University Hospitals Birmingham NHS Foundation Trust

CONTROLLED DOCUMENT

Clinical Standards and Audit Policy

CATEGORY:	Policy
CLASSIFICATION:	Governance
PURPOSE	To set out the principles and framework for the implementation and monitoring of local and national standards and clinical audit throughout the Trust.
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Controlled Document Lead:	Head of Clinical Governance and Patient Safety
Approved By:	Chief Executive
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Distribution: • **Essential Reading for:** • **Information for:**	All operational managers within the Trust, all governance staff and clinical staff employed by the Trust including students, locum and agency staff and staff employed on honorary contracts. Other staff not listed above involved in clinical standards or clinical audit

Contents

1. Policy Statement

1.1 The purpose of this policy is to set out the principles within University Hospitals Birmingham NHS Foundation Trust (the Trust) for ensuring that:

1.1.1 The Trust takes into account best practice as defined in National Confidential Enquiries and Inquiries (NCE) and National Institute for Health and Clinical Excellence (NICE) guidance;

1.1.2 Clinical Audit is undertaken in a robust and systematic manner;

1.1.3 Relevant national clinical standards including NICE guidance are incorporated into Trust practice; and

1.1.4 Patients receive safe and effective care based on the best available evidence.

1.2 Trusts have a statutory obligation through the production of Quality Accounts to publish clinical audit information, including participation in national clinical audits.

1.3 The NHS is legally obliged to implement NICE Technology Appraisal Guidance within three months[1].

1.4 Adherence to this policy and its associated procedures will assist the Trust in meeting Care Quality Commission (CQC) Fundamental Standards. The CQC make it clear that healthcare organisations must 'assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity and … evaluate and improve their practice'.

2. Scope

This policy applies to all Divisional Directors, Directors of Operations, Clinical Service Leads, Audit Leads, Auditors, Governance Leads, all clinical areas of the Trust, all clinical staff employed by the Trust including students, locum and agency staff and staff employed on honorary contracts.

3. Framework

3.1 This section describes the broad framework for the Clinical Standards and Audit Policy. Detailed instructions are provided in the associated procedural documents.

[1] NICE Into practice guide (2013)

3.2 The Director of Corporate Affairs shall approve all 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.

3.3 Definitions

Care Quality Commission (CQC)	The Independent regulator of health and social care in England.
Clinical Audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring (re-audit) is used to confirm improvement in healthcare delivery.
Clinical Guidelines	Clinical Guidelines contain evidence based recommendations on the appropriate treatment and care of patients with specific diseases and conditions. These do not include Patient Group Directions.
NICE Diagnostics Guidance	Diagnostic Guidance evaluates new, innovative diagnostic technologies. It includes all measurements and tests that are used to evaluate a patient's condition.
NICE Highly Specialised Technologies Recommendations	Highly Specialised Technologies Recommendations on the use of new and existing highly specialised medicines and treatments for very rare conditions.
NICE Interventional procedures guidance	Guidance which evaluates the safety and efficacy of such procedures where they are used for diagnosis or treatment.
NICE Medical Technologies	Medical technologies guidance is designed to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.
National Confidential Enquiries (NCE) and National Confidential	Exist to investigate the contribution of deficiencies in care to serious adverse patient outcomes, to identify areas where

Enquiries into Patient Outcome and Death (NCEPOD)	clinical practice needs to be improved and to make appropriate recommendations for changes that will improve outcomes for patients.
National Institute for Health and Clinical Excellence (NICE)	An independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health: www.nice.org.uk.
NHS Resolution (formerly NHSLA)	NHS Resolution is part of the NHS responsible for handling negligence claims made against NHS bodies in England.
Public Health Guidance	Recommendations on the promotion of good health and the prevention of ill health.
Quality Improvement or Quality Improvement Projects (QIPs)	Projects that seek to implement, embed and sustain improvements in any aspect of healthcare. There is typically more emphasis on the intervention and sustaining change than in the Clinical Audit model.
Technology Appraisals	Recommendations on the use of new and existing medicines and treatments in the NHS.

3.4 The Trust recognises the need to undertake, complete and acting upon, and report on Clinical Audit in a systematic manner, and to take into account agreed best practice, as defined in NCE reports and NICE clinical guidelines, and considers this to be a vital part of practice to provide high quality evidence based patient care.

3.5 The Trust's process for ensuring full review of national guidance consists of the following stages:

3.5.1 Responding to requests for NCE data by the deadline given.

3.5.2 Identifying relevant documents from the NCE and NICE websites.

3.5.3 Disseminating relevant documents to Standard Lead(s), who are the nominated clinical lead for the standard. This will be the relevant Clinical Service Lead by default, but they may nominate an appropriate colleague where suitable. Who must conduct a gap analysis to identify gaps in practice.

3.5.4 Ensuring recommendations are acted upon throughout the Trust.

3.5.5 Documenting decisions not to implement NICE or NCE recommendations and receiving formal approval for this decision from the Executive Medical Director.

3.6 The Trust's process for ensuring clinical audits are undertaken, completed and reported on in a systematic manner consists of the following:

3.6.1 Setting the priorities for local and national clinical audit by developing yearly specialty audit programmes.

3.6.2 Registering all clinical audits and Quality Improvement Projects with the Trust's Clinical Governance and Patient Safety Department.

3.6.3 Ensuring all registered clinical audits are approved by an appropriately senior audit supervisor, and designated specialty audit lead where applicable.

3.6.4 Completing clinical audits and sharing audit reports.

3.6.5 Making improvements, monitoring action plans and carrying out re-audits.

3.6.6 Monitoring and reporting on audit activity and outcomes.

3.7 Further details regarding the Trust's processes can be found in the relevant associated procedural documentation.

4. Duties

4.1 Executive Medical Director

The Executive Medical Director is responsible for:

4.1.1 Ensuring all specialties implement this policy; and

4.1.2 approving any non-compliance with NICE guidance or recommendations and any non-participation in a national audit.

4.2 Director of Corporate Affairs

The Director of Corporate Affairs is responsible for:

4.2.1 Monitoring compliance with this policy and its associated procedures;

4.2.2 Approval of amendments to the policy and its associated procedures; and

4.2.3 Monitoring the Trust's compliance with/participation in relevant national guidance and clinical audit.

4.3 Clinical Governance and Patient Safety Department

Members of the Clinical Governance and Patient Safety Department will be responsible for the following:

4.3.1 Monitoring audit activity, completion and outcomes including maintaining the clinical audit database;

4.3.2 Identifying and disseminating relevant NICE/NCE guidance and recommendations; and

4.3.3 Producing reports describing the Trust's position on clinical audit and standards.

4.4 Divisional Directors, Heads of Nursing and Directors of Operations

Divisional Directors, Heads of Nursing and Directors of Operations are responsible for:

4.4.1 Obtaining a response from the Standard Lead when no response is escalated by the Clinical Governance and Patient Safety Department;

4.4.2 Discussing, and where applicable, approving proposals for divergence from NICE guidance or NCE recommendations;

4.4.3 Ensuring divergence is added to the local risk register and remains on the risk register while the divergence is still in place and relevant;

4.4.4 Receiving a quarterly report from the Clinical Governance and Patient Safety Department, reviewing the report and taking action, when necessary, to support Standard Leads to meet recommendations;

4.4.5 Monitoring clinical audit activity;

4.4.6 Considering placing any significant gaps in practice identified from clinical audit onto the risk register for action and monitoring;

4.4.7 Confirming NICE and NCE recommendations are applicable to the Trust and confirming the Standard Lead;

4.4.8 Progressing overdue responses from Standard Leads; and

4.4.9 Receiving and discussing the exception reports provided by the Clinical Governance and Patient Safety Department.

4.5 Clinical Quality Monitoring Group

Members of the Clinical Quality Monitoring Group will be responsible for receiving, discussing and where necessary taking action in response to the regular reports provided by the Clinical Governance and Patient Safety Department.

4.6 Chief Pharmacist

The Chief Pharmacist, or their nominated member of staff, is responsible for:

4.6.1 Reviewing all newly published medicines-related technology appraisals and where applicable notifying a relevant clinical lead of the publication;

4.6.2 Ensuring all applicable NICE Technical Appraisals are on the formulary; and

4.6.3 Liaising with the relevant clinical lead if the advice on the TA is inconsistent with the Formulary and ensuring discussion and action at the Medicines Management Advisory Group.

4.7 Medicines Management Advisory Group (MMAG)

Members of the MMAG are responsible for the safe, clinical and cost-effective use of medicines within the Trust. MMAG will review new guidelines, or guidelines with significant changes, to ensure prescribing advice is consistent with the Trust agreed prescribing rules.

4.8 Standard Lead

The Standard Lead, sometimes referred to as the Guidance Lead, is responsible for:

4.8.1 Responding to requests for compliance identifying any gaps against NICE guidance or NCE recommendations within 4 weeks of receiving the request;

4.8.2 Compiling an action plan where there are gaps in practice or placing the gaps in practice on the local risk register for review;

4.8.3 Recommending an alternative or additional Standard Lead where applicable;

4.8.4 Requesting Divisional approval, for any divergence from recommendations;

4.8.5 Ensuring divergence from recommendations is placed on the risk register once approved; and

4.8.6 Updating the action plan, at a minimum, every 6 months.

4.9 Supervisor/Audit Leads (auditor)

4.9.1 Supervisors are responsible for the delivery of their clinical audit. The Audit Lead must be a Consultant, Senior Nurse or Senior Therapist. Audit Leads or their auditor will ensure that:

4.9.2 Their clinical audit and Quality Improvement Projects are registered with the Trust for shared learning and reporting on the Trust audit system, CARMS at QEHB or the audit database in place at HGS.

4.9.3 They follow a structured format for the clinical audit report/poster/publication or presentation which will preferably include methodology, conclusions and action planning.

4.9.4 Audit results/reports are appropriately disseminated and recorded on the database.

4.9.5 They create and update their action plan on the audit database.

4.9.6 They review National Audit reports and where gaps in practice are identified, complete an action plan and send to the Clinical Governance and Patient Safety department via the ClinicalAudit@uhb.nhs.uk address.

4.9.7 Notify the Clinical Service Lead of improvements made/needed based on the results of clinical audit.

4.9.8 Notify the Divisional Director of any significant gaps in local practice.

4.10 Clinical Service Leads

Clinical Service Leads are responsible for:

4.10.1 Developing a relevant specialty clinical audit programme on an annual basis by the beginning of the financial year for which it applies; and

4.10.2 Supporting the Audit Lead/Auditor if any improvements are needed based on the results of clinical audit.

4.11 All clinical staff

All clinical staff must ensure that their day-to-day practice is compliant with all relevant guidance that has been approved and introduced by the Trust.

5. Implementation and Monitoring

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

6. References

Care Quality Commission (2014) Guidance for Providers on Meeting the Regulations (2015).
http://www.cqc.org.uk/sites/default/files/20150324_guidance_providers_meeting_regulations_01.pdf

Department of Health (2012) A mandate from the Government to the NHS Commissioning Board: April 2013 to March 2015 https://www.wp.dh.gov.uk/publications/files/2012/11/mandate.pdf

7. Associated Policy and Procedural Documentation

Clinical Audit Procedure

Clinical Standards Procedure

Risk Management Policy

APPENDIX A: Monitoring Matrix

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
Clinical Audit				
Setting priorities for audit - local requirements	Head of Clinical Governance and Patient Safety	Divisional Clinical Quality Group Divisional Quality and Safety meetings	An exception report containing a list of outstanding audit programmes.	Annual
Setting priorities for audit – national requirements	Head of Clinical Governance and Patient Safety	Clinical Quality Monitoring Group	An exception report to the Clinical Quality Monitoring Group detailing national audits the Trust is not participating in, or not fully participating in.	As Required
Monitoring audit activity	Head of Clinical Governance and Patient Safety	Divisional Clinical Quality Group Divisional Quality and Safety meetings	A report listing recommendations or outcomes from completed clinical audits. A report listing the number of audits registered, completed and abandoned.	Quarterly
Monitoring audit completion	Head of Clinical Governance and	Divisional Clinical Quality Group Clinical Quality Monitoring Group	Report on ratio of audits completed: action plans received and the number	Quarterly

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
	Patient Safety	Divisional Quality and Safety meetings	of action plans completed. Report on the number of re-audits.	
Monitoring audit outcomes	Head of Clinical Governance and Patient Safety	Divisional Clinical Quality Group Clinical Quality Monitoring Group Divisional Quality and Safety meetings	Exception report of sub-par outcomes.	Quarterly
Clinical Standards				
A gap analysis between NICE/NCE recommendations and current practice	Head of Clinical Governance and Patient Safety	Divisional Clinical Quality Group Clinical Quality Monitoring Group Divisional Quality and Safety meetings	Report on 'overdue responses' from Standard Leads and a report on recommendations categorised as 'under review' where no review date has been received.	Quarterly
Development of action plans in response to gap analysis.	Head of Clinical Governance and Patient Safety	Divisional Clinical Quality Group Clinical Quality Monitoring Group Divisional Quality and Safety meetings	Report including update on actions taken to meet NICE or NCE recommendations and planned dates for compliance, including when no action plan has been received or gaps	Quarterly

MONITORING OF IMPLEMENTATION	MONITORING LEAD	REPORTED TO PERSON/GROUP	MONITORING PROCESS	MONITORING FREQUENCY
			have not been placed on the risk register.	
Recording of decisions not to implement NCE or NICE recommendations	Head of Clinical Governance and Patient Safety	Divisional Clinical Quality Group Clinical Quality Monitoring Group Divisional Quality and Safety meetings	Report on divergences with NICE or NCE recommendations including confirmation of their addition to the risk register.	Quarterly
NICE Medicines-related Technology Appraisals	Chief Pharmacist	Medicines Management Advisory Group	Report on additions to the Formulary and any exceptions.	Bi-monthly