

Leicestershire Medicines Code Policy

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Author / Originator(s):	Elizabeth McKechnie, Medication Safety Pharmacist
Name of Responsible Committee/Individual:	Medicines Optimisation Committee
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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

July 2019 – New format

amendments to monitoring appendix to bring it into line with current practice to reflect electronic prescribing systems and medicines management quarterly audits

Addition of self administration e learning to training section

Nursing associates added.

September 2022 – minimal changes made. Prescribing has been altered to reflect that most wards are now on electronic system rather than a paper drug chart. The procedure for monitoring the medicines code detailed in appendix 1 has had the prescribing element removed from it and datix incidents added to the monitoring table.

KEY WORDS

Medicines code

1 INTRODUCTION

- 1.1 This document provides the overarching statements for the Leicestershire Policy for the Ordering, Dispensing, Storage, Prescription and Administration of Medicines, known as the **Leicestershire Medicines Code**. The Medicines Code is applicable to both NHS Provider Trusts within Leicestershire, University Hospitals of Leicester NHS Trust and Leicestershire Partnership NHS Trust.
- 1.2 Both Leicestershire NHS provider Trusts will be contractually required to adhere to this Policy. **Variations in practice may occur in certain specialist areas where specific additional guidelines will be locally available. Under these circumstances it is required that there will still be strict observance of the basic safety principles embodied in the Leicestershire Medicines Code.**
- 1.3 The Leicestershire Medicines Code defines the policies and procedures to ensure safe medicines practice. Although the sections of the policy may relate to the activities of separate groups of individuals, it is important to view the document as a whole. Safe and efficient practices in the use of medicines remain a shared responsibility, irrespective of the independence of the professional or Trust. The integration of the activities of hospital and community sectors is essential in providing high quality safe and continuous care for patients.
- 1.4 Each section is available as individual linked documents and are accessible via the Policy and Guideline section of INsite .
- 1.5 The potential for error at all stages of the process of administration of medicines should not be under-estimated. Maintenance of high standards requires attention to detail of all professionals involved in this process. Medication errors can occur at any stage of the medicines use process and are usually due to “systems failures” and/or mistakes arising from a lack of knowledge (human error). Detailed Trust policy and procedures are available to support the safe and effective use of medicines, in addition to published national and professional practice standards. These are available on Insite
- 1.6 This document also outlines monitoring requirements for the Medicines code and the process to allow exemptions to medicines related policies.

2 POLICY SCOPE

- 2.1 This policy applies to all staff within UHL who are involved in any aspect of handling medicines; including ordering, dispensing, prescribing , administration and storage. Staff include (although this list is not exhaustive) Medical Staff; Registered Nursing staff, Nursing Associates; Midwives; Pharmacy staff; Operating Department Practitioners; Radiographers; Allied Health Professionals/Healthcare Scientists, Portering.
- 2.2 Exemptions required for specialist use or outside the scope of policy within UHL must be formally risk assessed and approved by the Medicines Optimisation Committee – see appendix 1

3 ROLES AND RESPONSIBILITIES

This policy applies to all healthcare staff involved in medicines management processes, prescribing, dispensing, storage, transportation and administration of medicines.

The Executive lead for this policy is the Medical director

3.1 Medical Director (executive lead) and Chief Pharmacist are responsible for:

- Ensuring that appropriate processes are in place across the Trust and monitoring the overall compliance with this policy.

3.2 Clinical Management Group (CMG) management teams are responsible for:

- Ensuring that all their staff are made aware of this policy and undertake training as appropriate.
- Monitoring auditing and compliance with this policy and procedures.

3.3 Heads of Service / Ward Sister / Charge Nurse / Senior Pharmacists/Line Manager are responsible for:

- Making sure that all staff are made aware of this policy and undertake appropriate training.
- Adhering to the procedures within this policy for safe and effective use of medicines
- Contributing to all audit requirements

3.4 Individuals who are involved in any aspect involving medicines are responsible for

- Ensuring they undertake appropriate training to enable compliance with the medicines code
- Adhering to the procedures within this policy for the safe and effective use of medicines

3.5 Medicines Optimisation Committee is responsible for:

(Chair of the committee is the Deputy Medical Director)

- Review of audit results and CMG action plans to ensure compliance with this policy and procedures
- Identification of improvements required to ensure compliance and safe medicines management practices
- Review of medication policies and sections of the medicines code updating in line with changes in legislation and best practice.
- Review of trends in medication errors and actions required to ensure compliance and safe medicines management practices.

4 POLICY STATEMENTS AND PROCEDURES

4.1 The policy statements and procedures are contained in individual sections pertaining to the different aspects of the medicines process as shown in Table 1.

Table1 :Leicestershire Medicines Code Sections

SECTION NUMBER	SECTION NAME
2	Prescribing
3	Procurement/Acquisition of Medicines
4	Receipt of Medicines Procedure
5	Supply of Medicines by Pharmacy
6	Administration of medicines
7	Removal and disposal of medicines
8	Transport of medicines
9	Security and storage of medicines
10	Medicines Defect Reporting
11	Clinical Trials
12	Unlicensed Medicines
13	Prescribing and administration of medicines in children (including neonates)
14	Prescribing and administration of Cytotoxic chemotherapy
15	Medicines in Operating Theatres
16	Supply and administration of medicines by midwives
17	Personal Use and Self Prescribing
18	Complementary and Alternative Medicines

5 EDUCATION AND TRAINING REQUIREMENTS

5.1. Medicines management minimum core training is detailed below. Individual medicines policies may outline details regarding additional training:

5.2 For specific staff groups:

5.2.1 Prescribers:

Prescribing competency assessment at final year undergrad. FY1

Antimicrobial –annual 45mins web based presentation

5.2.2 Registered nurses, nursing associates and midwives:

Nursing/Midwifery- Initial medicines administration competency assessment which includes observation, workbook and medication calculation paper. Competency refresher must be repeated at a minimum of every 3years, with the exception of high risk areas such as paediatrics and neonates, where the assessment is repeated annually.

All nursing and midwifery staff involved with self-administration on the wards must complete the e-learning package once only available through e-UHL.

5.2.3 Pharmacy staff:

Dispensing and where appropriate professional check and final check competency assessment must be completed on induction then repeated every 3 years

Complete matrix of assessments dependent on role are outlined in the Pharmacy SOP 801 Completion of competency assessments.

All pharmacists and pharmacy technicians involved on wards with self-administration must complete the e-learning package once only available through e-UHL.

5.2.4 Allied healthcare professionals and healthcare assistants

Initial training and assessment if undertaking an extended role involving aspects of medicines. This must be repeated at a minimum frequency of every 3 years

5.3 For specific tasks:

5.3.3 Preparation and administration of Intravenous therapy

All staff involved in the preparation and administration of intravenous therapy must complete face to face IV training and assessment with 3 yearly refresher updates. IV policy (B25/2010)

5.3.4 Intrathecal chemotherapy

All medical and pharmacy staff involved with intrathecal chemotherapy must complete an annual refresher training as defined by the Trust Intrathecal Lead. See Management of Intrathecal Chemotherapy Policy – Adult and Paediatric A2/2003

5.4. Staff training must be verified as part of their annual appraisal. Training records for relevant courses identified will be maintained on the central UHL training record accessed via Helm where available or within personnel files.

6 EQUALITY IMPACT ASSESSMENT

- 6.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
- 6.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

7 **PROCESS FOR MONITORING COMPLIANCE**

The audit and monitoring arrangements for the Leicestershire Medicines code are defined in Appendix 1

8 **DOCUMENT CONTROL, ARCHIVING AND REVIEW OF THE DOCUMENT**

- 8.1 Unless there is a change in national guidance or a requirement within the Trust this policy will be reviewed every 3 years.
- 8.2 This document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.

9. **EVIDENCE BASE AND RELATED POLICIES**

- Medicines Act 1968 and Poisons Act 1972 and subsequent legislation.
- Safe and Secure Handling of Medicines (Duthie Report) 2005 , Royal Pharmaceutical Society
- Guidance from Department of Health, NPSA, MHRA in relation to medicines processes
- Guidance from professional bodies, GMC, NMC, GPhC in relation to medicines

- The Assessment of Administration of Medicines by Nurses and Midwives (B13/2009)
- Management of Intrathecal Chemotherapy Policy – Adult and Paediatric (A2/2003)
- IV policy (B25/2010)
- Self administration of medicines policy (B13/2004)

- RPS Professional Guidance on the safe and secure handling of medicines issued December 2018. NICE accredited.
- RPS Professional standards for Hospital Pharmacy version 3 December 2017

- GPhC standards for pharmacy professionals July 2021

PROCEDURE FOR MONITORING THE LEICESTERSHIRE MEDICINES CODE

PROCEDURE STATEMENT

Medicines prescribing and administration will be audited by utilisation of:

- a) Annual medicines code audit undertaken by all clinical management group (CMG) co-ordinated by the Medication Safety lead pharmacist.
- b) An action plan must be completed by each CMG in response detailing measures to improve compliance.

MONITORING STANDARDS

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Lead(s) for acting on recommendations	Change in practice and lessons to be shared
Storage	Medicines safety Pharmacist	Medicines code audit	annual	To Medicines Optimisation committee, CMGs, and as part of the quality schedule to CCGs	CMG clinical director lead nurse and lead pharmacist	Within CMGs & through Medicines Optimisation committee
Controlled drugs	Medicines safety Pharmacist	Controlled drug ward audit	Bi-annual	To Medicines Optimisation committee, CMGs, and as part of the quality schedule to CCGs	CMG clinical director lead nurse and lead pharmacist	Within CMGs & through Medicines Optimisation committee
Datix incidents reported relating to any chapter of the LMC	Medicines safety Pharmacist	Datix	On going	To Medicines Optimisation committee,	CMG clinical director lead nurse and lead pharmacist	Within CMGs & through Medicines Optimisation committee

Further details of the elements to be monitored are described below

1. Storage

Minimum criteria for measurement across all CMGs

Indicators :

- Oral medicines within stated shelf life
- IV medicines within stated shelf life

- IV fluids stored in appropriate clean areas
- Fridges and cupboards locked at all times
- Medicine keys held by a qualified member of staff

Thresholds:

Green - 1 or less ward / area non compliant
 Amber - 2 or 3 wards/ areas non compliant
 Red - 4 or more non compliant

- All ward areas will have an annual audit of storage arrangements checking against standards in chapter 9. This will include all cupboards and refrigerators used for the storage of medicines and will assess:
 - ❖ Custody of keys
 - ❖ Requirements from NPSA specific alerts
 - ❖ Security of medicines
 - ❖ General housekeeping and expiry dates of medicines
- Results will be collated and fed back to individual CMGs plus overall results to be presented to the medicines management board and as part of performance report to CCGs. Action plans must be developed and monitored by individual clinical management groups
- Incidents relating to the safe custody and storage of medicines must be reported using Datix the incident reporting system in place. Individual incidents of inappropriate storage and security of medicines must be actioned by CMGs through the Quality and safety arrangements in place. CMGs should audit storage systems and processes more frequently as a result of an increase in medication incidents
- Quarterly report of incidents will be presented to the Medicines Optimisation Committee for review and action.
- Quarterly spot audits on all wards will be undertaken by the medicines management team and reported to wards, CMGs and the Medicines Optimisation Committee. Individual support for those areas not achieving the standards will be provided by the team.

2. Dispensing

Standards

External dispensing error rate - less than 0.03% items dispensed
 Near misses error rate - less than 0.3% items dispensed

- All incidents of dispensing errors must be reported on Datix, incident reporting system.
- Near misses of dispensing errors must be recorded on internal error sheets which are collated onto a central database and reported monthly to the pharmacy Quality and Safety Board.

3. Controlled Drugs:

Standards:

- 100% compliance with regulations relating to;
- Standard Operating Procedures
 - Record keeping

- Storage
 - Access
 - Transfer/ transport between wards/ hospitals
-
- a. 3 to 6 monthly controlled drug audits will be undertaken for all ward and departments as detailed in the Controlled Drug Policy . Audits should be undertaken more frequently as a result of an increase in controlled drug incidents
 - b. On going review of incidents related to Controlled Drugs will be through incident reports on Datix the incident reporting system.
 - c. All incidents of missing controlled drugs must be reported to the Accountable Officer and an investigation conducted.
 - d. An bi-annual report on the arrangements for safe use of controlled drugs will be part of performance reports to CCGs
 - e. Custody and record keeping of controlled drugs at ward level will be audited quarterly as part of medicines management spot audits.

4. Safe Disposal of Medicines

- a. There will be an annual review of incidents relating to inappropriate disposal of drugs

5. Additional monitoring

Spot checks may occur at intervals between the regular audits especially where poor practice has been highlighted by individual feedback from staff. A security/ storage and CD spot check will be carried out at least monthly.

Additional specific audits on sections of the Leicestershire medicines code will be carried out when trends in incidents have been noticed or concerns have been raised.

1. INTRODUCTION

There are occasions when practice in specialist clinical areas is not compatible with the general statements and procedures outlined in the Medicines code. In such cases an exemption may be requested.

This procedure aims to ensure that all exemptions are risk assessed, documented and authorised to cover staff working in these clinical areas.

2. PROCEDURE

- 2.1 Any requirement for an exemption to the medicines code or related medication policies must first be made to the Chief Pharmacist outlining the exemption required and the reasons for this exemption.
- 2.2 Once agreed in principle by the Chief Pharmacist a formal risk assessment for the exemption must be carried out by the appropriate multi-professional staff within the CMG covering the following:
 - Exemption required
 - Reason
 - Risks identified
 - Risk rating (following the risk assessment in the UHL risk policy)
- 2.3 Possible controls to be considered to minimise the risk may include:
 - New guideline/ Standard operating procedure
 - Competency assessment
 - New equipment
 - Review of storage arrangements, separation of products.
 - Alerts
- 2.4 The completed risk assessment, with all newly written procedures if required, must be submitted to the CMG General Manager, Clinical Director and Head of Nursing for authorisation.
- 2.5 Authorised risk assessments with accompanying documentation must then be sent to the secretary for the Medicines Optimisation Committee to be considered at the next meeting.
- 2.6 The Medicines Optimisation Committee will finally approve all exemptions or refer back to CMGs if further information is required or the process is considered to be unsafe.
- 2.7 Agreed exemptions and risk assessment will be stored on a central database maintained within the pharmacy department by the Medication Safety Pharmacist.
- 2.8 All exemptions must be reviewed by CMGs, every 2 years if not earlier to reassess if the practice is to be continued.

- 2.9 The risk assessment and exemption must be reviewed following a related medication incident.
- 2.10 Exemptions will be considered when the medicines code or relevant medication policy is reviewed and added to the policy if felt appropriate.