# Clinical Standards and Audit Policy

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<th><strong>CATEGORY:</strong></th>
<th>Policy</th>
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<tr>
<td><strong>CLASSIFICATION:</strong></td>
<td>Governance</td>
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<tr>
<td><strong>PURPOSE</strong></td>
<td>To set out the principles and framework for the implementation and monitoring of local and national standards and clinical audit throughout the Trust.</td>
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| **Controlled Document Number:** | 592 |
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| **Controlled Document Lead:** | Head of Governance |
| **Approved By:** | Chief Executive |
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**Distribution:**
- **Essential Reading 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.
- **Information for:** All non clinical staff not listed above involved in clinical standards or clinical audit.
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1. Policy Statement

1.1 The purpose of this Policy and its associated Procedures is to set out the principles within University Hospitals Birmingham NHS Foundation Trust (the Trust) for:

1.1.1 Taking 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 Ensuring clinical audits are undertaken, completed and reported on in a systematic manner.

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.

1.4 Adherence to this Policy and its associated Procedures will assist the Trust in meeting Care Quality Commission (CQC) Essential Standards. The CQC make it clear that healthcare organisations take into ‘account relevant guidance…which relates to the care, treatment and support provided by the service which is published by a professional or expert body that is relevant’ and guidance is audited, and findings are used to ensure ‘action is taken to protect people who use services from risks associated with unsafe care, treatment and support.’

1.5 Adherence to this Policy and its associated Procedures will assist the Trust in meeting the NHS Litigation Authority (NHSLA) Standards related to NICE, NCE and Clinical Audit.

2. Definitions

This section lists the meaning of terms used within the Policy and its associated procedures:

2.1 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.

2.2 Technology Appraisals

Recommendations on the use of new and existing medicines and treatments in the NHS.

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1 NICE (2005) How to put NICE guidance into practice
3 Care Quality Commission (2010) Essential Standards of Quality and Safety
4 NHS Litigation Authority (2012) Risk Management Standards
2.3 Medical Technologies
Medical technologies guidance is designed to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.

2.4 Interventional procedures
Guidance which evaluates the safety and efficacy of such procedures where they are used for diagnosis or treatment.

2.5 Clinical guidelines
Recommendations based on the best available evidence on the appropriate treatment and care of people with specific diseases and conditions.

2.6 Public Health guidance
Recommendations on the promotion of good health and the prevention of ill health.

2.7 NHS Litigation Authority (NSHLA)
The NSHLA is part of the NHS responsible for handling negligence claims made against NHS bodies in England: www.nhsla.com.

2.8 Care Quality Commission (CQC)

2.9 National Confidential Enquiries (NCE)
National Confidential Enquiries into Patient Outcome and Death (NCEPOD) exists to investigate the contribution of deficiencies in care to serious adverse patient outcomes, to identify areas where clinical practice needs to be improved and to make appropriate recommendations for changes that will improve outcomes for patients.

2.10 Clinical Audit
Defined as
‘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’\(^5\)

3 Scope
This policy applies to all Divisional Directors, Directors of Operations, Clinical Service Leads, Audit Leads, Auditors, Standard 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.

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\(^5\) Healthcare Quality Improvement Partnership (HQIP) (2011) New Principles of Best Practice in Clinical Audit
4 Taking into account agreed best practice, as defined in NCE reports and NICE clinical guidelines

The Trust’s process for ensuring full participation in national guidance consists of the following stages:

4.1 Responding to requests for NCE data by the deadline given.
4.2 Identifying relevant documents from the NCE and NICE websites.
4.3 Disseminating relevant documents to Standard Lead(s).
4.4 Conducting a gap analysis to identify gaps in practice.
4.5 Ensuring recommendations are acted upon throughout the Trust.
4.6 Documenting decisions not to implement NICE or NCE recommendations.

5 Ensuring clinical audit is undertaken, completed and reported on in a systematic manner

To ensure the Trust is following agreed best practice, the Trust’s process for ensuring clinical audits are undertaken, completed and reported on in a systematic manner consists of the following:

5.1 Setting the priorities for local and national clinical audit.
5.2 Registering clinical audit.
5.3 Formatting audit reports.
5.4 Completing clinical audit and sharing audit reports.
5.5 Making improvements, monitoring action plans and carrying out re-audits.

6 Duties

6.1 Medical Director

The Medical Director will be responsible for:

6.1 The implementation of the Policy and its associated Procedures.
6.2 Amends to the Policy and its associated Procedures.
6.3 The Trust’s participation and monitoring of all relevant national guidance and clinical audit.

6.2 Associate Medical Director for Clinical Standards and Governance

The Associate Medical Director for Clinical Standards and Governance will be responsible for supporting the Medical Director with the Medical Director’s duties listed above and for Chairing the Clinical Standards and Audit Group.
6.3 Governance Department
The Governance Department will be responsible for:

**Clinical Standards**

6.3.1 Contacting Health Informatics for NCE data requests, ensuring the data is put into the format required by the NCE and submitting by the deadline given by the NCE.

6.3.2 Scanning the NICE and NCE websites for newly published recommendations each month and logging onto the NICE or NCE spreadsheet.

6.3.3 Disseminating NICE guidance and NCE reports by e-mail to the Clinical Standards and Audit Group for their approval of the Standards Lead.

6.3.4 Disseminating NICE guidance and NCE reports by e-mail to the Standard Lead for their gap analysis.

6.3.5 E-mail newly published medicine-related technology appraisals to the Chief Pharmacist or their delegated Lead Pharmacist.

6.3.6 Escalate divisional ‘no responses’ to the Divisional Director, or Director of Operations either by e-mail or at the Divisional Clinical Quality Group or local specialty meeting.

6.3.7 Escalate trust-wide ‘no responses’ to the Clinical Standards and Audit Group either by email or at the meeting.

6.3.8 Where no response has been received from the Standard Lead categorise ‘no response’ on the spreadsheet.

6.3.9 Facilitate Divisional Director approval for divisional decisions to diverge from NCE recommendations or NICE guidance.

6.3.10 Facilitate Clinical Standards and Audit Group approval for trust-wide decisions to diverge from NCE recommendations or NICE guidance.

6.3.11 Record decisions to diverge from NICE guidance or NCE recommendations on the NICE or NCE spreadsheet.

6.3.12 Facilitate placing divergence from NICE guidance or NCE recommendations on the risk register.

6.3.13 Update the compliance category on the NICE or NCE spreadsheet once compliance status has been confirmed by the Standard Lead.

6.3.14 For guidance categorised as ‘under review’ or ‘working towards compliance’ with no review date, action plan or placement onto the risk register, request this information every 8 weeks until the information is received.

6.3.15 Two years after NICE guidance and NCE recommendations are categorised as compliant or not applicable enquire whether this is still the case by sending an e-mail to the Standard Lead or Clinical Standards and Audit Group requesting assurance.

6.3.16 Save e-mail responses, action plans and evidence in the relevant NICE or NCE folders and record action planning progress on the NICE or NCE spreadsheet.

6.3.17 Prepare a quarterly exception report for the Divisional Clinical Quality Group, Clinical Standards and Audit Group and the Clinical Quality Monitoring Group as detailed in the Monitoring Matrix.
6.3.18 Review the effectiveness of the procedures described in this procedure reporting findings to the Clinical Standards and Audit Group on an annual basis.

6.3.19 The Head of Governance is the named Local Reporter for NCE studies for the Trust.

**Clinical Audit**

6.3.20 Disseminate suggestions for auditing to the Clinical Service Leads, or their Clinical Governance Leads or nominated individuals by the 30\textsuperscript{th} June.

6.3.21 Scan the healthcare quality improvement partnership website for new national clinical audits each quarter.

6.3.22 Register clinical audits received.

6.3.23 Facilitate approval for clinical audits of care provided to Military Personnel by the Royal Centre of Defence Medicine.

6.3.24 Ensure that participation in national clinical audits not listed on the Quality Accounts list is approved by an Executive Director or the Clinical Quality Monitoring Group.

6.3.25 Ensure that organisational questionnaires are approved by an Executive Director or the Clinical Quality Monitoring Group.

6.3.26 Update the Audit Database to include where audit results have been disseminated or presented.

6.3.27 Request an action plan from the Audit Lead/Auditor where clinical audit results have shown areas that require improvement.

6.3.28 Request confirmation from the Audit Lead/Auditor if there is a plan to re-audit and record on the Audit Database.

6.3.29 Request confirmation of actions completed and improvements made after the date of the last action for implementation.

6.3.30 Report to the Divisional Clinical Quality Groups and Clinical Standards and Audit group as detailed in the Monitoring Matrix.

6.3.31 Undertake an annual review of the effectiveness of the procedures described in the *Clinical Audit Procedure* and report to the Clinical Standards and Audit Group.

**6.4 Clinical Standards and Audit Group**

The Clinical Standards and Audit Group are responsible for:

6.4.1 Confirming NICE and NCE recommendations are applicable to the Trust and confirming the Standard Lead.

6.4.2 Progressing overdue responses from Standard Leads.

6.4.3 Discussing, and where appropriate, approving trust-wide divergences from NICE guidance or NCE recommendations.

6.4.4 Receiving and discussing the exception reports provided by the Governance Department.
6.4.5 Undertaking an annual review of the effectiveness of the procedures described in the Clinical Audit Procedure and in the Clinical Standards Procedure and report findings to the Clinical Standards and Audit Group.

6.5 Chief Pharmacist

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

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

6.5.2 Ensuring all applicable NICE Technical Appraisals are on the formulary.

6.5.3 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.

6.6 Medicines Management Advisory Group (MMAG)

The MMAG is 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.

6.7 Standard Lead

The Standard Lead is responsible for:

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

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

6.7.3 Recommending an alternative or additional Standard Lead where applicable.

6.7.4 Requesting Divisional or Clinical Standards and Audit Group approval for any divergence from recommendations.

6.7.5 Ensuring divergence from recommendations is placed on the risk register once approved.

6.7.6 Update the action plan, at a minimum, every 6 months.

6.8 Audit Leads/Auditor

Audit Leads 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:
6.8.1 Their clinical audit is registered with the Trust for shared learning and reporting
6.8.2 They use the up-to-date clinical audit registration form available on the Intranet
6.8.3 The clinical audit is approved by the Audit Lead
6.8.4 They follow a structured format for the clinical audit report/poster/publication or presentation which will preferably include methodology, conclusions and action planning
6.8.5 Ensure the dissemination of audit results/reports and confirming that the audit results have been disseminated or presented to the Governance Department
6.8.6 Provide an action plan to the Governance Department where results have shown areas that require improvement
6.8.7 Review National Audit reports and where gaps in practice are identified complete an action plan and send to the Governance Department
6.8.8 Notify the Clinical Service Lead of improvements made/needed based on the results of clinical audit
6.8.9 Notify the Divisional Director of any significant gaps in local practice

6.9 Divisional Directors and Directors of Operations and the Divisional Clinical Quality Monitoring Group (DCQG)
Divisional Directors, Directors of Operations, or their nominated deputies and the Divisional Clinical Quality Monitoring Groups are responsible for:

6.9.1 Obtaining a response from the Standard Lead when no response is escalated by the Governance Department
6.9.2 Discussing, and where applicable, approving divergence from NICE guidance or NCE recommendations
6.9.3 Ensuring divergence is added to the local risk register and remains on the risk register while the divergence is still in place and relevant
6.9.4 Receiving a quarterly report from the Governance Department and taking action, when necessary, to support Standard Leads to meet recommendations
6.9.5 Monitor clinical audit activity
6.9.6 Consider placing any significant gaps in practice identified from clinical audit onto the risk register for action and monitoring

6.10 Clinical Service Leads
6.10.1 Develop a specialty clinical audit programme prioritising the department’s audit programme on an annual basis by 30th September
6.10.2 Support the Audit Lead/Auditor if any improvements are needed based on the results of clinical audit

6.11 Executive Directors and the Clinical Quality Monitoring Group (CQMG)

The Executive Directors and the Clinical Quality Monitoring Group are responsible for:

6.11.1 Discussing and where applicable approving decisions to diverge from NICE guidance or NCE recommendations

6.11.2 Receiving a quarterly report from the Governance Department and taking action, when necessary, to support Divisions and the Clinical Standards and Audit Group to meet recommendations

6.12 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.

7 Implementation and Monitoring

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

8 References


Care Quality Commission (2010) Essential standards of Quality and Safety

NHSLA (2012) Risk Management Standards
http://www.nhsla.com/Pages/Publications.aspx?library=safety%7cstandards
9 Associated Policy and Procedural Documentation

Clinical Standards Procedure
Clinical Audit Procedure
# APPENDIX A: Monitoring

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<th>MONITORING PROCESS</th>
<th>MONITORING FREQUENCY</th>
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<tr>
<td>Requirements that audits are conducted in line with the registration process, that audit reports are shared and formatted (h) How the organisation monitors compliance with all of the above</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group</td>
<td>A review to be undertaken determining how the procedures and duties have been applied</td>
<td>Annual</td>
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<tr>
<td>Setting priorities for audit - local requirements</td>
<td>Head of Governance</td>
<td>Divisional Director or Director of Operations or the Divisional Clinical Quality Group</td>
<td>An exception report containing a list of outstanding audit programmes</td>
<td>Within Quarter Three</td>
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<td>Setting priorities for audit – national requirements</td>
<td>Head of Governance</td>
<td>Clinical Quality Monitoring Group</td>
<td>An exception report to the Clinical Quality Monitoring Group detailing national audits the Trust is not participating in, or not fully participating in</td>
<td>Quarterly</td>
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<tr>
<td>How the organisation makes improvements</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group</td>
<td>A report listing recommendations or outcomes from completed clinical audits.</td>
<td>Quarterly</td>
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<td>MONITORING OF IMPLEMENTATION</td>
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<td>REPORTED TO PERSON/GROUP</td>
<td>MONITORING PROCESS</td>
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<td>A report listing the number of audits registered, completed and abandoned.</td>
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<td>How the organisation monitors action plans and carries out re-audits</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group</td>
<td>Report on ratio of audits completed: action plans received and the number of action plans completed</td>
<td>Quarterly</td>
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<td>How the organisation identifies which NICE clinical guidelines and NCE Enquiries are relevant to it’s services</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group</td>
<td>A review to be undertaken determining how the procedures and duties have been applied</td>
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**Clinical Standards**

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<td>Report on ratio of audits completed: action plans received and the number of action plans completed</td>
<td>Quarterly</td>
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<td>Clinical Standards and Audit Group</td>
<td>A review to be undertaken determining how the procedures and duties have been applied</td>
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<td>How a gap analysis is conducted to identify shortfalls</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group, Divisional Clinical Quality Group, Clinical Quality Monitoring Group</td>
<td>Report on ‘overdue responses’ from Standard Leads and a report on recommendations categorised as ‘under review’ where no review date has been received.</td>
<td>Quarterly</td>
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<td>How action plans are developed to address any shortfalls</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group, Divisional Clinical Quality Group, Clinical Quality Monitoring Group</td>
<td>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 have not been placed on the risk register.</td>
<td>Quarterly</td>
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<tr>
<td>Recording decisions not to implement NCE or NICE recommendations</td>
<td>Head of Governance</td>
<td>Clinical Standards and Audit Group</td>
<td>Report on divergences with NICE or NCE</td>
<td>Quarterly</td>
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<td>NICE Medicines-related Technology Appraisals</td>
<td>Chief Pharmacist</td>
<td>Medicines Management Advisory Group</td>
<td>Report on additions to the Formulary and any exceptions</td>
<td>Bi-monthly</td>
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<td>recommendations including confirmation of their addition to the risk register</td>
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