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
Will this Controlled Document impact upon any contracts held by the Trust?	☐ Yes[1] ☒ No
Approved By:	Board of Directors
On:	July 2019
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Distribution: • **Essential Reading for:** • **Information for:**	 All Staff involved in the prescribing, dispensing, supply, handling, storage, administration and disposal of medicines within the Trust. All Staff

[1] If this Controlled Document will have an impact on any contracts held by the Trust, once approved, this will need to be sent to the Procurement Team requesting that it be added to the Procurement Policy Portal

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 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; 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.

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.

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 MMAG is responsible, on behalf of the Medical Director, 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, by the Medical Director.

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 Medical Director 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 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 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 and Sepsis Steering Group (ASSG) and the Antimicrobial Group (TAG)** 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 groups provide 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 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 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 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 associated Purchasing for Safety Procedure.

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 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) and, where in use, through the use of the appropriate System Amendments form for the JAC pharmacy system.

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

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 Medical Director

The Medical Director 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.

4.3 **Executive Directors, Divisional Directors, Associate Divisional Directors, Divisional Directors of Operations, Group Managers, Clinical Service Leads, Associate Chief Pharmacists, Associate Directors of Nursing, Matrons and other Line Managers**

Managers are responsible for:

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

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

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

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

4.4 **All Staff**

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

4.4.2 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.
- 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.

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. 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

7. Associated Procedural Documentation

ASSOCIATED MEDICINES PROCEDURES

UHB Wide Supporting Procedures For All Sites
The Medicines Code (443)
Hospitality, Gifts and Sponsorship policy UHB (62)
Controlled Drugs Procedures (816)

Equivalent supporting procedures for services provided at QE, Heartlands, Good Hope and Solihull hospitals.

QEH	**Heartlands, Good Hope and Solihull**
Title (Controlled document number)	**Title** (Document reference)
Non-Medical Prescribing Guidelines (351)	Non-Medical Prescribing Procedure V1.0
Business Continuity Plan (573)	Electronic Prescribing System Disruption Procedure v1.0
Procedure for the Safe Storage and Accurate Record Keeping for Controlled Drugs in Operating Theatre Departments (970)	
Expanded Practice Protocol for the Administration of Intravenous Drugs and Infusions by Registered Practitioners (232) Expanded Practice Protocol for the	Intravenous Infusions and Intravenous Medicines Administration procedure v1.0

Performance of Peripheral Venous Cannulation (229) Guidelines for the Insertion, Care and Removal of Peripheral Venous Cannula (225) Guidelines for the Care of Central Venous Access Devices (42) Guidance Notes for the Use of Invasive Line Flags (215)	
Expanded Practice Protocol for the Administration of Systemic Anti-Cancer Therapy by Registered Nurses (249) Procedure for the Safe Prescribing, Handling and Administration of Cytotoxic and Chemotherapeutic Agents (504) Guidelines for the Management of Spillage of Cytotoxics (593) Guidelines for the Prevention, Recognition and Management of Extravasation and Infiltration (46) Policy for the Safe Prescribing, Handling and Administration of Intrathecal Chemotherapy (840)	Procedure for the safe prescribing, handling and administration of systemic anti-cancer therapy (SACT) V2.6 Procedure for the prescribing, dispensing and administration of vinca alkaloids V1.0 Network Guidance for Handling the Spillage of Cytotoxic and Anti-Cancer Drugs (West Midlands Expert Advisory Group for Systemic Anti-Cancer Therapy (SACT)) Guidelines for the management of extravasation Procedure for Intrathecal Chemotherapy Procedure for the Administration of Intra-Vesical Chemotherapy (Mitomycin-C 40mg / Epirubicin 50mg) V1.0 Procedure for Administration of Intra-Vesical Bacillus Calmette-Guerin (BCG) v1.0
Guidelines for Self-Administration of Medicines (578)	Patient Self-Administration of Medicines in Adults Procedure v1.0
Homecare Medicines Procedure	Homecare Medicines Procedure v1.0
Policy for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation (181) Procedure for the Reporting and Management of Incidents including Serious Incidents Requiring Investigation(685)	Incident Reporting and Management Policy and Procedure v8.1

Procedure for Medicines Reconciliation (575)	Medicines Reconciliation Procedure v1.0 (collating, checking and communicating of a patient medication history on admission)
Procedure for Prescribing, Procurement, Dispensing, Supply and Administration of Unlicensed Medicines (350)	Unlicensed And “Off Label" Medicinal Products For Adults & Children V1.0 Procedure
Procedure for the Supply of Pre-packed Medication (349)	Issue of Pre-packed Medicines Procedure(1.0)
Policy on Alcohol and Substance Abuse (33)	Clinical Guidelines for the Management of Alcohol Withdrawal Opioid and Sedative Hypnotic Drug Addiction
Parenteral Nutrition Procedure(657)	Adult Parenteral Nutrition guidelines v3.0

Supporting procedures applicable at QEH based services:

Guidelines for the Assessment and Care of Patients with Known or Suspected Dementia or Delirium (205)
Procedure for the Introduction of New Drugs or Formulary Changes (811)

Supporting procedures applicable at Heartlands, Good Hope and Solihull based services:

Intravenous Potassium Procedure v1.0
Medicines procedure for Nurses, midwives and AHPs practising in the community
Non registered practitioners and medicines administration procedure v1.0
Purchasing for Safety Procedure for Medicines v2.0
Visiting Pharmaceutical Representatives Procedure V1.0
Prescribing and Dispensing Medication - Recovery at Home Procedure
Managing Patients Who May Require A Monitored Dosage System (MDS Blister Pack) On Discharge Procedure

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	Safe Medication Practice Group and Non-Medical Prescribing Group	Clinical pharmacist review as set out in the local procedural document, Clinical Pharmacy Standards	Continuous monitoring Exceptions reported 8 weekly Full report annually
	Chief Pharmacist		Monitoring of EPMA system reports measuring missed doses and adherence to the Clinical Pharmacy Standards	Continuous monitoring Exceptions reported 8 weekly Full report annually
	Principal Pharmacist – Electronic Prescribing	SMPG	Monitoring of Electronic Prescribing System “overrides”	Monthly
	Associate Chief Pharmacist – Governance & Education (Medication Safety Officer)	SMPG	Monitoring of incidents/near misses	Daily monitoring Exceptions reported 8 weekly Full report annually
Incidents Related to Medicines	Head of Clinical Risk and Compliance	SMPG	Summary Incident Report	Quarterly
Compliance with NHSI Patient safety alerts	Chair of Safe Medication Practice Group	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 – Governance & Education	SMPG Annual report to Trust Audit Committee	Controlled Drug Audits Safe and Secure Handling of Medicines Audit	3-6 monthly Bi-annually