a week. These practitioners have access to the DAWN electronic dose module and ideally all in-patients requiring warfarin should be dosed by the specialist team. The nomogram for prescribing warfarin in TRUST prescribing guidelines must be followed at all times. If, for clinical reasons, the guidelines cannot be followed the reason must be clearly documented in the patient's notes. Warfarin should be prescribed on the appropriate warfarin section of the prescription chart. All prescribers and pharmacists should be aware of medicines which interact with warfarin and hence affect the INR. Further information is available in the current BNF and from Pharmacy Medicines Information. All patients newly commenced on warfarin must be issued with an anticoagulant booklet (either from the ward, pharmacy or clinic) and be counselled so that they can manage their medication safely. All patients discharged on anticoagulants must have the discharge dosage clearly documented in their anticoagulant booklet and have a follow up appointment arranged prior to discharge. This is the responsibility of the prescriber. The discharge letter <u>must</u> state the indication for the anticoagulant, the duration of treatment, the target INR range and arrangements for follow up monitoring of the INR. Detailed guidance on the initiation, monitoring and discharge arrangements of patients on warfarin can be located in the relevant clinical guidelines and drug monographs in the TRUST Clinical Guidelines. <p>v. Dalteparin</p> <ul style="list-style-type: none"> Dalteparin for routine thromboprophylaxis must be prescribed in the pre-printed section of the regular prescription chart for PROPHYLAXIS. N.B. the dose must be prescribed in accordance with the UHNM guidelines after the Venous Thromboembolism (VTE) assessment has been completed. Dalteparin for treatment of thrombotic events must be prescribed on the dalteparin TREATMENT section of the prescription chart in accordance with TRUST guidelines. <p>vi. Heparin</p> <ul style="list-style-type: none"> Heparin infusions, both loading doses and continued infusions must be prescribed on the UHNM heparin supplementary prescription in accordance with Trust guidelines. <p>iv New Anticoagulants</p> <ul style="list-style-type: none"> New parenteral anticoagulants include argatroban and fondaparinux. New oral anticoagulants include dabigatran, apixaban, edoxaban and rivaroxaban. These medicines can only be prescribed in accordance with clear guidance available within UHNM Guidelines. The new parenteral anticoagulants must be prescribed on the regular section of the prescription chart. The new oral anticoagulants (NOAC/DOAC) must be prescribed on the pre-printed NOAC section on the anticoagulant section of the prescription chart. Prescribers must be extra vigilant when prescribing these anticoagulants to ensure 	<p>Warfarin, heparin and other anticoagulants are frequently involved in serious medication errors and the NPSA issued a Patient Safety Alert relating to oral anticoagulants in 2007. If therapy is not monitored properly, or the patient's clinical condition or concurrent drug therapy changes, over- or under-anticoagulation can result with potentially fatal consequences. Good communication between Primary and Secondary Care is essential.</p>

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	<p>that other anticoagulants are NOT inappropriately prescribed concomitantly.</p> <ul style="list-style-type: none"> • NOACs/DOACs may interact with some commonly prescribed medicines which may result in adverse incident. If in doubt about potential interaction consult the BNF or Medicines Information. • If patients are discharged on NOACs/DOACs, the discharge letter <u>must</u> state the indication for the anticoagulant, the duration of treatment and required monitoring. • For patients discharged on NOACs/DOACs the patient must be counselled as for warfarin above. The patient must be given a patient information leaflet and informed to present it every time they consult with a healthcare professional for advice or treatment (e.g. G.P., community pharmacist). 	
9	<p>Prescribing Injectable Medicines</p> <ul style="list-style-type: none"> • Medicines to be given by injection must be prescribed in the appropriate section of the prescription chart: <ul style="list-style-type: none"> ○ For IV bolus, IM or SC bolus routes use the relevant section of the prescription chart e.g. regular section for medicines required daily, antimicrobial section for antibiotics. ○ Medicines to be administered by intravenous infusion must be prescribed on the intravenous infusion page of the prescription chart. ○ Intravenous fluids for fluid replacement should be prescribed on the fluid prescription section at the back of the prescription chart. • Prescribers should ensure that the following specific issues are carefully considered and documented on the prescription chart when writing a prescription for an injectable medicine: <ul style="list-style-type: none"> ○ A clear indication on the prescription of the specific route to be used, where appropriate (e.g. subcutaneous, intravenous). • The method of administration i.e. bolus, intermittent infusion, continuous infusion. ○ The dose/total quantity of the active medicine to be administered. ○ The name and volume of the diluent or infusion fluid, or both. ○ Concentration or total quantity of medicine in the final infusion container or syringe. ○ The duration of the infusion and/or calculated rate at which the infusion is to be administered (the use of calculators to determine the volume of quantity of medication should not act as a substitute for arithmetical knowledge and skill). ○ Date on which treatment should be reviewed (for regular prescriptions). ○ Any required parameters for clinical monitoring according to local protocols and clinical need. 	
10	<p>Prescribing Epidural Medicines</p> <ul style="list-style-type: none"> • Epidural medicines must be prescribed on the pre-printed supplementary prescription dedicated to epidurals only. 	
11	<p>Prescribing of Oral Methotrexate</p> <p>The following safe prescribing checklist has been developed to minimise the potential for error:</p> <ul style="list-style-type: none"> • Information on the risks and benefits of oral methotrexate should be given to the patient by the prescriber initiating treatment. F1 doctors should not prescribe oral methotrexate in line with guidance from the Deanery and F2 doctors should <u>not</u> initiate treatment with methotrexate. • Confirmation of the patient's understanding and consent should be sought, baseline tests conducted, monitoring schedule explained and patient-held monitoring booklet issued. • The prescriber is responsible for ensuring that the correct dosage (in mgs) and frequency is recorded on the prescription (in-patient, discharge or out-patient) and monitoring booklet. • Methotrexate is usually taken as a weekly dose on the same day each week. The prescriber must ensure that all prescriptions for methotrexate clearly state the day of the week that the dose is to be taken (e.g. 15mg to be taken weekly on a MONDAY). • On the in-patient prescription chart the prescriber must cross out the six days of the 	<p>The NPSA issued a Patient Safety Alert 'Reducing the harm caused by oral methotrexate' in 2006 aimed at reducing the risks of serious harm that can arise from the use of once weekly oral methotrexate in rheumatology,</p>

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	<p>week when a dose must not be given by clearly placing a cross in the corresponding administration box.</p> <ul style="list-style-type: none"> • Methotrexate is available as 2.5mg and 10mg tablets. Only the 2.5mg tablet strength is stocked by the pharmacy at UHNM, but the 10mg strength is used in the Primary Care / community pharmacy setting so extreme care must be taken when information is shared between primary and secondary care. • For patients admitted to UHNM already taking methotrexate: <ul style="list-style-type: none"> ○ The Person taking the drug history must be absolutely certain of what dose the patient is taking and ensure that it is prescribed weekly as above. Healthcare professionals must never assume the strength of the tablet being taken by patients and must always be checked before methotrexate is prescribed, dispensed or administered. ○ If in any doubt about the dose of methotrexate the patient usually takes it is safer to omit it from the prescription and confirm with the initiating doctor as soon as possible after admission. ○ Extra care must be taken when in-patient prescription charts are rewritten so that all relevant information is accurately transcribed. • All prescribers and pharmacists should be aware of medicines which interact with methotrexate, and the prescription and co-administration of medicines which may induce methotrexate toxicity should be avoided. Further information is available in the current BNF and from Pharmacy Medicines Information. • Before a patient is discharged from hospital ensure that the patient is clear regarding their dose, frequency and strength of tablets and that the discharge letter is clear and unambiguous. 	<p>dermatology and other clinical areas. The Safety Alert does not apply to the use of methotrexate when used as chemotherapy for patients with malignant disease.</p>
12	<p>Medicines with a Narrow Therapeutic Index</p> <p>Certain medicines have a narrow therapeutic range for them to be effective and not cause toxicity. It is therefore important that therapeutic drug monitoring (TDM) of blood levels of these medicines are monitored closely to ensure that dosing is effective.</p> <p>Medicines which require particularly close monitoring include:</p> <ul style="list-style-type: none"> ○ Digoxin (oral and IV) ○ Gentamicin IV – must be prescribed in the dedicated section on the prescription chart and TRUST guidelines followed at all times. ○ Tobramycin IV ○ Lithium (oral) ○ Phenytoin (oral and IV) ○ Theophylline (oral) ○ Aminophylline (oral and IV) ○ Vancomycin (IV) ○ Heparin (unfractionated) – treatment dose (IV or SC) ○ Warfarin ○ Immunosuppressant drugs ○ Amphotericin – must be prescribed as generic and brand <ul style="list-style-type: none"> • Information on monitoring of these medicines can be found in the current edition of the BNF and The Bedside Clinical Guidelines Partnership Medical and Surgical Guidelines. • It is the responsibility of the medical team looking after the patient to ensure that: <ol style="list-style-type: none"> i. Clear instructions and communication occur regarding monitoring of these medicines (including over the weekend / bank holidays). ii. The prescription of the medicine is reviewed on a regular basis. iii. Blood levels are checked and results acted upon in a timely manner thus ensuring that patient care is not adversely affected. • Ideally patients on drugs with a narrow therapeutic index should be ‘flagged’ to the relevant ward pharmacist by medical or nursing staff so that specialist advice can be provided. 	
13	<p>Medicines That Require Extra Vigilance</p>	<p>Prescription form for</p>

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	<p>Prescribers must be extra vigilant when prescribing medicines that can cause serious harm when prescribed incorrectly or omitted. For extra guidance consult the most recent BNF or the Trust Bedside Partnership Guidelines.</p> <ul style="list-style-type: none"> • Insulin <p>Extreme care must be taken when prescribing insulin to ensure that patients get the correct insulin for their clinical needs, the correct strength and the correct device. There are now a number of insulins available in higher strengths and it is critical that the correct strength is prescribed to avoid a serious adverse incident. The introduction of biosimilar insulins has also introduced the risk of an adverse incident if a patient is inadvertently switched from one brand to another. Prescribers must ensure that they prescribe the dose clearly and specify units in full – ensure no opportunity for ambiguity as this can lead to serious error. Anyone prescribing insulin must:</p> <ul style="list-style-type: none"> ○ Prescribe by brand ○ Prescribe the strength of the preparation required – should be 100units per ml in most cases. In rare cases there may be a requirement for 200 units/ml, 300 units/ml or 500 units/ml. ○ Prescribe the device required ○ Prescribe the dose clearly in units ○ Ensure that the patient/carer understands clearly what insulin to administer at what time of day and the number of units to administer. ○ Regular insulin should be prescribed on the regular section of the prescription chart. Extra care should be taken to ensure that the dose is written correctly. For patients admitted who take insulin regularly it is essential that the drug history accurately records the correct number of units. ○ Variable Rate Insulin Infusion - Use the appropriate UHNM supplementary prescription for prescription of insulin infusions in surgical patients. For all other indications the infusion should be prescribed on the infusion section of the prescription chart. ○ New insulin prescriptions – if patients are commenced on new insulin the patient should be issued with a patient information leaflet and an Insulin passport card specific to the brand and device prescribed. • Potassium <ul style="list-style-type: none"> ○ If potassium supplementation is required, the oral route should always be considered first line. The duration of treatment must be specified and potassium levels monitored daily. ○ If intravenous potassium is indicated refer to UHNM Bedside Clinical Partnership Guidelines for the correct concentration/volume. Pre-prepared bags must always be used. The standard potassium infusion solutions are available from the Supplies department. If there is no suitable infusion fluid available, consult the ward pharmacist/on-call pharmacist. ○ Concentrated potassium solutions must only be used in exceptional circumstances and only approved practitioners can prescribe or administer – see Standard Operating Procedure for the Supply, Storage, Prescription and Administration of Potassium Chloride Concentrate and other strong potassium solutions. • Paracetamol IV <ul style="list-style-type: none"> ○ Extreme care is required when prescribing and administering intravenous paracetamol to ensure that the correct dose is given. Failure to prescribe according to product license can lead to overdose, liver failure and possibly death. For all patients (adult and paediatric), dose is based on weight. 	<p>Management of Diabetic Patients in Surgery can be ordered from Harlow printers order number NSH 8055</p>
14	<p>Prescribing for patients who may be Pregnant or Breastfeeding</p> <ul style="list-style-type: none"> • Extra vigilance is required for patients who may be pregnant or breastfeeding. It is essential that the prescriber considers the impact of the medicine on the foetus/baby. Contact Medicines Information for further information on 74537. 	
15	<p>Oxygen</p> <ul style="list-style-type: none"> • Oxygen must be prescribed on the appropriate section of the prescription chart, A&E treatment chart or anaesthetic chart. 	

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	<ul style="list-style-type: none"> • The prescription must state the mode or device for administration and flow rate (e.g. nasal cannulae, face mask, venturi mask, rebreath device ensuring that flow is compatible with the manufacturer's advice), percentage oxygen, frequency and duration of oxygen to be given. • In some circumstances, prescribers may prescribe oxygen to be given to maintain oxygen saturation above a certain level. • In patients with conditions such as chronic obstructive pulmonary disease (COPD) or other known risk factor for hypercapnic respiratory failure, it may be appropriate for the independent prescriber to state an upper limit to the amount of oxygen such patients may be given. • Oxygen administration must be checked by a registered nurse or midwife at intervals appropriate to the patient's condition, situation and the equipment being used. Each check must be recorded on the appropriate prescription/treatment chart.

Related Documents

- **MM03** - Policy for the Storage, Prescription, Supply and Administration of Medicines
- **MM04** - Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines
- **MM06** - Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs
- **MM02** - Trust Policy for the Prescription, Safe Handling and Storage, Supply and Administration of Cytotoxic Agents and Cytotoxic Monoclonal Antibodies
- **MM05** - Policy for the Supply and Administration of Medicines via Patient Group Directions
- **IC24** - Trust Antimicrobial Stewardship Policy

Supply of Medicines

PROCUREMENT

1. Contracts

To ensure cost efficient prescribing it is essential that medicines are procured to achieve best value for money. As a result medicines are purchased on negotiated contracts. These may be at a National level (brokered by the Commercial Medicines Unit - CMU), Regional level via the West Midlands Procurement Alliance or individual Trust level via Pharmacy. These processes ensure fair competition for the manufacturers whilst delivering medicines at the best price, thus ensuring value for money. Refer to Pharmacy Policies and procedures for further information if required.

2. Purchasing Medicines

All medicines should be purchased through the Pharmacy, either directly from the manufacturer (which may include the Pharmacy Manufacturing Unit within the Trust) or from a wholesaler. In either case the continuity of supply is of paramount importance and should be considered first, above the cost. The urgency of the medicine may determine the route of supply (e.g. goods from a wholesaler may be obtained in a matter of hours whereas those directly from the manufacturer may take several days). Refer to Pharmacy policies and procedures for further information if required.

3. Homecare

Healthcare delivery companies are utilised to supply a limited number of high cost medicines direct to the patient's home. Ideally these schemes should be managed by the Pharmacy Directorate, however, where this is not the case Associate Directors of Divisions are responsible for ensuring that robust clinical and financial governance arrangements are in place regarding the management of these scheme(s).

ORDERING OF MEDICINES

Nursing/midwifery/ODP staff are responsible for ensuring that all medicines required for patients under their care are available at the appropriate time.

Medicines that are not controlled drugs can legally be supplied by Pharmacy in three ways:

1. Supplied as stock to a ward or department for the purpose of being administered to a patient in accordance with a legal prescription.
2. Use of Patients' own drugs
3. In accordance with a legal prescription

Stock Medicines

Stock Lists

A list of medicines to be held as stock on a ward or department must be agreed between the directorate/ward pharmacist and the registered practitioner in charge of the area. The list should include prudent levels of medicines of a sufficient range to be able to administer the most commonly prescribed agents in the clinical speciality which the ward or department serves. This will allow the majority of prescribed doses to be administered within the first 24 hours of admission. Stock lists must be reviewed at least annually to ensure that the medicines held as stock are relevant to the clinical speciality of the ward.

Injectable Medicines: A risk assessment of all injectable medicines must be undertaken and reviewed annually by a Pharmacist and Senior Practitioner to determine the safest presentation and location for storage and preparation.

Ordering Stock Medicines

Pharmacy Top-Up System

Some wards / clinical areas have their stock medicines replenished by a Pharmacy 'topping-up' service whereby appropriate pharmacy staff check the cupboards and order stock medicines to the agreed levels. All medicines received on the ward / clinical area should be checked against the order by appropriate ward / department staff or Pharmacy staff where appropriate.

The frequency of the 'top-up' depends on the ward / clinical area and site.

Pharmacy staff will check expiry dates of stock medicines when the top-ups are undertaken.

If a ward / clinical area require additional stock medicines before the next top-up (e.g. if additional stocks are required to cover an acute situation), it is the responsibility of nursing staff to ensure supplies are ordered. Appropriate mechanisms include contacting Pharmacy Stores directly or via the medicines management technician / ward pharmacist depending on the area.

Areas without a Top-Up System

These areas will order stock via a ward stock sheet order form or requisition book. The responsibility for managing stock levels and ordering stock items rests with the ward / Department Manager / Appointed Nurse / Midwife.

Nursing / departmental staff are responsible for checking the expiry dates of stock where a top-up service is unavailable.

Responsibility for keys: The supervising nurse/ODP/midwife-in charge of the ward is responsible for the keys to the medicines cupboards at all times. Therefore if ordering of medicines is delegated to a support worker, the nurse/ODP/midwife must open the cupboard, retain the keys, and lock the cupboard again after ordering is complete. Only approved healthcare assistants/housekeepers may be given the medicine cupboard keys and the nurse/ODP/midwife must be aware of the security of medicines at all times.

Patients Own Drugs / Medicines (PODs)

Actively encouraging patients to bring their medicines with them to hospital has been demonstrated to improve the quality of care no extra cost. Within the Trust patients medicines can be used to administer doses to patients provided they have been approved as fit for purpose. This can be undertaken by a registered pharmacist, a registered pharmacy technician with the ACT qualification. PODs remain the property of the patient and consent for their use must be obtained. The PODs must be securely stored at all times and they must be stored in the dedicated POD lockers on the wards or in a dedicated locked medicine cupboard. It is essential that patient's medicines are transferred with them when the patient is moved to a different ward or department to ensure that doses are not missed.

Supply in Accordance with a Legal Prescription

• **Prescription**

- Prescriptions must be written in accordance with MSOP11 and MSOP12.
- The prescription should be validated in accordance with Pharmacy SOPs:
 - ✓ PHA 89 Procedure for the Triaging of Prescriptions in the Pharmacy Dispensary
 - ✓ PHA 76 Procedure for the Clinical Check of Prescriptions on the Wards

N.B. Pharmacists have a responsibility to alert the prescriber if he or she has written a prescription for a medicine which is outside the normal dosage range for the route prescribed, is not covered by a product license, or may interact with another medicine/drug which has been prescribed for the patient/client. They may refuse to dispense it if the consultant responsible for the patient's care/treatment is not willing to accept responsibility formally for any adverse effects of the

administration of the medicine/drug. All ambiguities or potential risks should be identified, and clarified with the prescriber before dispensing.

- **Requesting In-patient Non-stock Medicines**

- For medicines not routinely stocked by a ward / clinical area, a patient specific supply will be made. It is the responsibility of nursing staff to initiate such supplies. A clinical check by a Pharmacist MUST be made before patient specific supplies are issued by Pharmacy. Ideally medicines should be ordered at ward level by the ward pharmacist or medicines management technician (MMT) during their visit. If a ward Pharmacist is unavailable (e.g. at weekends) the prescription chart should be sent to pharmacy for supply.
- Outside Pharmacy opening times: Nursing staff are responsible for making a clinical judgement to determine the clinical significance of prescribed non-stock items. See Appendix H MSOP13 Trust SOP for Administration of Medicines.
- Temporary stock will only be supplied in exceptional circumstances and must be authorised by a clinical pharmacist or the Chief Technician Patient Services.

- **Dispensing of Prescriptions**

- All dispensing of prescriptions must be undertaken by Pharmacy staff in accordance with Pharmacy SOPs for dispensing and checking prescriptions.
- On wards / departments nursing staff must not transfer medicines from one container to another. Only a pharmacist may alter a label or authorise re-labelling of a container.

Dispensing for Discharge – where possible any non-stock medicine that is required for a patient may be labelled with appropriate directions such that the medicine can be issued at discharge without further dispensing by Pharmacy. This is in accordance with the Pharmacy Directorate SOPs.

Total Parenteral Nutrition (TPN) and Central Intravenous Additive Service (CIVA)

Total parenteral nutrition infusions and CIVAs are made according to a patient specific prescription by the Aseptic department within the Pharmacy Manufacturing Unit. The service will operate routinely during normal working hours from Monday to Friday and the Pharmacy will prepare TPN infusions for the weekend and Bank Holiday periods in advance. TPN cannot be commenced for new patients out of hours or during the weekend period.

Cytotoxics

- Supplies of prepared parenteral cytotoxic medicines are made by the Pharmacy Chemotherapy Service within the Pharmacy Manufacturing Unit according to a patient specific prescription. **For further details relating to the storage, supply, prescription and administration of chemotherapy agents please refer to Policy MM02.**

Discharge (TTO) Prescriptions -

- See Policy C05 – Discharge Policy and associated SOPs
- All medicines must be included on the discharge prescription i.e. the electronic discharge summary or hand written TTO at the back of the prescription chart. This is to ensure that the GP receives an accurate and up to date record of all medicines prescribed for the patient at the point of discharge.
- Ideally TTOs should be written at least 24 hours in advance to support safe discharge with minimal delay for patients at the point of discharge.
- Where possible discharge prescriptions should be clinically checked by a pharmacist to ensure that all medicines prescribed at discharge are safe and clinically appropriate to continue after discharge. Therefore every effort should be made to ensure discharge prescriptions are written and sent to Pharmacy during Pharmacy opening hours.

There are some agreed medicines where it is appropriate for nurses to issue a pre-pack of a medicinal product that has been supplied by the hospital Pharmacy service for that purpose. This would usually be against pre-printed discharge prescriptions where the directions on the pre-pack exactly match the prescription or outside Pharmacy opening times where prescribers must write the prescription exactly to match the directions on the pre-pack. Only authorised, competent registered nursing/midwifery staff may issue these pre-packs in accordance with the MSOP 18

Transport, Transfer & Receipt of Medicines

- Medicines should be transported between the Pharmacy and the wards / departments in the following manner:
 - Stock medicines should be transported in a sealed green Tote box, a sealed red bag or a sealed cool bag. These containers are transported to the wards and departments by Sodexo portering staff or Pharmacy portering staff.
 - Non-stock medicines should be transported in sealed red bags by Sodexo or Pharmacy porters or through the UHNM air tube system for appropriate items.
 - Containers of medicines must never be left unattended in areas accessed by patients/public. They must be handed directly to a member of the ward/department staff or placed directly in the secure clinical room.
- If medicines sent from the Pharmacy fail to reach their destination ward or department. Such non-deliveries should be reported to the Pharmacy immediately.

Borrowing of Medicines

- Medicines, including controlled drugs, should not be borrowed from other wards/clinical areas except in a clinical emergency, out-of-hours for the pharmacy service or when authorised by a pharmacist or pharmacy technician at weekends / bank holidays / out-of-hours. This is in the interest of patient and staff safety, ensures that suitable clinical checks are performed and that staff are familiar with the medicines required. For controlled drugs see Policy MM06.
- If borrowing is approved, the following process must occur:
 - If a complete original pack of medication is to be borrowed, an untrained member of staff can collect it from a donor ward.
 - If a complete, original pack is not available, a registered nurse or midwife should:
 - Take the prescription chart to the donor ward
 - Check the prescription with the medication
 - Take the medication in it's container back to the receiving ward
 - Administer the medication in the approved manner
 - Return the container to the ward
 - A record of medicine given to other wards or departments should be maintained on the donor ward
 - The borrowing of medicines across Directorates and Divisions should not, under any circumstances, compromise patient care.

Stock Discrepancies

- Any suspected stock discrepancy must be reported on Datix and fully investigated.
- If a full investigation fails to locate the missing medicines the senior pharmacist on duty must be informed and the incident escalated to the Associate Chief Nurse for the Division and the Clinical Director of Pharmacy.
- If a member of staff is suspected of committing fraud or theft then this must be investigated in accordance with appropriate Trust policies and procedures.

Out of Hours pharmacy service

Outside Pharmacy opening times, an out-of-hours service is available from Pharmacy for **emergencies only**. This may include:

- For medicines where an omitted dose may result in harm it is essential that registered practitioners obtain the medicine as described in MSOP13 – Trust SOP for Administration of Medicines. If in any doubt contact the on-call pharmacist.
- Urgent requests for advice on medicines
- Pharmaceutical support in major clinical incidents

Waste Medicines/Medicines no Longer Required by a Ward or Department

- Medicines no longer required on a ward or expired medicines must be returned to Pharmacy according to MSOP1 Trust Procedure for the return of pharmacy products and intravenous fluids (appendix G).

Spillages

All wards/clinical areas should have COSHH assessments for potentially hazardous materials within their areas together with procedures and control mechanisms in place for and additional reporting mechanisms (see Trust Policy on Control of Substances Hazardous to Health).

Dropped/spilled solid doses (e.g. tablets, capsules, suppositories) must not be reused but disposed of as clinical waste.

Care must be taken with broken glass (e.g. from ampoules, bottles). Gloves should be worn and the residues disposed of as sharps via the clinical waste route.

All wards/clinical areas dealing with cytotoxics must keep a cytotoxic spillage kit within that area. For full details please refer to MM02.

Disposal of Sharps

Sharps must only be disposed of safely. Careless disposal of needles and venflons is a continuing health hazard for staff.

Administration of Medicines – General Principles

To be used in conjunction with MM03 – SOP – 7 TRUST SOP FOR Administration of Medicines

1. General Principles

- Medicines can only be administered in accordance with one or more of the following:
 - A valid prescription on UHNM approved prescription stationary
 - Patient group direction (PGD)
 - Medicines Act Exemption – see appendix 1
- Administration of prescribed medication may be undertaken by a wide range of **appropriately trained and competent registered practitioners** within the Trust:
- Medical doctors
- dental practitioners
- Registered nurses and midwives
- Other health professionals who are registered with a recognised professional body may administer medicines specific to their area of expertise (e.g. ODPs, radiographers, perfusionists and allied health professionals).

2. Responsibilities

- All registered practitioners are accountable for their actions and their omissions and act in the best interests of the patient at all times.
- Registered nurses and midwives must comply with the NMC Standards for Medicine Management, April 2010 or any superseding standards issued by the NMC.
- All registered practitioners who administer medicines must ensure that they comply with the requirements and guidance of their professional bodies with regard to knowledge, skills and competency. Evidence of training and competences with regard to medicines management must be retained in their personal records.
- All registered practitioners who administer medicines must ensure that they are familiar with and follow the Trust SOP for Administration of Medicines and only administer medicines that they are authorised and deemed competent to do so. The Trust has adopted the Royal Marsden Manual of Clinical Nursing Procedures (9th edition) for procedures involved in administration of medicines and these are available via UHNM intranet. All staff who administer medicines are responsible for ensuring knowledge and compliance with these procedures (or any local modification).
- Registered practitioners must acknowledge any limitations in their knowledge and competence and decline any duties or responsibilities unless able to perform them in a safe manner.
- Registered practitioners must avoid any improper delegation to others, which compromises the interests, wellbeing or safety of patients and clients.
- All staff who prepare and administer parenteral doses are responsible for personal elements of safety including infection control of their activities and the disposal of sharps.
- Ward and departmental managers and others responsible for clinical governance, are responsible for:
 - Ensuring that staff have the knowledge, skills and competency to administer medicines that are routinely prescribed within their ward/department.
 - Ensuring that areas in which parenteral doses are prepared are maintained in a safe and clean environment.
- Competent registered practitioners have a duty and responsibility to teach students and recently qualified practitioners concerning the administration of drugs and medicines in order to assist them towards practicing unsupervised when competent to do so. NB. Students must not practice unsupervised.
- All staff who administer medicines are responsible for ensuring that they, or others nearby, are

able to manage patients in the event of severe adverse reactions (e.g. anaphylaxis).

3. Accountability for Administration

(i) Record of Administration

A specimen copy of the signature, printed name and initials of every registered practitioner who prescribes, dispenses, signs or initials prescription sheets or controlled drugs record books in their area of responsibility is obtained corporately as part of the UHNM staff induction process. The signatures are stored on a database for reference. Need to check this is still the case

Single person checking

With the exception of medicines listed in (iii) below, registered practitioners with approved competencies may administer medicines unsupervised. In this case the registered practitioner must sign in the appropriate box to indicate that a medicine has been administered. In accordance with the NMC Code of Conduct (2010), all practitioners including registered bank/agency nurses are accountable for their practice and must not administer medicine unsupervised unless they believe themselves competent to do so.

(ii) Two people checking

- Two people must be involved in the checking and administering of the following:
- Controlled Drugs – See Policy MM06
- **Children** – All medication for neonates and children (up to the age of 16) with the exception of those medicines listed in appendix 2 of MM03 – SOP 7 – Trust SOP for Administration of Medicines which is an agreed list of commonly used medicines in children. Only these medicines may be administered by a single registered paediatric nurse with approved competencies to administer medicines to children.
- Cytotoxic drugs via all routes (except those administered orally) – see MM02
- Potassium chloride concentrate and other strong potassium injection solutions see – SOP
- All intravenous drug administration
- Insulin
- Treatment doses of dalteparin (low molecular weight heparin)
- Blood and Blood Products
- Where the dose has to be calculated (e.g. a liquid dosage form without pharmacy annotation).
- Anaesthetists and Doctors working in Emergency situations – it is recognised that in an emergency situation or in theatres that it is not practical to have a second person checking a drug prior to administration. In these situations the anaesthetist or emergency doctor must ensure that they have followed all the required procedures in MM03 – SOP – 7 for ensuring that they have the correct drug, correct dose and there are no contraindications. The doctor is responsible for checking that the correct drug has been selected and that the expiry date is still valid.

The person acting as the second check or signature on the administration record is signing to acknowledge that the medicine has been given and hence it should not be completed unless the second practitioner has witnessed the entire process of the medicine being administered. One of the practitioners administering must be approved as competent to administer medicines unsupervised. The second person should be either a registered practitioner competent to administer medicines unsupervised or a second or third year pre-registration nursing/midwifery student, or any practitioner approved by stated local protocols (e.g. paramedics). At UHNM the following staff **cannot** provide the second check: nursery nurses; play specialists; medical student; clinical support worker.

4. Ambiguous Prescriptions

In any of the following situations:

- a. The prescription is unclear or incomplete.
- b. The prescription has been incorrectly altered (see SOP for Prescribing for Inpatients).

- c. The registered practitioner has any doubt regarding the safety/appropriateness of the medication.

It is the registered practitioners' responsibility to seek clarification from the prescriber. Administration of such medication should be withheld until the prescription has been clarified, unless the practitioner makes a professional decision to administer the medication on clinical grounds. In this case any decisions/actions must be documented in the patient's medical record. Any problems practitioners encounter relating to the administration of medicines that cannot be resolved locally should be brought to the attention of the senior nurse for their area or Nurse Practitioner covering the hospital.

5. Allergies

- See MM03 – SOP 7
- Many medicines have names which do not immediately suggest that they contain penicillin (e.g. Tazocin®; co-amoxiclav®). It is essential for all staff who handle medicines to understand their constituents.
- In order to distinguish between serious allergy and less harmful drug intolerance, the symptoms of any reported allergy should be documented in the medical notes.

6. Parenteral Drug Administration

The intravenous route is the quickest and most direct route for drug administration. The effect of the medication begins almost immediately. Hazards of IV drug therapy are numerous and patient safety is therefore paramount. This was recognised by the NPSA who issued a Patient Safety Alert relating to the administration of injectable medicines. The Alert states that all Trusts should undertake: annual risk assessments on the aseptic preparation and administration of injectable medicines on wards / departments; and that injectable medicines should be risk assessed and that appropriate risk reduction strategies should be employed to minimise the risks involved, and that

In order to ensure the safety of the patient:

- the prescription and patient must be checked
- the medicine should be administered correctly and its effect monitored (including observing for side effects)
- All intravenous equipment – medication, fluid, giving sets and cannulae should be handled correctly and safely.

For parenteral administration of medication the relevant guidelines in the UHNM Medical and Surgical Guidelines must be consulted in addition to the procedures in the Royal Marsden Manual of Clinical Nursing Procedures (8th edition). Additional information can be found in the current edition of the BNF (Appendix 6), the Medusa injectable database (access via UHNM intranet site Clinicians, Medical and nursing, Pathways and Guidelines) and the relevant Summary of Product Characteristics.

Preparation of IV doses - Ready to use injectable preparations must be used where available. If a prepared product is not available it will be necessary for registered and competent medical staff or nurses with the required training to add drugs to intravenous diluents / fluids. Any preparation and calculation must be carried out by a registered competent practitioner and checked by another registered competent practitioner.

Intravenous bags or syringes prepared in clinical areas:

- (i) Must be labelled with the UHNM approved labels and include all relevant information.
- (ii) Have a twenty-four hour expiry unless advised otherwise.
- (iii) Must be initiated immediately after preparation and not put aside for later use.

- (iv) Administration must be completed within 24 hours of preparation. Any solution remaining 24 hours after preparation must be discarded.

6.1 Flushing of intravenous lines and cannulae

- The procedure for flushing of intravenous lines and cannulae must be followed (Royal Marsden Manual of Nursing Procedures 9th edition).
- All flushes must be prescribed on the appropriate prescription chart. Sodium chloride 0.9% is pre-printed on the adult prescription chart on the when required (PRN) page - Follow the UHNM Guidelines on flushing of lines.
- Practitioners completing cannulation of a patient must flush the cannula to check patency after completion of the procedure.

6.2 Infusion Device

Good practice suggests that the Asset ID number of the infusion device used to administer parenteral infusions by any route should be documented on the prescription sheet next to the drug being administered via that device. Following instances of adverse incidents the Asset ID number must be recorded in the patient's medical records.

7. Administration of Medicines in Accordance with Patient Group Directions (PGDs)

Please refer to UHNM Policy on PGDs (MM05)

Cytotoxic drugs

Please refer to UHNM Policy on the Storage, Prescription, Supply and Administration of Chemotherapy (MM02).

The Covert Administration of Medicines (i.e. disguising medication in food and drink)

Please see appendix

Administration of Epidurals

All practitioners involved in prescribing, preparing, administering and monitoring epidural injections and infusions must receive documented formal training and updates (NPSA alert 21 – March 2007). Senior staff should supervise recently trained staff and make sure that they have the necessary work competencies to undertake their duties safely and effectively.

- All registered practitioners must follow the relevant SOP for epidurals in the clinical area in which they are working.
- All infusion bags and syringes for epidural use must be clearly labelled with the UHNM yellow epidural label and the label must include the wording 'FOR EPIDURAL USE ONLY'.
- All administration sets and catheters must be clearly labelled with the yellow 'EPIDURAL' labels and clearly identified as being for epidural use only.
- Only the yellow Infusion pumps and syringe driver devices identified for epidural infusions can be used to administer epidural infusions and must be clearly identified that they are being used for epidural use.

Administration of Medicines/drugs by Midwives who are Employed in the Obstetric and Gynaecology Directorate

See MM03 – SOP - 7

8. Patient Self-Administration

Patient self-administration (SA) is a system where selected patients maintain or gain a level of independence during their hospital admission. It seeks to identify and resolve any difficulties which patients may be experiencing with their medicines and increase their understanding of them.

Any clinical wards wishing to implement self-administration must liaise with the Clinical Director of Pharmacy or Principal Pharmacist Clinical Services regarding this matter. Robust standard operating procedures and competency training and assessments must be in place and approved by the UHNM Safe Medicines Committee.

9. Nil by Mouth in Anticipation of Surgery

Patients labelled Nil By Mouth (NBM) prior to surgery should take their usual medication, unless otherwise directed, at their usual times pre-operatively. Sips of water are allowed if required to aid swallowing. Medication that is usually taken with or after food can be taken on an empty stomach with sips of water as a 'one-off'. Failure to continue a patient's usual medication can potentially cause an exacerbation of their chronic condition or adverse effects from abrupt withdrawal to occur. In some cases it is beneficial to stop or alter certain drug regimens, due to potential interactions with anaesthetic agents, other drugs, or complications related to surgery. However, it is not appropriate to simply omit an oral medicine without first clarifying the instruction with the relevant clinical team/anaesthetist.

10. COVID-19 Vaccination Programme

Competencies and training of all staff involved in the UHNM Vaccination programme:

All staff involved in the vaccination programme for COVID-19 must meet the defined competencies and training / knowledge required to utilise the most up to date version of the PSD and PGD. This includes: successful completion of the relevant e-learning packages with certificates, knowledge of the relevant Chapter of the Green Book, the MHRA Information for Healthcare Professionals and the most up to date versions of relevant SOPs including the 'Assessment, Prescription, Reconstitution and Administration of the COVID 19 vaccine(s). Authorised named train the trainers are in place to support training and must be utilised.

Legal Framework

There are two legal frameworks for the administration of the COVID-19 vaccine (all brands) at UHNM (County Hospital and Royal Stoke University Hospital) sites. Vaccination is in accordance with the UK Joint Vaccination and Immunisation Committee priority list and includes UHNM staff, wider health and social care workers in the Staffordshire and Stoke on Trent STP, patients and general public.

1. Patient Group Direction (PGD) – Please see MM05 Trust Policy on Patient Group Directions. The COVID-19 vaccine PGDs are national documents and as such must be followed in their entirety to ensure indemnity. There is a local UHNM front sheet containing the reference number on the Trust PGD register and the Trust list of signatories for the PGD. The national legal framework for PGDs only specifies a defined number of registered healthcare professionals who can **supply and administer medicines** (in this case the COVID-19 vaccine) under this framework. This list cannot be amended locally. The same registered person must supply (including preparation) and administer the vaccine. A medical prescriber should not use a PGD as he / she can prescribe.

Registered staff groups which are not listed in the national PGD framework CANNOT legally supply and administer the vaccine via this route. This includes: operational department practitioners (OPDs), pharmacy technicians, medical students, etc.

2. Patient Specific Direction (PSD) or prescription – this has been adapted locally from the national PSD template and has been signed off by the UHNM COVID Clinical Forum. A medical or non-medical prescriber (e.g. registered nurse or pharmacist on the Trust non-medical prescribing register) must complete the clinical assessment, consent and prescription on a PSD. They can also prepare, dilute and administer the vaccine. However, there is the option locally to look at different staff groups who can undertake the preparation, dilution and administration of the vaccine.

Appendix I of MM03 clearly defines which staff groups can routinely administer medicines including the second check, their responsibilities and accountability. However, in order to facilitate the volume of vaccinations required in the COVID vaccination programme UHNM has

extended the list of professional staff that are permitted to prepare, dilute, administer and where appropriate undertake the second check elements in the PSD. These are identified as 'Locally agreed registered Staff/Senior Students':

- FY1 medical doctors
- Registered clinical scientists
- Operation Department / Theatre practitioners (ODP)
- 5th year **medical** students and 3rd year **nursing** students (NB this is in the capacity of their training placements NOT as bank shifts for which they are contracted as HCA who as non-registered staff are not included)

In summary, the following staff groups can complete the following stages of the vaccination process:

Stage of process	Currently		Proposed from January 15.01.2021	
	PGD	PSD	PGD	PSD / Prescription
Clinical assessment, consent and supply (PGD) and / or prescription of COVID-19 vaccine	Defined registered professional listed in PGD	Trust authorised Prescriber (medical or non-medical)	Defined registered professional listed in PGD	Trust authorised Prescriber (medical or non-medical)
Dilution and withdrawal	The same defined registered professional as above	Trust authorised Prescriber (medical or non-medical)	The same defined registered professional as above	Trust authorised Prescriber (medical or non-medical) or as per MM03 Appendix I or locally agreed registered Staff/Senior Students
Administration	The same defined registered professional as above	Trust authorised Prescriber (medical or non-medical)	The same defined registered professional as above	Trust authorised Prescriber (medical or non-medical) or as per MM03 Appendix I or locally agreed registered Staff/Senior Students

Deployment of locally agreed registered Staff/Senior Students

In any one vaccination centre session there would be a maximum of two vaccinators from the 'Locally agreed registered Staff/Senior Students' group working as 'buddies' with a medical prescriber. The same paperwork will apply to all three vaccinators in this 'set' i.e. the UHNM PSD. The patient will be assessed and consented by the prescriber and move to the RS/SS for vaccination.

Locally agreed registered Staff/Senior Students will be trained as per the PGD staff. They will have practical training in the preparation of the vaccine and for those from professional groups who do not routinely administer intra-muscular injections, this additional training will be provided. Training must be via one of the Trust approved Train the Trainers for COVID vaccination. Training records (including certificates) must be signed and collated by the Deputy DIPC or a designated member of his team. All of the documentation must be in place and confirmed prior to allocation of vaccinator shifts.

Standard Operating Procedure (SOP)

MM03-SOP-7

Administration of Medicines

January 2019



University Hospitals
of North Midlands

NHS Trust

The purpose of this SOP is to ensure that administration of all medicines at Trust is in accordance with legislation and Trust policies and supports safe and effective Medicines Optimisation for patients at the Trust.

This SOP applies to all staff who administer medicines at the Trust. The Trust has adopted the Royal Marsden Manual of Clinical Nursing Procedures (8th edition) (<http://www.rmmonline.co.uk/>) for procedures involved in administration of medicines. All staff who administer medicines are responsible for ensuring knowledge and compliance with these procedures. Trust Bedside Clinical Partnership Guidelines must be followed where in place. This SOP does not apply to the administration of Cytotoxic Agents and Cytotoxic Monoclonal Antibodies covered under MM02. It does not cover intrathecal chemotherapy. Please refer to Trust Policy MM07: Policy and Procedure for the Safe Handling, Use and Administration of Intrathecal Chemotherapy.

No.	Description of Procedural Steps	
1	<p>The key principles for safe drug administration:</p> <ul style="list-style-type: none"> ✓ Right Patient ✓ Right Medicine ✓ Right Dose ✓ Right formulation ✓ Right Route ✓ Right rate (if given by infusion) ✓ Right Time ✓ Right monitoring 	<p>N.B. All non-oral medicines must be administered separately from the routine oral medicine round, to reduce the risk of errors</p>
2	<p>Healthcare professionals permitted to administer medicines after appropriate training and competency assessment:</p> <ul style="list-style-type: none"> • Medical doctors • Dental practitioners • Registered nurses and midwives • Other health professionals who are registered with a recognised professional body may administer medicines specific to their area of expertise (e.g. ODPs, radiographers, perfusionists and allied health professionals). 	
3	<p>Authorisation Required for Medicines to be Administered:</p> <ul style="list-style-type: none"> ✓ A valid prescription on Trust approved prescription stationary or Trust approved electronic prescription. ✓ Patient group direction (PGD) ✓ Doctors may administer medicines without a prescription in situations where it would compromise patient care to write a prescription in advance e.g. emergency situations or in theatres. An accurate record of the administration must always be made in the patient's prescription chart, anaesthetic record or other approved prescription as soon as possible after the administration. This record must be made before the patient leaves the ward or department where the administration took place. ✓ Medicines Act Exemption <ul style="list-style-type: none"> • Midwives exemption see link 1 and 2 • Administration during emergency resuscitation see appendix 1 	<p>Link 1 - Midwives Exemptions May 2013 http://Trust/media/257898/130521%20SOP%20MW%20Exempti ons%2017th%20May%202013%20FINAL.pdf</p> <p>Link 2 – SOP for the supply and administration of medicines by midwives from the midwifery exemptions list</p> <p>http://Trust/media/257898/130521%20SOP%20MW%20Exempti ons%2017th%20May%202013%20FINAL.pdf</p>
4	<p>Accountability for Administration</p>	

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> • Single person checking With the exception of medicines listed in point below, registered practitioners with approved competencies may administer medicines unsupervised. In this case the registered practitioner must sign in the appropriate box to indicate that a medicine has been administered. In accordance with the NMC Code of Conduct (2010) (or subsequent update), all practitioners including registered bank/agency nurses are accountable for their practice and must not administer medicine unsupervised unless they believe themselves competent to do so. • Two Person Checking Two people must be involved in the checking and administering of the following: <ul style="list-style-type: none"> ○ Controlled Drugs – See Policy MM06 ○ Children – All medication for neonates and children (up to the age of 16) with the exception of those medicines listed in appendix 2 of this SOP which is an agreed list of commonly used medicines in children. Only these medicines may be administered by a single registered paediatric nurse with approved competencies to administer medicines to children. ○ Cytotoxic drugs via all routes (except those administered orally) – see MM02 ○ Potassium chloride concentrate and other strong potassium injection solutions – SOP ○ All intravenous drug administration ○ Insulin ○ Treatment doses of dalteparin (low molecular weight heparin) ○ Blood and Blood Products ○ Where the dose has to be calculated (e.g. a liquid dosage form without pharmacy annotation). <p>The person acting as the second check or signature on the administration record is signing to acknowledge that the medicine has been given and hence it should not be completed unless the second practitioner has witnessed the entire process of the medicine being administered. One of the practitioners administering must be approved as competent to administer medicines unsupervised. The second person should be either a registered practitioner competent to administer medicines unsupervised or a second or third year pre-registration nursing/midwifery student, or any practitioner approved by stated local protocols (e.g. paramedics). At UHNM the following staff cannot provide the second check: nursery nurses; play specialists; medical student; clinical support worker.</p> <ul style="list-style-type: none"> • Anaesthetists and Doctors working in Emergency situations – it is recognised that in an emergency situation or in theatres that it is not practical to have a second person checking a drug prior to administration. In these situations the anaesthetist or emergency doctor must ensure that they have followed all the required procedures in MM03 – SOP – 7 for ensuring that they have the correct drug, correct dose and there are no contraindications. The doctor is responsible for checking that the correct drug has been selected and that the expiry date is still valid 	
5	<p>Required Checks before Administration of any Medication to a Patient</p> <ul style="list-style-type: none"> i. Check the Prescription is Clear and Legal <ul style="list-style-type: none"> ✓ See MM03 - SOP – 6 Procedure for Inpatient Prescribing 	Confirm patient identity in line with C12 Trust Policy for Ensuring Correct Patient Identification

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> ✓ Confirm that the prescription is for the correct patient – check name on prescription with name on wrist band and confirm name and date of birth with patient where possible. ✓ Check that allergy section has been completed and that any documented allergies have been recorded on the red wristband. Confirm that the patient does not have an allergy to prescribed medication. ✓ Confirm that the age and weight of any patient younger than 16 years is documented ✓ Check that the weight is documented if the dose of any prescribed medicine is calculated on weight. ✓ Ensure that each prescription is signed and dated by a prescriber. ✓ Practitioners must ensure that the once only section on the medicine chart is checked for valid prescriptions. <p>ii. Check the prescription is Safe for the patient</p> <ul style="list-style-type: none"> ✓ Confirm that the dosage, method of administration, route and timing of administration is appropriate to the patient's condition. The prescription must specify: <ul style="list-style-type: none"> • the substance to be administered using its generic name (or brand name where appropriate) • the form (e.g. tablet/syrup) and strength • the dosage, timing, and frequency of administration • route of administration. All non-oral medicines must be administered separately from the routine oral medicine round • start and finish dates (where appropriate) ✓ The administering practitioner must have knowledge of the medicine to be administered and be familiar with its actions and potential side effects. ✓ Ensure that any dose calculations are checked by a second qualified person e.g. nurse, pharmacist, doctor, ODP. 	<p>http://vmwebsrv/policies/HR_Policies/C12%20Policy%20for%20Ensuring%20Correct%20Patient%20ID%20Version%203.pdf</p> <p>Medication must not be administered to a patient if a prescription is illegible, ambiguous, incorrect, incomplete or there is any doubt about its clinical appropriateness and safety. The prescriber must be contacted to amend prescription appropriately.</p> <p>If unsure about the action, dose, or any aspect of the medication, the administering practitioner must look up the current edition of the BNF or BNFC, or the Bedside Clinical Guidelines. If still unsure, consult the prescriber, a senior colleague, the ward pharmacist, Medicines Information Service or the on-call pharmacist out of hours.</p>
6	<p>Select the Correct Medicine</p> <ul style="list-style-type: none"> ✓ Obtain the medicine from the patient's locker, the drug trolley, the ward/department drug cupboard or fridge. ✓ Check the medicine name, strength and form correspond to the prescription and if dispensed for the patient that the correct patient's name is on the label. ✓ Check the expiry date. 	<p>For medicines dispensed by Trust Pharmacy department, where the expiry date is not specified on the container, assume an expiry date of 6 months from the date of dispensing.</p>
7	<p>Administer the Correct Medicine</p> <p>i. Confirm</p> <ul style="list-style-type: none"> ✓ The patient's identity as in step 4 above ✓ The name of the medicine /dose against the prescription ✓ The route ✓ The time due ✓ That the medicine has NOT already been administered ✓ That the prescription is valid (i.e. not crossed through for omission, within prescribed period e.g. set number of days for antibiotics) ✓ The patient is NOT allergic to the agent. Only administer the medication if the allergy box has been completed. <p>ii. Check Dose units</p>	<p>Examples of procedures listed in the Marsden Manual in chapter 12 for commonly prescribed routes are: :</p> <ul style="list-style-type: none"> • Oral drug administration • Topical Administration • Transdermal drug administration • Vaginal drug administration • Administration using

No.	Description of Procedural Steps	
	<ul style="list-style-type: none"> ✓ Consider the number of single dose units required to make up the dose (for example a single dose unit might be one tablet, one ampoule etc). ✓ In adults, if a calculation suggests that less than half a dose unit or more than three dose units are required to make up a dose, re-check the calculation (by a second person if unsure). ✓ Check BNF to determine if lower or higher strength preparations exist. <p>iii. Injectable Medicines – additional points to consider</p> <ul style="list-style-type: none"> ✓ For each route the appropriate procedure specified in the Marsden Manual must be followed. ✓ Confirm the directions for administering the medicine – n.b. can use the latest edition of the BNF, TRUST Bedside Clinical Partnership Guidelines, product information contained in product packaging, Medusa or Medicines Information. ✓ All medicines given by intravenous injection, insulin and treatment doses of dalteparin require a second check. The second check or signature on the administration record acknowledges that the medicine has been given and it should only be completed if the second practitioner has witnessed the medicine being administered and has checked the prescription as above. One of the practitioners administering must be approved as competent to administer medicines unsupervised. The second person should be either a registered practitioner competent to administer medicines unsupervised or a second or third year pre-registration nursing/ midwifery student, or any practitioner approved by stated local protocols (e.g. paramedics). ✓ Preparation of IV doses - Ready to use injectable preparations must be used where available. If a prepared product is not available it will be necessary for registered and competent medical staff or nurses with the required training to add drugs to intravenous diluents/ fluids. Any preparation and calculation must be carried out by a registered competent practitioner and checked by another registered competent practitioner. The following must be checked: <ul style="list-style-type: none"> • Access route chosen is appropriate for the medicine • Name and formulation of the medicine • Concentration or total quantity of medicine in the final infusion container or syringe • Name and volume of diluent and/or infusion fluid • Rate and duration of administration • Type of rate-control pump or device(s) to be used ✓ Intravenous bags or syringes for continuous infusion must be labelled with the white UHNM approved label, must include all relevant information and have a twenty-four hour expiry unless advised otherwise. ✓ Injections must be initiated immediately after preparation by the person who has prepared it. ✓ Administration must be completed within 24 hours of preparation. Any solution remaining 24 hours after preparation must be discarded – unless there are UHNM guidelines that specify otherwise e.g. epidural ✓ Multiple dose vials may pose a particular risk in that administration of the entire contents in a single dose could be harmful. Some presentations of injectable medicines contain enough medicine to 	<p>metered dose inhalers</p> <ul style="list-style-type: none"> • Administration using nebulisation • Administration of Eye Drops <p>For advice on administration of injectable drugs contact ward pharmacist, Medicines Information, On-call Pharmacist or MEDUSA Injectable Medicines Guide via the Trust intranet Medusa Homepage</p>

No.	Description of Procedural Steps	
	<p>treat one patient for weeks or to treat several patients (multidose vials). Extra care must be taken to calculate the required amount to be taken from multiple dose units.</p> <ul style="list-style-type: none"> ✓ Medicines intended for single use must only be used for a single patient. ✓ When an injectable medicine is given by an infusion a controlled infusion device must be used. The controlled infusion device should be used in accordance with the manufacturer’s instructions. If in doubt about whether an infusion device is required check the Bedside Clinical Guidelines or the BNF. If it is acceptable for an infusion to be administered via gravity then caution should be taken regarding the calculation and regulation of the infusion rate. The practitioner involved in providing the second check must include these aspects of administration in the check. ✓ If the administering practitioner has any concerns about the administration of an infusion the dose should not be given and the prescriber consulted immediately. <p>iv Epidural Administration</p> <ul style="list-style-type: none"> ✓ All practitioners involved in prescribing, preparing, administering and monitoring epidural injections and infusions must receive documented formal training and updates with SOPs local to the specific area. ✓ The yellow epidural labels must be used to label all epidural infusions. ✓ All registered practitioners must follow the relevant SOP for epidurals in the clinical area in which they are working. ✓ Senior staff should supervise recently trained or newly appointed staff and make sure that they have the necessary work competencies to undertake their duties safely and effectively. <p>V Measurement of Liquid Doses for Oral or Enteral use</p> <ul style="list-style-type: none"> ✓ If a 5ml spoon cannot be used to measure an oral liquid, a purple oral/enteral syringe must be used. ✓ All enteral devices MUST be labelled “Enteral”, including syringes and giving sets. If the manufacturers have not supplied these devices labelled in this way, it is the responsibility of the healthcare practitioner to label them in use. ✓ There is a system in place within the Trust to ensure that there are designated oral syringes that are compatible with the enteral feeding system in use. The dieticians will advise which one for each clinical situation. <p>Vi Administration of Insulin</p> <ul style="list-style-type: none"> ✓ All regular and single insulin (bolus) doses must be measured and administered using an insulin syringe or commercial insulin pen device (never use intravenous syringes). ✓ For nurses administering insulin using pen devices there are approved safety needles available on all wards. Insulin must always be administered by dialling the appropriate dose on the pen and injecting directly from the pen. Insulin must NEVER be withdrawn from a pen or a cartridge for administration using a syringe. This can lead to serious harm through incorrect dosing. ✓ Extreme caution is required to ensure that the correct brand and strength of insulin is selected to administer the dose. There are a number of brands available with biosimilar insulins available and they must be prescribed by brand. The most common strength of insulin is 	<p>Ensure that each ward/clinical area has sufficient purple oral/enteral syringes in varying sizes for administration. Under no circumstances must an intravenous syringe be used – please refer to NPSA Safety Alert No. 19.</p>

No.	Description of Procedural Steps	
	<p>100units/ml but some insulins are now available in higher strengths – EXTREME CAUTION is required to ensure that the correct strength is administered.</p>	
8	<p>Ensure the patient takes the medication.</p> <ul style="list-style-type: none"> ✓ The practitioner must supervise the patient taking the medication before signing for administration. ✓ Never leave medication exposed on lockers or at the bedside with the patient to take at a later time. 	
9	<p>Sign for administration</p> <ul style="list-style-type: none"> ✓ The administering practitioner must sign the appropriate box against the date and time the medicine is administered. ✓ If a second practitioner has checked administration e.g. for IV medicines they must also sign in the same box. 	
10	<p>Inability to Administer Medicines - Omission of Doses</p> <ul style="list-style-type: none"> ✓ Practitioners must ensure that ALL medicines are administered at the prescribed time. From a patient safety perspective it is important that all reasonable steps are taken to administer all prescribed medication with a particular focus on those medicines which are deemed critical – i.e. the patient may come to harm if they do not receive the medicine at the prescribed time (e.g. insulin, anti-microbial agents, anticoagulants, anti-Parkinson medication). For a list of medicines that are deemed critical refer to the TRUST list online – link 3 ✓ If a dose is missed one of the following codes must be recorded in the appropriate administration box: <ul style="list-style-type: none"> X – Omit at doctor’s request n.b. 2 - Patient not on ward – see below 3 – nil by mouth – see below 4 – patient refused – see below 5 – medicine not available – see below 6 – clinical reason – must record reason in appropriate space of prescription 7 – self administration – only on approved wards – refer to local SOP ✓ It is the administering practitioner’s responsibility to ensure that all critical medicines (see link) are administered. If unable to administer due to route unavailable, patient unavailable or patient refused the administering practitioner must inform the prescriber so that a decision can be made regarding a suitable alternative. This must be documented in the patient’s medical notes. 	<p>See NPSA Rapid Response Report NPSA/2010/RRR009 to reduce the harm arising from omitted and missed doses of medicines.</p> <p>Link 3 - Drugs that must not be missed or delayed:</p> <p>http://Trust/media/332139/Drugs%20that%20must%20not%20have%20a%20missed%20dose%20-%20critical%20list%20Oct%20013.pdf</p>
11	<p>Patients with Difficulty Swallowing</p> <ul style="list-style-type: none"> ✓ If a patient cannot swallow tablets or capsules, or tolerate oral medication, the ward pharmacists are able to advise on different formulations or alternative products. These might be available commercially or made as (unlicensed) “specials”, for individual patients (see MM04 Policy for the Prescribing, Supply and Use of Unlicensed Medicines). 	

No.	Description of Procedural Steps	
	<p>✓ Practices such as crushing tablets and opening capsules transfers legal product liability for a medicine from the manufacturer to the health professional and the Trust. In most cases this practice would be reasonable but there may be circumstances when it may cause harm. Therefore the administering practitioner must first check with their ward pharmacist or Medicines Information, unless sure that the practice is safe or the pharmacist has endorsed the prescription accordingly.</p>	
12	<p>Medication Unavailable It is essential that patients do not miss medication. Patients can come to harm as a result of a missed dose of a critical medicine. It is not acceptable for practitioners to record the “medication unavailable” code i.e. 5 without taking all reasonable steps to locate a supply:</p> <p>i. During Pharmacy Opening Hours</p> <ul style="list-style-type: none"> ✓ Check the patient’s locker including all patient’s possessions to locate any medicines the patient has brought with them (patient own drugs PODS) ✓ Check the ward stock cupboard ✓ If the patient has been transferred from another ward contact the ward and request that they transfer all medicines for the patient. ✓ Contact the ward Pharmacist or Pharmacy technician ✓ Send chart to Pharmacy to request the medicine <p>ii. When Pharmacy Closed</p> <ul style="list-style-type: none"> ✓ Check the patient’s locker including all patient’s possessions to locate any medicines the patient has brought with them (patient own drugs PODS) ✓ Check the ward stock cupboard ✓ If the patient has been transferred from another ward contact the ward and request that they transfer all medicines for the patient. ✓ Check if it is stock on another ward – this can be done by accessing the Trust Intranet - link. As far as possible any medicines required for a particular disease state are kept as stock on the specialist wards e.g. medicines for epilepsy are kept as stock on the neurology wards. ✓ Check if medicine available in the Emergency Drug Cupboard – check Trust Intranet - link. This can be obtained by contacting the Site Manager on duty who has access to the Emergency Drug Cupboard. ✓ Contact the On-call Pharmacist. 	<p>See SOP for assessing patients own medicines - http://Trust/media/42360/One%20Stop%20Dispensing%20-%20nurse%20training%20pack.pdf</p> <p>To ensure that all essential medicines are administered in a timely manner refer to following documents on the intranet:</p> <ul style="list-style-type: none"> ✓ The critical medicines list ✓ List of drugs kept in the Emergency Drug Cupboard (EDC) ✓ List of medicines stocked in wards and departments <p>Go to the online section, click on “critical medicines list” and this leads to the 3 documents – see link.</p>
13	<p>Nil by Mouth in Anticipation of Surgery Patients labelled Nil By Mouth (NBM) prior to surgery should take their usual medication, unless otherwise directed, at their usual times pre-operatively. Sips of water are allowed if required to aid swallowing. Medication that is usually taken with or after food can be taken on an empty stomach with sips of water as a ‘one-off’. Failure to continue a patient’s usual medication can potentially cause an exacerbation of their chronic condition or adverse effects from abrupt withdrawal to occur. In some cases it is beneficial to stop or alter certain drug regimens, due to potential interactions with anaesthetic agents, other drugs, or complications related to surgery. However, it is not appropriate to simply omit an oral medicine without first clarifying the instruction with the relevant clinical team/anaesthetist.</p>	

Related Documents

- **MM03** - Policy for the Storage, Prescription, Supply and Administration of Medicines
- **MM04** - Policy for the Prescribing, Supply and Use of Unlicensed and Off-Licence Medicines
- **MM06** - Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs
- **MM02** - Trust Policy for the Prescription, Safe Handling and Storage, Supply and Administration of Cytotoxic Agents and Cytotoxic Monoclonal Antibodies
- **MM05** - Policy for the Supply and Administration of Medicines via Patient Group Directions
- **Marsden Guidelines 8th edition.** (<http://www.rmmonline.co.uk/>)
- **C39** – Policy for Accidental Infiltration or Extravasation of Prescribed Intravenous Drugs: Prevention, Recognition and Effective Management

Appendix 1 to MM03–SOP-7

Medicines Exempt from Prescription Requirements in an Emergency

The Human Medicines Regulations 2012 (regulation 238, schedule 19) specifies that for the purpose of saving a life in an emergency an appropriate practitioner may administer, by the parenteral route, the following medicines:

Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis
Atropine sulphate and obidoxime chloride injection
Atropine sulphate and pralidoxime chloride injection
Atropine sulphate injection
Atropine sulphate, pralidoxime mesilate and avizafone injection
Chlorphenamine injection
Dicobalt edetate injection
Glucagon injection
Glucose injection
Hydrocortisone injection
Naloxone hydrochloride
Pralidoxime chloride injection
Pralidoxime mesilate injection
Promethazine hydrochloride injection
Snake venom antiserum
Sodium nitrate injection
Sodium thiosulphate injection
Sterile pralidoxime

Medicines Approved for Single Nurse check for Paediatric Patients

As Described in MM03 all medicines administered to children under 18years (or 16years if nursed on a non-paediatric ward) require a two person check, unless in this approved lists of non-IV medicines.

Medicine	Route
Antacids	Oral
Dietary supplements	Oral
Laxatives	Oral
Vitamins	Oral
Dioralyte	Oral
Paracetamol (BNFc banded dose)	Oral
Peptac/Gaviscon	Oral
Pancreatic enzyme supplements (Creon, Pancrex)	Oral
Sucrose	Oral
Phosphate enema	Rectal
Glycerine suppositories	Rectal
Microlax Enemas	Rectal
Inhaled medications.	Inhaled
Nebulised medications	Nebulised
• Apart from Adrenaline.	
Creams / Emollients / Gels/ Sprays	Topical
Eye drops (excluding oncology)	Topical
Ear drops	Topical
Nasal spray (Not desmopressin)	

Guidance for the Prescribing and Administration of Covert Medicines in Adults

Purpose and Scope

- To be read in conjunction with MM03 Policy for Storage, Prescribing, Supply and Administration of Medicines.
- To provide a structure to safeguard the welfare of adult patients and staff pertaining to covert administration of medication.
- To support staff in the decision-making process when an adult patient lacks the capacity to consent to take prescribed medicines.
- For staff to have an increased awareness of their responsibilities and limitations.
- When the use of covert administration of medicines would be appropriate.
- The process of implementing covert administration of medicines

What is Covert Administration of Medication?

- Involves disguising the administration of a medicine usually in food or drink without the patient's knowledge or consent.
- Is only likely to be necessary or appropriate in the case of patients who directly refuse medication but who are assessed as not having capacity to understand the consequences of the decision to refuse.
- Should not be confused with disguising the administration of a medicine for a person who has the capacity to consent, which would constitute a tort or civil wrong of trespass to the person.
- **Must never** be given to someone who is capable of deciding about medical treatment.

There is a common misunderstanding around the practice of putting medication into food or drink to make it more palatable often at the request of the patient. This could still be regarded as deceitful and open to abuse unless clear documentation supports the practice in the individual care plan. This is overt administration and is a co-operative process that is transparent and open to scrutiny and audit.

Context

- Covert administration of medication is a complex issue that has provoked widespread concern. It involves the fundamental principles of patient autonomy and consent to treatment, which are set out in common law and statute and underpinned by the Human Rights Act 1998
- Under Human Rights Law, people who are capable of making the decision have the right to accept or refuse medical treatment even if that may lead to their death.

- The Mental Health Act 2007 (MHA) overrides that right in specific circumstances. It gives authority to provide psychiatric treatment to a patient detained under its powers without their consent. This may include authority to give psychiatric medication covertly. Treatment powers under the MHA are limited to treating a patient's mental health. Where the patient has capacity to make decisions about their treatment, it is never appropriate to give medicines covertly to treat any patient's physical health.
- Covert administration to patients detained under the MHA and who have capacity is not covered within this guidance. If such a situation should arise the MDT team should contact the Mental Health Liaison Team if based at Royal Stoke site and the Dementia Liaison Team and/or Psychiatric Liaison Team in office hours if based at County Hospital and out of office hours SSSFT Access Team (see flow chart).
- The Mental Capacity Act 2005 (MCA) may give authority to provide health treatments only where the patient is aged over 16 years, is assessed as lacking capacity, and where the treatment is reviewed and assessed in a best interests meeting to be in the patient's best interests.
- If the medication is being given covertly, this should have been explicitly considered in the best interest meeting and documented in the medical notes.

Professional Guidance

- The British Medical Association (BMA) provides resources to support doctors to help in good decision making when providing care and treatment for people who lack, or who may lack, the mental capacity to make decisions on their own behalf. <https://www.bma.org.uk/advice/employment/ethics/mental-capacity/mental-capacity-toolkit>
- The Nursing and Midwifery Council (NMC) Code of Practice and NMC standards for medicines management provide advice for nurses in supporting non-compliant patients in their care. It is important that they are not asked to perform actions outside of their code of practice. <https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.pdf>
- Any health professional wanting to consider administering a medicine covertly may wish to contact their professional organization for advice.
- The National Institute for Health and Social Care Excellence (NICE) <https://www.nice.org.uk/guidance/qs85/chapter/quality-statement-6-covert-medicines-administration> and PrescQUIPP have produced guidance on issues to be considered when medicines are given covertly <https://www.prescgipp.info/resources/send/216-care-homes-covert-administration/2147-b101-covert-administration>
- The Care Quality Commission (CQC) also refers to covert administration in regulation 12 of their regulations for service providers and managers. <http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-12-safe-care-treatment#guidance>

General Principles to consider prior to administration of covert medication

In certain exceptional circumstances, in which covert administration may be considered to prevent a patient from missing out on essential treatment and where it has been established that the patient is incapable of providing informed consent (see C43 Consent to Treatment including MCA Policy), the following considerations should apply:

- The medication must be considered essential for the patient's health and well-being, or for the safety of others.
- Disguising medication simply for convenience of the health care team is

unacceptable.

- All decisions must be in the patient's best interest with due consideration to the holistic impact on the patient's health and well-being. The final decision to proceed must be authorized by a Consultant.
- The decision to administer medication covertly should be considered as a contingency measure during an emergency period when a patient requires medication for a physical health condition.
- Covert administration is the least restrictive when all other options have been tried.

Consent to Treatment/Lacking capacity

- Medication would be administered covertly on a best interest's basis. An assessment of a patient's capacity to consent to treatment using the two stage capacity test is essential. If the patient lacks capacity complete the Best Interests checklist which should be available on the ward or alternatively located in Appendix 5 C43 Consent to Treatment including MCA Policy - http://vmwebsrv/policies/HR_Policies/C43%20Consent%20Policy%20V8%20July%202017%20to%20July%202020.pdf.
- If a patient is subject to a Deprivation of Liberty Safeguards (DOLs) and you are considering administering any medication covertly you must inform the supervisory body (Local Authority).

Decision Making

- There should be a broad and open discussion among the clinical team and the patient's relatives, carers or advocates before the decision to administer medication covertly. However all efforts should be made to reach a decision as soon as possible, in order to ensure the patients mental or physical health does not deteriorate.
- Those involved should include carers, relatives, advocates, court appointed deputies and the multidisciplinary team (including pharmacy). Family involvement in the care process should be positively encouraged. Any pertinent advance statements must be considered. The method of administration of the medicines should be agreed with the pharmacist
- Regular attempts should be made to encourage the patient to take their medication. This might best be achieved by giving regular information, explanation and encouragement, preferably by the team member who has the best rapport with the individual
- The MCA requires that Local Authorities and NHS Bodies must instruct an Independent Mental Capacity Advocate (IMCA) when: An eligible decision is to be made (e.g. Serious Medical Treatment), the person has been assessed as lacking capacity to make that decision, there are no family or friends willing, able or appropriate to be consulted as part of the best interests decision making process.
- IMCA Services across Staffordshire and Stoke-on-Trent are provided by assist advocacy services (Stoke) and TotalVoice (Staffordshire). Referral forms can be found on the Trust intranet <http://uhn/clinicians/medical-and-nursing/nursing-essentials/safeguarding-adultsmcadols/>.
- [Consultant or Nurse in Charge of the ward should complete Form A MDT Checklist and Consensus agreement prior to covert administration and retain copy within medical notes.](#)
- Consultant to complete medical review of medication and document this on Form B

Advice and Support from Pharmacy

- The need must be identified for each medication prescribed. Prior to considering covert medication advice from pharmacy should be sought, as some medications could be converted to syrups.
- Once a decision has been made further involvement of pharmacy is especially important as adding medication to food or drink can alter its chemical properties and thereby affects its performance.

- An agreement can then be reached as to the most appropriate regime for the patients during the period while they are on a covert medication regime
- The previous drug chart should be cancelled and a separate standard drug chart should be commenced and used for the period of administration of covert medication
- Covert Medication Assessment Form C to be completed by pharmacy

Care Plan / Medical Notes

- The decision and action taken, including the names of all parties concerned, should be documented in the patients care plan / medical notes and regularly reviewed. This should include specific time scales.
- The administration of medication to a service user within food or drink should always be subject to a care plan

Capacity to Consent and Review Meetings

- It is important to review whether the treatment continues to be necessary. A formal meeting can be arranged for all to share their views. The timescale for this formal meeting will depend on individual circumstances e.g. the expected duration of treatment.
- The patients capacity to consent should always be decision specific and be regularly reviewed
- Covert administration should be used for as short a time as possible.
- Regular attempts should be made to encourage the patient to take medication voluntarily
- The decision to administer a medication covertly should **not** be considered routine, and should be a contingency measure. Any decision to do so must be reached after assessing the care needs of the patient individually. It should be patient specific, in order to avoid the ritualized administration of medication in this way.

Transfer / Discharge of Patients

It is good practice to pass on and information including the care plan about covert administration of medicines when a patients care is being transferred / discharged e.g. from hospital to a care home. The care plan in place for this should be shared with the hospital or care home who will be able to refer to their own policies and procedures.

Form A – MDT Checklist and Consensus Agreement (to be completed by Consultant or Nurse in Charge of the Ward)

Patient name: Unit number: Review date:

The above named patient is refusing to take their prescribed medication and is unable to fully understand the consequences of this. In the opinion of the following members of the multi-disciplinary clinical team and after consultation with supporters(relevant carers, family members, advocates) it is in their best interests to be given their medication covertly disguised in food or drink to prevent deterioration to their health.

Multi-disciplinary Covert Administration Checklist		Multi-disciplinary Consensus Agreement to use Covert Administration		
Action	Tick and Date when Complete	Name	Role	Signature
Assessed capacity of patient to consent to treatment				
Prescriber has approved the use of covert administration				
Prescriber has assessed the necessity for current modification				
Supporters of the patient have been consulted and agreed to the use of covert medication				
There are no current and pertinent advance statement or a 'living will'				
Pharmacist has reviewed medication				

Form B - Medical Review of Medication To be completed by Consultant

Patient name:

Unit number:

Medication	Rationale	Risk if refused
Example XXXXXXXXXXXXX	Life threatening	Significant deterioration

Signature:

Date:

Form C - Covert Medication Assessment To be completed by Pharmacist

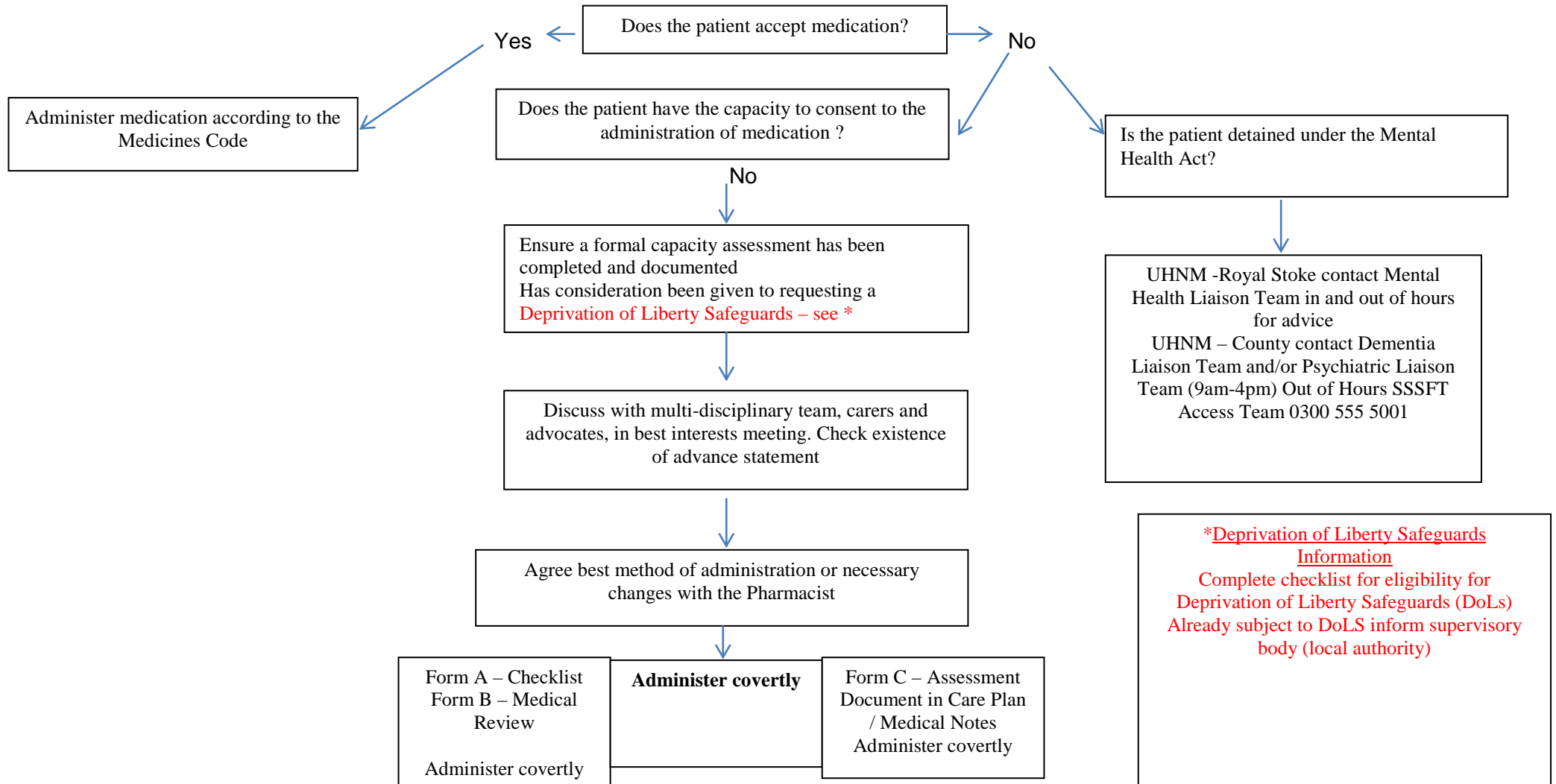
Patient name.....Unit Number.....

NB medication must not be crushed unless there is no alternative; doing so makes the medication unlicensed

Prescribed medication	Liquid available Y/N	May be crushed Y/N	Food or drink vehicle if crushed	Reference	Alternative preparation

Pharmacist Name: Signed: Date:

Covert Administration Flow Chart



Standard Operating Procedure (SOP)

MM03-SOP-8 Supply, Storage, Prescription and Administration of Potassium Chloride Concentrate and other strong potassium solutions January 2019



University Hospitals
of North Midlands
NHS Trust

APPENDIX L

The purpose of this SOP is to ensure that the prescription, supply, storage or administration of intravenous concentrated potassium and other strong potassium products is in accordance with the NPSA alert and that it is only used for dilution at ward level in exceptional circumstances when pre-prepared dilutions are not available.

This SOP applies to all staff involved in the prescription, supply, storage or administration of concentrated potassium solution.

Preparations included in this SOP:

- 10% (100mg potassium in 1ml)
- 15% (150mg (2mmol) potassium in 1ml)
- 20% (200mg potassium in 1ml)
- Solutions of potassium hydrogen phosphate and potassium di-hydrogen phosphate in ampoules and vials (e.g. Addiphos).

No.	Description of Procedural Steps	
1	<p>General precautions</p> <ul style="list-style-type: none"> • Clinical Directors and Ward Managers must ensure that all relevant staff are trained in the safe prescribing, administration and preparation of concentrated potassium and the potentially fatal risks associated with these processes. • In those critical care areas at Trust where potassium chloride concentrate is stocked, Ward Managers must ensure that all relevant staff are trained in the potentially fatal risks of rapid administration of potassium chloride concentrate solutions and in the management of mal-administration. • All staff involved in the preparation and administration of potassium containing infusions from potassium chloride concentrate should practice due vigilance in its dilution and administration to the patient. 	<p>Intravenous Potassium can be fatal if given inappropriately.</p>
2	<p>Storage</p> <ul style="list-style-type: none"> • Concentrated potassium chloride solution is restricted to the Pharmacy Department and to those designated 'critical care' areas where the concentrated solutions are needed for urgent use – see appendix • Must be stored in a designated Concentrated Potassium cupboard or may be stored in CD cupboard if no concentrated Potassium cupboard available. • To ensure compliance, each year those designated 'critical care' wards where concentrated potassium ampoules or vials are stored will need to justify their need to stock concentrated potassium solution by reviewing availability of ready made potassium containing fluids. Any area where concentrated potassium solution is used must have approved procedures in place for how the concentrated potassium chloride should be 	

No.	Description of Procedural Steps	
	<p>used.</p> <ul style="list-style-type: none"> Stock of concentrated potassium solution must be recorded in a controlled drug register and its use recorded according to the SOPs for storage, stock checking and administration of controlled drugs. Refer to MSOP 005: Trust SOP for Administration of Controlled Drugs for further details. 	
3	<p>Ordering</p> <ul style="list-style-type: none"> Potassium chloride concentrate and other strong potassium solutions may only be held as a stock item in the designated areas listed in appendix 1. Designated wards must order Potassium chloride concentrate in the same way as a Controlled Drug – refer to Trust SOP for ordering controlled drugs. Wards permitted to order and stock concentrated potassium chloride must only request supplies from the Pharmacy department. Wards must NEVER borrow or lend ampoules or vials of concentrated potassium chloride solution. 	
4	<p>Prescription</p> <ul style="list-style-type: none"> Intravenous treatment of hypokalaemia must only be instigated when the oral/ enteral route is unavailable or will not achieve the required elevation of serum potassium within a clinically acceptable time. Advisory guidance on the management of electrolyte disturbances (including hypokalaemia) is provided in the Bedside Clinical Guidelines available on the Trust Intranet and must be followed. Prescribers must ensure that commercially available dilutions of intravenous fluids containing potassium are prescribed wherever possible All prescribing of potassium must be expressed in terms of millimoles of potassium. If, in exceptional circumstances, a dilution that is not commercially available is deemed clinically necessary, the prescription MUST state: <ul style="list-style-type: none"> Final concentration of potassium solution Rate of administration – confirm with guidelines specific to clinical area. Generally in adult patients the maximum rate of infusion is 20 mmols per hour. Route of administration – concentrations of 40mmol/100ml or greater must be administered through a central line. The exception is critical care where concentrated potassium solution is added continuous Venous-Venous Haemodialysis (CVVHD) – see below. All patients being treated with intravenous potassium must have at least once daily measurement of serum potassium until levels are shown to be satisfactory. 	<p>All dilutions recommended in the clinical guidelines are available to order from NHS Supplies with the exception of 40mmol potassium in 100ml sodium chloride 0.9% which is available from the Pharmacy Department.</p>
5	<p>Administration</p> <p><u>General instructions</u></p> <ul style="list-style-type: none"> In adults the usual maximum rate of infusion of potassium is 20mmol per hour. Nurses and midwives should ensure that commercially available dilutions are administered whenever possible. If a particular dilution prescribed is not available for any reason this should be drawn to the attention of the medical staff with a view to finding an alternative dilution. If it is essential that a concentrated potassium solution is used for a suitable dilution for a specific patient the dose must be checked 	<p>Refer to MSOP013: TRUST SOP for the Administration of Medicines</p>

No.	Description of Procedural Steps	
	<p>as appropriate for the condition by a second practitioner before the product is administered – this must be a registered practitioner.</p> <ul style="list-style-type: none"> • All administration must be checked by a second person as per administration of intravenous drugs in MSOP013. • Infusion pump - All intravenous infusions containing potassium MUST be delivered via an appropriate infusion pump to control infusion rate and volume. NEVER administer these solutions using gravity or rely on drip rate counting. • In the event of misadministration or 'near miss' an adverse incident report should be completed on Datix and escalated through to the relevant Professional Head of Nursing and / or Divisional Clinical Governance Manager. 	
6	<p>Preparation of Solutions containing Concentrated Potassium</p> <ul style="list-style-type: none"> • In all clinical areas where concentrated potassium chloride is added to an infusion solution, local SOPs must be followed for the preparation of solutions. Only staff who have been trained in the procedure may be involved in the preparation of solutions containing concentrated potassium. • Following preparation of the solution, <u>thorough mixing must take place</u> by agitation of the final solution as the molecular density of the concentrate will mean that without agitation, pooling of the potassium chloride concentrate will take place at the base of the infusion bag or burette. • Within the Adult Critical Care Unit only, during continuous Venous-Venous Haemodialysis (CVVHD), potassium chloride concentrate will be added to a five litre bag of dialysis fluid. This must be checked by two people, one of whom is deemed to be competent to administer medicines. Only two bags of fluid will be prepared at any one time and must be labelled appropriately, one will be administered immediately to the respective patient the other will be stored in the fluid warmer, prior to use this will again be checked by two practitioners. 	
7	<p>Supply</p> <ul style="list-style-type: none"> • The Pharmacy staff will follow PHA 45 SOP for supply of concentrated potassium solutions. • In those designated areas permitted to stock concentrated potassium chloride solution it must be ordered according to the procedures for ordering a controlled drug – MSOP 008. • Potassium chloride concentrate must not be transferred between clinical areas. • Commercially available dilutions are held by NHS Supplies with the exception of potassium chloride 40mmol/100ml which is held in Pharmacy. Pharmacy will ensure sufficient stock of this product to meet normal ward requirements. In circumstances where there are major supply problems Pharmacy should inform clinical areas and guidance given on alternatives. • When no longer required unused stock of potassium chloride concentrate should be returned to Pharmacy. 	

APPENDIX to MM03-SOP-8:

TRUST WARDS AND DEPARTMENTS PERMITTED TO ORDER CONCENTRATED POTASSIUM CHLORIDE / ADDIPHOS

Concentrated potassium chloride is treated as a Schedule 3 Controlled Drug. It does not require register entry but must be kept in the CD Room.

Intravenous potassium can be FATAL if given inappropriately.

This guidance MUST be adhered to.

Wards authorised to order concentrated Potassium Chloride N. B This must never be supplied to a department that is not on this list without prior authorisation from an 8B Pharmacist or above.	
Critical Care Pod (CCP) 1	Ward 215
CCP2	NICU
CCP3	Theatre 30
CCP4	Theatre 31
CCP5	Theatre 32
Early Pregnancy Unit (Two ampoules at a time only for specified procedure no sooner than one day before the procedure) Must be clinically checked by a pharmacist	

Wards authorised to order Addiphos N. B This must never be supplied to a department that is not on this list without prior authorisation from an 8B Pharmacist or above.	
Critical Care Pod (CCP) 1	CCP3
CCP2	CCP4
CCP5	215

Related Documents

- **Trust Policy MM03:** Policy for the Storage, Prescription, Supply and Administration of Medicines
- **Trust Policy MM06:** Policy for the Prescribing, Storage, Supply and Administration of Controlled Drugs
- **PHA45:** Pharmacy SOP for Supply of Concentrated Potassium Solution
- **MSOP010:** Trust SOP for Storage and Safe Custody of Medicines
- **MSOP012:** Trust SOP for the Prescription of Medicines to Inpatients where electronic prescribing is not used
- **MSOP013:** Trust SOP for the Administration of Medicines
- **MSOP 009:** Trust SOP for Delivery and Receipt of Controlled Drugs from Pharmacy
- **MSOP 006:** Trust SOP for Storage and Safe Custody of Controlled Drugs
- **MSOP 005:** Trust SOP for Administration of Controlled Drugs
- **MSOP 008:** Trust SOP for Ordering of Controlled Drugs and Associated Stationary

Medicines Alerts, Reporting of Adverse Drug Reaction and Medication related Incidents

Medicines Alerts and Warnings

Medicines alerts and warnings are issued by the MHRA. MHRA Alerts are classed according to the following prioritisation system:

Class 1	Action now (including out of hours)
Class 2	Action within 48 hours
Class 3	Action within 5 days
Class 4	Caution in use

Alerts and warnings will be managed by the Pharmacy Directorate according to local Pharmacy standard operating procedures. This may necessitate removal of medicines from wards / clinical areas and sometimes from patients at home. Pharmacy will ensure that relevant Directorates / Divisions are informed and that replacement supplies are arranged where appropriate. Cooperation is required from all healthcare staff to ensure that medicines related alerts and warnings are dealt within the required time frame.

Pharmacy will liaise with the Clinical Governance, Audit and Risk Department to ensure that medicines alerts and warnings together with actions taken are logged on SABs.

Reporting of Adverse Drug Reactions to the MHRA

An adverse drug reaction (ADR) is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs or vaccines under normal conditions of use and is suspected to be related to the medicine.

Any member of staff who suspects a patient is experiencing, or has experienced, an adverse drug reaction should bring this to the attention of the doctor in charge of that patient's care. Certain reactions should be reported to the Committee on Safety of Medicines (CSM).

What to report:

New Drugs (marked with a ▼ in the BNF or Summary of Product Characteristics) - report ALL suspected reactions, however minor. Even reactions that are recognised should be reported. Reports should be made despite any uncertainty about a causal relationship; irrespective of whether the reaction is well recognised, and even if other drugs have been given concurrently.

Established Drugs including vaccines, medicines bought over the counter and herbal medicines - report all serious suspected adverse reactions. This includes all reactions that:

- Patient died due to reaction
- Were life threatening
- Caused congenital abnormality
- Involved or prolonged inpatient hospitalisation
- Involved persistent or significant disability or incapacity
- Serious reactions should be reported even if they are well recognised
- Medically significant

How to Report

Yellow cards should be completed and sent to the MHRA via freepost 'Yellow Card' or alternatively can be sent to the Medicines Information Department within the Pharmacy Department at the Trust. Yellow cards are available at the back of the current British National Formulary (BNF). Further information and online reporting forms can be found at the Medicines and Healthcare Products Regulatory Agency's website on www.yellowcard.gov.uk

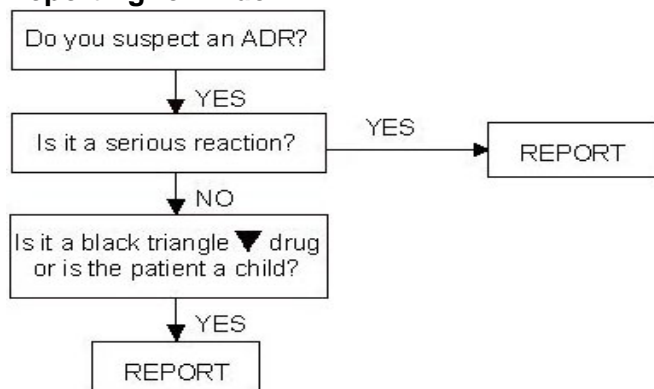
Who can Report

All healthcare professionals are able to submit yellow cards to the MHRA. In all circumstances, the doctor caring for the patient must be informed of the ADR and made aware of the fact that a yellow card is being submitted.

Patients, carers and their relatives may also submit reports through the Yellow Card Scheme

NOTE: If an adverse drug reaction is reported to the MHRA via the yellow card scheme a Trust DATIX adverse incident report must also be completed. The incident should be escalated to the Trust Medication Safety Officer.

Reporting reminder



Reporting Medication Incidents – Prescribing, Dispensing and Administration

In order for the organisation to learn lessons from medication incidents it is essential that all adverse incidents relating to the storage, prescription, dispensing, supply and administration of medicines are reported via the Trust adverse incident reporting system (Datix®).

It is the policy of the Trust that a fair-blame culture is fostered in which practitioners will be able to admit to errors without fear of unjustified retribution. It will be the responsibility of the Quality, Safety and Compliance Department to ensure that prescribing, dispensing and administration errors and 'near misses' are reported to the National Reporting and Learning System (NRLS). Reporting of all incidents involving medicines should be encouraged. Increased reporting of no and low harm incidents enables the identification of themes and supports learning across the Trust. This leads to improved practices when handling medicines and reduces the risks of moderate and severe harm occurring.

If a medication error occurs, the most important consideration is the welfare of the patient(s). If a medicine has been erroneously omitted or administered to a patient:

- It is essential that it is escalated to the patient's consultant and/or senior medical team as soon as it is identified who will decide on an appropriate course of action – this may require immediate medical attention and/or on-going additional monitoring.
- The patient and/or their carer must be informed of the error. The senior medical team must decide who the appropriate healthcare professional is to hold this discussion and may include a doctor, a nurse and a pharmacist.
- The error and any actions taken must be documented in the patient's medical record.
- The incident must be reported on the Datix system on the same day and all actions recorded.
- The error must be appropriately investigated. Adverse incidents with a minimum risk score of 6 must have an RCA completed.
- The Trust Medication Safety Officer will review all reported medication incidents

The Clinical Director of Pharmacy and Medicines Optimisation or the Trust Medication Safety Officer should be informed immediately of:

- Serious medication incidents where the patient has come to harm or potential harm
- Incidents where there has been a concern over a breach in security of medicines
- Incidents where there is concern over the competency of a member of the Pharmacy department.

- Incidents where a concern has been expressed that the labelling and/or packaging of the medicinal product could be improved so as to reduce the risk of recurrence of the incident
- If the investigation of the error requires the assistance of the Pharmacy Department.

Refer to the Trust Risk Management Policy (RM07) for full details regarding reporting arrangements.

Prescribing errors

If an error in prescribing is identified:

- Establish if the patient has come to harm or potential harm and act immediately as above.
- The registered prescriber who has made the error must be informed as soon as possible to ensure that any gaps in knowledge can be addressed.
- The clinical supervisor of the registered prescriber should be informed of the error so that it can be addressed with the individual
- It is good practice for the individual to complete a reflective statement to ensure any identified learning points can be shared.

Pharmacy Errors

Pharmacy errors may occur as a result of:

- If a pharmacist fails to identify a problem with a prescription during the clinical screening process
- If an error is made during the dispensing/checking process.
- An error occurs during the distribution of medicines process
- An error occurs during the manufacturing of medicines process
- An error occurs in the advice given regarding medicines to healthcare professionals or patients

In the event of any of these incidents, it is essential to establish as a matter of urgency if the patient(s) has received any medication erroneously. In this situation the procedure above must be followed. A senior pharmacist must be informed immediately if there is the potential for harm to the patient.

All errors that occur within the Pharmacy Department must be escalated to the senior pharmacist or pharmacy technician in charge of the relevant department. The Pharmacy Department have internal SOPs for dealing with and investigating adverse incidents.

Administration errors

An error in the administration process may occur as a result of:

- Administration of the wrong medicine, or incorrect dose, frequency or route of medicine.
- Mal administration of an infusion by incorrect use of syringe drivers/pumps
- Omission of a medicine without an appropriate reason – see MSOP 13 Administration of Medicines
- Administration of medication to the wrong patient

The person who identifies the error must act immediately and it is essential that the administration error is escalated to the medical team and patient/carer as above.

The following action should then be taken:

- Inform the relevant ward /department manager immediately
- Inform the lead clinician if the patient has received an incorrect medicine, an incorrect dose or a critical medicine has been omitted. They will need to review the patient and agree a course of management.
- Complete a Datix adverse incident report
- Inform the registered practitioner (s) involved in the incident if they are not present at the time.
- Inform the registered practitioner's line manager to ensure follow up with regard to competency assessment

- If a serious incident has occurred then the Associate Divisional Nurses, the Clinical Director of Pharmacy or the Trust Medication Safety Officer must be informed as soon as possible.

An adverse incident report form must also be completed in “near miss” situations, i.e. when a potential mal-administration error was identified prior to administration of the medicine to the patient.

Reviewing Medication Incidents

- All wards and departments should review medication incidents on a frequent basis and ensure that any actions required are undertaken within the agreed timescales.
- The Trust Medication Safety Officer reviews reported adverse medication incidents at least monthly. Identifies themes and supports shared learning for prescribers, nurses and pharmacy staff. Any concerns escalated at the Trust Medication Safety Group.
- Medication incidents are reviewed at each Divisional Safe Medications Group with a view to establishing any resulting harm, ensuring appropriate investigations and resulting actions are completed in a timely manner. Any concerns identified are escalated to the Trust Safe Medicines Group.
- The Trust Safe Medicines Group review trends in medication incidents in relation to occurrence and potential harm. All serious medication incidents are reviewed to ensure that an appropriate investigation is carried out and any resulting actions are undertaken in a timely manner. Any concerns with regard to trends or serious errors are escalated for further actions which may be a special “task and finish group” or a Trust wide alert.
- Any RCA undertaken as a result of a medication incident must be reviewed at the Trust Safe Medicines Committee.

Procedure to be followed when medicines and drugs are brought into hospital by patients, including respite care patients

N.B. These drugs/medicines are the property of the patient.

- It is not permitted under any circumstances to administer them to other patients.
- It is important that when patients are transferred between wards that **ALL** of their medicines are transferred with them.

Procedure for Handling Patient's Own Drugs

- Patients and/or their relatives should be encouraged to bring in their current medication when admitted to hospital.
 - Once medication brought into hospital by patients on admission has been checked by the prescriber, it should be placed in a green "Patients Own Drugs" bag and stored in the POD Locker until it has been assessed as suitable for re-use by pharmacy staff.
 - Any medication deemed suitable for re-use will be clearly labelled and stored in the POD Locker and can be returned to the patient for use on discharge if still suitable. Any medication not considered suitable for re-use will be destroyed by pharmacy staff with the consent of the patient or their carer/relative. If patients do not give consent to the destruction of this medication they will be counselled on the dangers of continuing to use such medication. These drugs will be labelled as being unsuitable for use by ward pharmacy staff and will be returned to the patient.
- If the patient's medication is changed in any way, during their stay in hospital, thorough explanations and education should be given by the prescribing practitioner regarding its use and side-effects. This change in medication must be identified clearly on the patient's electronic discharge summary.
- At the time of discharge:
 - For wards with a Medicines Management Technician, any TTO's should be left out for review by the technician, or, if needed urgently, the technician should be bleeped to review the prescription chart against the patients own supply of drugs which are stored in the POD Locker. Only the items which are not suitable for re-use, as per the MMT Policy, or, are newly prescribed will be dispensed by the pharmacy.
 - For wards who do not have a Medicines Management Technician and after Pharmacy ward service is finished, the green POD bag containing the Patients Own Drugs should be sent to Pharmacy with the TTO/Discharge Summary where the medication will be assessed for suitability for reuse. The consent section on the green POD bag must be fully completed before sending it to Pharmacy.

Procedure for the provision of discharge medication

Please refer to Appendix E “Medication For Discharge – Process And Actions To Take” in Policy C05 Trust Policy/Operational Guidelines for the Discharge of Adult Patients