CONTROLLED DOCUMENT

University Hospitals Birmingham NHS
NHS Foundation Trust

# Medicines Policy

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| **CATEGORY:** | Policy |
| **CLASSIFICATION:** | Clinical/Governance |
| **PURPOSE:** | This policy describes the framework for medicines, within University Hospitals Birmingham NHS Foundation Trust (The Trust) in line with current legislation and best practice |
| **Controlled Document Number:** | 85 |
| **Version Number:** | 5.0 |
| **Controlled Document Sponsor:** | Executive Medical Director |
| **Controlled Document Lead:** | Chief Pharmacist |
| **Approved By:** | Board of Directors |
| **On:** | 28th January 2016 |
| **Review Date:** | December 2018 |
| **Distribution:**<br>• **Essential Reading for:** | All staff involved in the prescribing, dispensing, supply, handling, storage, administration and disposal of medicines within the Trust. |

## Contents

## 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 objective of this policy is 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 of Health and Clinical Excellence (NICE), Medicines Healthcare products Regulatory Agency (MHRA), and the Health Protection Agency (HPA) are adopted within the Trust; and

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.

## 2. Scope

This policy applies to all staff within the Trust including individuals employed by the Trust, students, locum and agency staff and all staff employed 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 associated corporate procedural documents referred to in Section 9.

3.2 The Chair of the Medicines Management Advisory Group (MMAG) shall approve all corporate procedural documents associated with this policy and 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 denoted as 9.1. and 9.2. in section 9 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 and the Clinical Guidelines Group, a sub group of The Clinical Quality Monitoring Group (CQMG).

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

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

3.5.2 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 issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.

3.5.3 The MMAG reports to the Medical Director through the CQMG. The MMAG has representatives from all the major user groups and representation from the other organisations, for example the local Joint Strategic Operational Medicines Group who 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. The governance structure for these groups is outlined in Appendix B.

3.5.4 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).

3.5.5 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 Executive Medical Director will make recommendations for actions to be taken from the information provided

at its meetings; working with Divisional 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 shown in Appendix B provide a framework that enables the Trust to comply with relevant medicines legislation and guidance.

3.6.2 The role of **The Medicines Safety Group (MSG)** is to consider all aspects of medicines management which relate to the safe use of medicines within the Trust, promote continued improvement in 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 MSG will report exceptions relating to the safety of medicines to the MMAG.

3.6.3 The role of **The PICS Drugs Group** is to receive, discuss and inform of changes/edits made to the Prescribing Information Communication System (PICS) for the Trust and manage the PICS drug dictionary. The group provides a forum for system improvements related to medicines management to be discussed and developed and will report exceptions relating to PICS to the MMAG.

3.6.4 The role of **The Antimicrobial Steering Group (ASG)** is to 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 Antimicrobials Steering 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 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 undertaken and maintain an effective formulary for each clinical speciality. MMEPs will report any exceptions in prescribing 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 Management Procedures are developed and implemented in accordance with the Controlled Document Procedure and includes approval by MMAG.

3.7.3 Each medicines management procedure sets 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.

## 3.8 Training

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

## 3.9 Documentation, Record Keeping and Audit

3.9.1 Records are to be maintained, in accordance with the associated medicines management procedures to provide a full medicines audit trail complying with medicines legislation and best practice guidance.

3.9.2 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.

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

## 3.10 Incident Reporting

3.10.1 All medication related incidents and near misses must be managed through the Trust 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 MSG will receive an incident report summary from the Risk and Compliance Unit. MSG will then review the incidents/near misses and is responsible for implementing risk management strategies to address elements of risk identified.

## 3.11 Accuracy of Prescription Charts

3.11.1 The electronic Prescribing and Information Communication System (PICS) ensures that prescribing and administration of medicines is in accordance with approved and validated medication templates.

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

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.

## 4. Duties

4.1 A detailed description of 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 can be found in each associated procedural document.

### 4.2 Chief Executive Officer

The Chief Executive Officer is responsible for the safe and secure handling of medicines.

### 4.3 Medical Director

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

### 4.4 Chief Pharmacist

The Chief Pharmacist, on behalf of the Medical Director, 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 MMAG.

### 4.5 Executive Directors, Divisional Directors, Associate Divisional Directors, Divisional Directors of Operations, Group Managers, Clinical Service Leads, Associate Directors of Pharmacy, Associate Directors of Nursing, Matrons and other line managers

Managers are responsible for:

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

4.5.2 Making arrangements so that staff are able to implement the policy.

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

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

### 4.6 All Staff outlined of the scope

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

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

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

## 5. Implementation and monitoring

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 Overseeing delivery and compliance monitoring of the policy is the responsibility of the MMAG through exception reporting from the sub-groups identified within Appendix B.

5.5 Appendix B provides full details on how the policy will be monitored by the Trust.

## 6. References

Department of Health (2015), The “Never Events” List 2015/2016

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 (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

## 7. Associated Documentation and Procedural Documentation

Medicines Procedures(Controlled Document 443)

Controlled Drug Procedures (Controlled Document 835)

Guidelines for Prescribing, Procurement, Dispensing, Supply and Administration of Unlicensed Medicines (Controlled Document 350)

Guidelines for Non Medical Prescribing (Controlled Document 351)

Procedure for Medicines Reconciliation (Controlled Document 578)

Guidelines for Self Administration of Medicines (Controlled Document 578)

Guidelines for the Supply of Pre-packed Medication (Controlled Document 349)

Procedure for the Safe Prescribing, Handling and Administration of Cytotoxic and Chemotherapeutic Agents (Controlled Document 504)

Guidelines for the Management of Spillage of Cytotoxic Drugs (Controlled Document 593)

Procedure for the Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy (Controlled Document 840)

Guidelines for Safe Handling and Administration of Monoclonal Antibodies and Related Substances (Controlled Document 555)

Peri-operative Medication Management Guidelines for Adult Patients (Controlled Document 680)

Procedure for the Reporting and Investigation of Incidents Including Serious Incidents Requiring Investigation (Controlled Document 685)

Procedure for the Quality Management of Medicines Data entering the Prescribing and Information Communication System (PICS) (Controlled Document 842)

Clinical Pharmacy Standards (Controlled Document 695)

**Appendix A** **Monitoring Matrix**

| MONITORING OF IMPLEMENTATION | MONITORING LEAD | REPORTED TO PERSON/GROUP | MONITORING PROCESS | MONITORING FREQUENCY |
|---|---|---|---|---|
| Quality of prescribing | Principal Pharmacist Medicines Optimisation | Medicines Safety Group and Non-Medical Prescribing Group | Clinical pharmacist review as set out in the local procedural document, Clinical Pharmacy Standards | Continuous monitoring<br><br>Exceptions reported 6 weekly<br><br>Full report annually |
| | Chief Pharmacist | | Monitoring of PICS reports measuring missed doses and adherence to the Clinical Pharmacy Standards | Continuous monitoring<br><br>Exceptions reported 6 weekly<br><br>Full report annually |
| | Principal Pharmacist Medicines Optimisation | PICS Drugs | Monitoring of PICS “overrides” | Monthly |
| | Chief Pharmacist | Medicines Safety Group | Monitoring of incidents/near misses | Daily monitoring<br><br>Exceptions reported 6 weekly<br><br>Full report annually |
| Incidents Related to Medicines | Head of Clinical Risk and Compliance | Medicines Safety Group | Summary Incident Report | Quarterly |
| Compliance with NHSE/NPSA safety alerts | Chair of Medicines Safety Group | Medicines Safety Group<br><br>Exception report to MMAG | Annual audit programme of compliance | Annually |
| Routine audit of record keeping, systems and documentation | Principal Pharmacist Medicines Optimisation | Medicines Safety Group | Controlled Drug Audits<br><br>Safe and Secure Handling of Medicines Audit | 3-6 monthly<br><br>Annually |

## Medicines Management Governance Structure