CONTROLLED DOCUMENT

University Hospitals Birmingham NHS Foundation Trust

Medicines Policy

CATEGORY:	Policy
CLASSIFICATION:	Clinical/Governance
PURPOSE:	This policy describes the framework for medicines' management within University Hospitals Birmingham NHS Foundation Trust (the 'Trust') in line with current legislation and best practice.
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Controlled Document Lead:	Chief Pharmacist
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Distribution: • **Essential Reading for:**	All staff involved in the prescribing, dispensing, supply, handling, storage, administration and disposal of medicines within the Trust.

Contents

Version Control

Version	Title	Issue Date
1	Medicines Policy	31/10/2008
2	Medicines Policy	27/11/2008
3	Medicines Policy	31/01/2012
4	Medicines Policy	01/02/2013
5	Medicines Policy	02/02/2016
6	Medicines Policy	06/08/2019
6.1	Medicines Policy	09/10/2020
7	Medicines Policy	06/05/2022

1. Policy Statement

1.1 University Hospitals Birmingham NHS Foundation Trust (the 'Trust') is committed to ensure the safe, appropriate and secure handling of medicines to protect its patients, staff and visitors.

1.2 The objectives of this policy are to ensure that:

1.2.1 Patients benefit from timely, safe, cost effective and efficient use of medicines;

1.2.2 Medicines are handled safely and securely minimising the risks associated with medicines management;

1.2.3 Relevant evidence based guidance and good practice relating to medicines management published by expert and professional bodies, including the Department of Health (DH), National Institute for Health and Care Excellence (NICE), Medicines Healthcare products Regulatory Agency (MHRA), and the Health Protection Agency (HPA) are adopted within the Trust;

1.2.4 Medicinal products used for clinical trials are handled in accordance with the clinical trial protocol which must be covered by a Clinical Trial Authorisation (CTA) issued by the MHRA, favourable ethical opinion from a Research Ethics Committee and Trust Research and Development approval.

1.2.5 Medical Gases are handled safely and securely in line with legislation and the Trust Medical Gas procedures.

1.3 It is essential that all staff involved in the prescribing, supply and administration of medicines are made aware of this policy on joining the Trust and practise at all times in accordance with it. The policy should be read in conjunction with the Trust Controlled Drugs procedures and the Medicines Code.

1.4 Failure by any member of staff to comply with this policy, the Medicines Code and/or associated procedures, will result in consideration of the use of disciplinary action which may result in dismissal.

2. Scope

This policy applies to all areas and activities of the Trust and to all individuals employed by the Trust including students, locum/ agency staff, bank staff and staff on honorary contracts who are involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of all medicines on and off, Trust premises.

3. Framework

3.1 This policy sets out the broad framework for the management of medicines throughout the Trust. Detailed requirements and instructions are provided in the Medicines Code and associated procedural documents referred to in Section 7.

3.2 The Chair of the Medicines Management Advisory Group (MMAG) shall approve the Medicines Code and associated procedural documents, including any amendments to such documents, and is responsible for ensuring that such documents are compliant with this policy, legislation and current guidance.

3.3 Due to the necessity for timely update of medicines management procedures in line with ever changing legislation, amendments to the procedural documents in section 7 of this policy may be approved by the Chair of MMAG without full stakeholder consultation (see exception in the Controlled Document Procedure).

3.4 Local procedural documents related to, or including, medicines (i.e. documents applicable to specific departments or areas) must be approved by the Clinical Service Lead in the respective area, the relevant Medicines Management Expert Panel (MMEP), the Clinical Guidelines Group (a sub group of the Clinical Quality Monitoring Group (CQMG)) and the Medicines Management Advisory Group (MMAG).

3.5 **Medicines Management Advisory Group (MMAG)**

3.5.1 The Chair of MMAG is responsible, on behalf of the Chief Medical Officer, for providing strategic direction for the implementation of medicines management and practice within the Trust.

3.5.2 The Terms of Reference for MMAG will be approved, periodically and no less than every 3 years , by the Chief Medical Officer.

3.5.3 The primary objective of MMAG is to ensure appropriate clinical and cost effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of the issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.

3.5.4 The MMAG reports to the Chief Medical Officer through the CQMG. The MMAG has representatives from all the major user groups, which directly and indirectly are responsible for ensuring seamless medicines management and practice across the interface of acute and primary care. The MMAG has a number of sub-groups responsible for implementing the objectives of the MMAG, details of which may be found in the Medicines Code.

3.5.5 Any exceptions under this policy or issues arising in the Trust impacting on the policy will be reported from MMAG to the Clinical Quality Monitoring Group (CQMG).

3.5.6 The CQMG will provide assurances to the Board of Directors that the clinical services offered by the Trust, including medicines management, are of the highest quality. The CQMG will assess and monitor the quality of care provided. The Chief Medical Officer will make recommendations for actions to be taken from

the information provided at CQMG meetings; working with Divisional Medical Directors and Divisional Clinical Governance Quality Groups and will monitor the measures taken.

3.6 Medicines Management Governance Framework

3.6.1 The MMAG and its sub-groups provide a framework that enables the Trust to comply with relevant medicines legislation and guidance.

3.6.2 The Terms of Reference for the sub-groups outlined below will be approved by MMAG.

3.6.3 The role of the **Safe Medicines Practice Group (SMPG)** is to consider all aspects of medicines management which relate to the safe use of medicines within the Trust, promote continued improvement in systems (including electronic prescribing systems) which relate to the safe use of medicines and to advise the Medicines Management Advisory Group on matters relating to the safe use of medicines. The SMPG will report exceptions relating to the safety of medicines to the MMAG.

3.6.4 The role of the **Antimicrobial Stewardship Group (AMSG)** is to provide oversight and input into the development, implementation and on-going review of the antimicrobial stewardship programme at the Trust. It will ensure that the Trust has robust systems in place to ensure the clinically effective, evidence-based, safe and cost effective use of antimicrobials as part of its overall governance structure. The group provides the Trust with the means to ensure corporate responsibility for the use of antimicrobial drugs across the organisation and will report exceptions relating to the use of antimicrobials to the MMAG.

3.6.5 The role of the **Non-Medical Prescribing Group** is to provide overarching multidisciplinary leadership for Non-Medical Prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a Non-Medical Prescriber and to prescribe, taking account of service redesigns and improved patient access to medicines. The NMP group aims to strengthen and monitor the governance issues associated with Non-Medical Prescribing, to determine potential and support existing Non-Medical Prescribers, advise the Medicines Management Advisory Group (MMAG) on matters relating to Non-Medical Prescribing and will report exceptions relating to Non-Medical Prescribing to the MMAG.

3.6.6 The role of the **Divisional Medicines Management Expert Panels** (MMEPs) is to provide each division with a forum to discuss any issues relating to the use of medicines and introduction of new medicines. The MMEPs (one per division) will provide a robust process for the introduction of new medicines to the Trust, monitor the clinical and cost effective use of medicines within the relevant division, forecast developments in healthcare

which involve the use of medicines and provide effective advice to the MMAG on such developments and their impact both clinically and financially. The MMEPs will rationalise the use of unlicensed drugs within the division and ensure risk assessments are undertaken and maintain an effective formulary for each clinical speciality. MMEPs will report any exceptions in prescribing to the MMAG.

3.6.7 The role of the **Medical Gas Group (MGG)** is to consider the safe use of medical gases within the Trust. It will provide assurance to the Trust regarding compliance with HTM 02-01(Medical Gas Pipeline System) and monitor the Trust Medical Gas Operational Procedure. MGG will report exceptions to the MMAG.

3.7 Medicines Management Procedures

3.7.1 The Trust implements operational procedures to cover all aspects of medicines management.

3.7.2 The Medicines Code and associated procedures are developed and implemented in accordance with the Controlled Document Procedure and includes approval by MMAG.

3.7.3 The Medicines Code and associated procedures set out the respective training and competence required to work against the procedure, documentation, monitoring, and audit requirements.

3.7.4 Compliance with all such procedures is mandatory. Failure by any member of staff to comply with this policy or any of its associated procedures will result in consideration of the use of disciplinary action, which may result in dismissal.

3.8 Documentation, Record Keeping and Audit

3.8.1 Records are to be maintained in accordance with the Medicines Code, Controlled Drugs procedure and associated procedures to provide a full medicines audit trail complying with medicines legislation and best practice guidance.

3.8.2 Routine audit of record keeping, systems and documentation will be undertaken in accordance with the procedures, together with the implementation and monitoring of appropriate actions where identified.

3.8.3 Risk assessments for associated procedures must be undertaken where appropriate.

3.9 Purchasing of Medicines

3.9.1 The Chief Pharmacist (with delegation as appropriate) is responsible for obtaining all medicinal products that are required in the hospitals of the Trust, ensuring that they are of a suitable quality, and for their issue against an appropriate order. Other employees of the Trust are not empowered to purchase

medicines for use within the Trust other than by the delegated authority of the Chief Pharmacist**.**

3.9.2 In purchasing medicines for the Trust, the Pharmacy Department makes full use of national and procurement hubs purchasing contracts to minimise the acquisition costs of medicines but also for the assurance that contract lines have undergone additional NHS Quality Assurance prior to the awarding of contracts. In certain circumstances, consideration is also given to the impact of differential pricing between primary and secondary care.

3.9.3 All medicines procurement must be carried out in line with the relevant associated controlled documents.

3.10 **Incident Reporting**

3.10.1 All medication related incidents and near misses must be managed through the Trust Policy and Procedure for the Reporting and Investigation of Incidents Including Serious Incidents Requiring Investigation.

3.10.2 Incidents must be reported through the Trust's incident reporting system using the electronic reporting system, Datix.

3.10.3 The Chief Pharmacist will receive daily notification of all medication related incidents/ near misses and ensure that an appropriate review is undertaken and any necessary actions are implemented.

3.10.4 To ensure lessons are learned from both actual incidents and near misses, the SMPG will receive regular incident report summaries from the Clinical Governance and Patient Safety team. SMPG will then review the incidents/ near misses and is responsible for implementing risk management strategies to address any elements of risk identified.

3.11 **Accuracy of Prescription Charts**

3.11.1 The electronic prescribing systems in place in the Trust ensure that prescribing and administration of medicines is in accordance with approved and validated medication templates. Electronic prescribing systems are operational in most clinical areas; however, there are clinical areas in the Trust which continue to use approved paper prescriptions. All prescription proformas or charts must be authorised for use by the MMAG before implementation.

3.11.2 All templates must be approved through the Procedure for the Quality Management of Medicines Data entering the Prescribing and Information Communication System (PICS).

3.12 **Research Medicines**

3.12.1 All medication that is to be used as part of any research undertaken within the Trust, whether licensed or unlicensed, must be managed via the Pharmacy department. The

responsibility for the quality of any products involved rests with the trial investigator/sponsor whilst the management of medicines within the Trust is the responsibility of the Chief Pharmacist.

3.13 Medical Gases

3.13.1 Medical Gases must be managed in line with the Trust Medical Gas Operational Procedure and associated documents. The Medical Gas Operational Procedure outlines the duties and responsibilities associated with the Medical Gas Pipeline System and use of Medical Gases within the Trust. The Chief Pharmacist is responsible for convening the Medical Gas Group(s) which will oversee compliance with the procedure, regularly review any reported incidents associated with Medical Gases, and report exceptions to the Board via the Medicines Management Advisory Group.

4. Duties

Specific duties and responsibilities of individuals involved in all aspects of the use of medicines (i.e. prescribing, supply, dispensing, handling, storage, administration and disposal of all medicines, including controlled drugs) within the Trust are set out in the Medicines Code and associated procedures. In respect of this policy:

4.1 Chief Medical Officer

The Chief Medical Officer is responsible for ensuring compliance with standing legal and quality frameworks relating to the safe and secure handling of medicines.

4.2 Chief Pharmacist

The Chief Pharmacist is responsible for the implementation and monitoring of this policy through the MMAG, its subgroups and the CQMG. To maintain multidisciplinary involvement in medicines related issues the Chief Pharmacist will liaise with the Chair of the MMAG. The Chief Pharmacist currently acts as the Controlled Drug Accountable Officer for the Trust.

4.3 Chair of the Medicines Management Advisory Group (MMAG)

The Chair of MMAG is responsible for liaising with the Chief Pharmacist to ensure oversight of the implementation of this policy and associated procedures at MMAG, and for providing strategic direction for the implementation of medicines management and practice within the Trust.

4.4 Executive Directors, Divisional Medical Directors, Managing Directors, General Managers, Clinical Service Leads, Associate Chief Pharmacists, Divisional Directors & Deputy Directors of Nursing, Matrons and other Line Managers

Managers are responsible for:

4.4.1 Incorporating the Medicines Policy into their procedures and working practices.

4.4.2 Making arrangements so that staff are made aware of and are able to implement the policy.

4.4.3 Ensuring appropriate audit related to medicines management and practice is undertaken.

4.4.4 Ensuring that following audit, action plans to improve safe medicines practice are promptly implemented and monitored.

4.5 **All Staff**

4.5.1 All registered clinical staff are responsible for their own professional practice.

4.5.2 All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must:

- Attend appropriate training and assessment of competence before commencing their roles as detailed in the associated procedural documents
- Be familiar with this policy as well as relevant associated procedural documents; and
- Implement the policy within their own practice by incorporating the Medicines Policy and associated procedural documents into their working practices.

5. Implementation and monitoring

Implementation

5.1 A copy of this policy will be available on the Trust Intranet site.

5.2 All healthcare professionals and other appropriate clinical and non-clinical staff newly employed within the Trust must read this policy and adhere to it at all times when involved in the management and use of medicines.

5.3 All healthcare professionals and other appropriate clinical and non-clinical staff newly employed within the Trust will be made aware of their responsibilities in relation to medicines management as part of their induction as detailed in the Trust Mandatory and Statutory Training Policy.

5.4 Defined responsibilities, competences and training are in place for staff involved in medicines management and are set out in the Medicines Code and associated procedures and the Trust Mandatory and Statutory Training Policy.

Monitoring

5.5 Overseeing delivery and compliance monitoring of the policy is the responsibility of the MMAG through exception reporting from the sub-groups outlined in section 3.6.

5.6 Appendix A provides full details on how the policy will be monitored by the Trust.

6. Glossary of Terms

- **Antimicrobial medicines**: Medicines used to prevent and treat infections.
- **Controlled Drugs**: Medicines regulated by the Misuse of Drugs Regulations 2001 and amendments. Other medicines may be managed using CD procedures as part of Trust risk minimisation procedures
- **Dispense**: To prepare a clinically appropriate medicine for a patient - this will be self-administered or administered to the patient by another individual. Dispensing is performed under the supervision of a pharmacist, and will include such activities as checking the validity of the prescription, the appropriateness of the medicines for an individual patient,
- **Non-Medical Prescriber**: An individual, other than a doctor or dentist, who is qualified to prescribe under specified conditions and is registered to do so with their regulating professional body.
- **Medical Gases**: Medical gases may be defined as those gases, which are prescribed for a patient by a clinician. Medical Gases are medicinal products.
- **Medication Related Incident:** A distinct or definite occurrence/or near miss which involves a medication.
- **Medicines:** Any substance used for treating, preventing or diagnosing disease, for contraception, for inducing anaesthesia or otherwise affecting any normal physiological function.
- **Prescriber:** A registered healthcare professional who is legally entitled to prescribe medicines within University Hospitals Birmingham NHS Foundation Trust.
- **Unlicensed Medicines:** Medicines which do not have a UK Marketing Authorisation

7. References

Department of Health (2018), The “Never Events” List 2018

Care Quality Commission (2010), Essential Standards of Quality and Safety’

Great Britain (2007), Mental Capacity Act – Code of Practice

Department of Health (2007), Safer Management of Controlled Drugs: A Guide to Good Practice in Secondary Care (England)

Great Britain (2007), Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations

Great Britain (2006), The Controlled Drug (Supervision of Management and Use) Regulations

Great Britain (2006), The Health Act

Department of Health (2006), Safer Management of Controlled Drugs: (1) Guidance on Strengthened Governance Arrangements

Department of Health (2005), Research Governance Framework for Health and Social Care (2nd Edition)

Department of Health (2005), Medicine Matters – A Guide to Mechanisms for the Prescribing, Supply and Administration of Medicines

Department of Health (2004), Building a Safer NHS for Patients: Improving Medication Safety - A Report by the Chief Pharmaceutical Officer

Department of Health (2004), HealthCare Commission - Standards for Better Health

Great Britain (2001), Misuse of Drugs Regulations 2001 - The Stationery Office, London

Great Britain (2016), Misuse of Drugs Regulations (Amendment) - The Stationery Office, London

Great Britain (1984), Misuse of Drugs Act 1971- The Stationery Office, London

Great Britain (1973), Misuse of Drugs (Safe Custody) Regulations 1973 (as amended) - The Stationery Office, London

Great Britain (1972), Medicines Act 1968 (as amended) - The Stationery Office, London

8. **Associated Documentation and Procedural Documentation**

The Medicines Code (443)
Hospitality, Gifts and Sponsorship policy UHB (62)
Controlled Drugs Procedures (816)
Procedure for the Safe Prescribing, Handling and Administration of Cytotoxic and Chemotherapeutic Agents (504)
Policy for the Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy (840)
Procedure for the Introduction of New Drugs or Formulary Changes (811)
Procedure for implementing a new compassionate use scheme or free of charge (FOC) medicine in the Trust
NICE Technology Appraisal Procedure (893)
Guidelines for the Prevention, Recognition and Management of Extravasation and Infiltration (46)
Handling of Illegal Substances on Trust Premises (965)
Procedure for the safe prescribing, handling and administration of vinca alkaloids (862)
Procedure for Patient Self-Administration of Medicines (578)
Patient Group Directions Procedure (1150)
Procedure for Management of Unlicensed Medicines (350)
Non-Medical Prescribing Procedure (351)
Procedure for the Supply of Pre-packed Medication (349)
Procedure for Medicines Reconciliation (575)
Medical Gases Operational Procedure (1314)
Procedure for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation(685)
Policy for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation (181)

Appendix A Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Quality of prescribing	Associate Chief Pharmacist – Clinical Services	Clinical Quality Monitoring Group	Clinical pharmacist review as set out in the local procedural document, Clinical Pharmacy Standards	Full report quarterly to CQMG
	Chief Pharmacist		Monitoring of EPMA system reports measuring missed doses and adherence to the Clinical Pharmacy Standards	Full report quarterly to CQMG
	Advanced Pharmacist – Electronic Prescribing	SMPG	Monitoring of Electronic Prescribing System "type-ins"	Quarterly report
	Associate Chief Pharmacist – Clinical Governance & Medication Safety Officer	SMPG	Monitoring of incidents/near misses	Full report annually
Incidents Related to Medicines	Head of Clinical Risk and Compliance	SMPG	Summary Incident Report	Two monthly
Compliance with relevant NHSE & I Patient safety alerts	Head of Clinical Risk and Compliance	SMPG Exception report to MMAG Annual report to Trust Audit Committee	Annual audit programme of compliance	Annually
Routine audit of record keeping, systems and documentation	Associate Chief Pharmacist – Clinical Governance & Medication Safety Officer	SMPG; MMAG and CQMG	Controlled Drug Audits Safe and Secure Handling of Medicines Audit	3-6 monthly Bi-annually