The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Clinical Audit Policy

<table>
<thead>
<tr>
<th>Version No.:</th>
<th>5.1</th>
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<tr>
<td>Effective Date:</td>
<td>19 March 2019</td>
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<td>19 December 2021</td>
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<td>Ratified by:</td>
<td>Clinical Policy Group</td>
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1. Introduction

1.1 The purpose of this policy is to develop and sustain a culture of best practice within the Trust through the clinical audit process.

1.2 The expectation for healthcare professionals to participate in regular clinical audit was first established in the 1989 Government White Paper, ‘Working for Patients’. This has been reinforced and extended by a succession of key national publications, including:

- The New NHS — Modern, Dependable (Department of Health, 1997)
- A First Class Service (Department of Health, 1998)
- Clinical Governance — Quality in the NHS (Department of Health, 1999)
- Good Doctors Safer Patients (Department of Health, 2006)
- Trust Assurance & Safety (Department of Health, 2007)

1.3 The Trust is committed to the aims of clinical audit in improving patient outcomes by enhancing professional practice and the general quality of services delivered based on the principles outlined in section 2.

2. Policy scope

This Policy is aimed at all Trust Staff participating in Clinical Effectiveness and Audit.

The Trust philosophy for clinical audit is to:

- Ensure that audits are relevant and ensuring that the services provided are safe, of a high quality, and meet local, regional and national standards
- Encourage audit to be utilised to drive and monitor clinical improvement and changes in practice
- Ensure that all staff are supported and encouraged to participate in clinical audit
- Encourage multidisciplinary audit across the Trust
- Encourage patient, carer and public involvement in the audit process
- Encourage cross-organisational audit involving the local Health Economy.

3 Aim of policy

The aim of this policy is to set out a framework for the conduct of clinical audit within the Trust.

3.1 Clinical audit is a key and essential component of clinical governance within the Trust and involves all clinicians to ensure that patients receive optimum care based upon the best available clinical evidence.

3.2 The definition endorsed for Clinical Audit by the National Institute for Health and Clinical Excellence (NICE) and the Care Quality Commission is that it is “A quality improvement process that seeks to improve the patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structures, 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 is used to confirm improvement in healthcare delivery” (NICE, 2002).

3.3 The Healthcare Commission introduced an Engagement in Clinical Audit Indicator in 2008 which placed the following expectations on Trusts:

- To participate in local and/or national audits of the treatment and outcomes for patients in each clinical directorate covered by the Trust
- To have a clinical audit strategy and programme related to both local and national priorities with the overall main aim of improving patient outcomes
- To make available suitable training, awareness or support programmes to all clinicians regarding the Trust's systems and arrangements for participating in clinical audit
- To ensure that all clinicians and other relevant staff conducting and/or managing clinical audits are given appropriate time, knowledge and skills to facilitate the successful completion of the audit cycle
- To undertake a formal review of the local and national audit programme undertaken in the Trust to ensure that it meets the organisation's aims and objectives as part of the wider quality improvement agenda
- To provide the Trust's management and governance leads with regular reports on the progress being made in implementing the outcomes of national clinical audits, and review the outcomes, with additional or re-audits being conducted where necessary.
4 Duties

Structure and responsibilities

4.1 Chief Executive
The Chief Executive has overall responsibility for the strategic direction and operational management of the Trust and takes overall responsibility for this policy.

4.2 Trust Board
The Trust Board has a role in driving quality assurance, compliance, internal audit and “closing the loop” in accordance with Healthcare Quality Improvement Partnership (HQIP) document: Clinical Audit: A simple guide for NHS boards (2009a) available at [www.hqip.org.uk](http://www.hqip.org.uk).

4.3 Medical Director
The Medical Director is the Executive Lead for Clinical Audit and hence has ultimate responsibility for the delivery of the clinical audit programme.

4.4 Clinical Governance and Quality Committee
The Clinical Governance and Quality Committee is the Executive Committee with responsibility for clinical audit.

4.5 Clinical Effectiveness, Audit and Guidelines Committee (CEAGC)
The CEAGC is a sub-committee of the Clinical Governance and Quality Committee and has responsibility for providing advice and guidance to directorates in relation to clinical audit and effectiveness which includes participation in both national and local audit, establishing a system for the recording of audit activity, stimulating the evaluation of the implementation of change through reaudit and ensuring appropriate arrangements are in place for monitoring the implementation of prioritised clinical effectiveness and audit programme.

4.6 Clinical Governance and Risk Department (CGARD)
Within CGARD, clinical effectiveness and audit is managed by the Quality and Assurance Lead and is supported by the Clinical Effectiveness Manager for:
- Supporting the audit of Trust Priorities
- Providing training materials in relation to the concepts of clinical audit and the basic skills required to undertake clinical audit
- Establishing arrangements and providing information on the reporting of audit activity across the Trust.

In addition, CGARD staff have been allocated specific clinical directorates to whom they will provide clinical governance support, via the respective clinical governance leads.

4.7 Directorate Clinical Governance Committees
In relation to clinical effectiveness and audit, committees are responsible for:
- Promoting audit to monitor clinical practice against agreed standards, and in response to incidents and complaints
• Ensuring that non-compliant NICE guidelines are reported on the appropriate risk register
• Reviewing NICE guidelines rated high or greater on a meeting by meeting basis
• Regularly reviewing non-compliant NICE guidelines rated Moderate or below and undertaking full review of non-compliant guidelines on a six monthly basis and reporting to CEAGC
• Ensuring that where audits have identified areas for improvements that an action plan is developed and monitored by the Directorate including arrangements for reaudit in the next year’s Directorate audit programme
• Ensuring all reaudits are identified, undertaken and reported in the Directorate’s annual report to the Clinical Effectiveness, Audit and Guidelines Committee
• Policies and systems for maintaining standards of staff training and clinical competency are in place and attendance is monitored
• Any training issues identified through incidents, audits, complaints or claims are addressed.
• Escalation of risk issues occur as appropriate through the Trust reporting mechanisms.

4.8 Lead Clinicians (Directorate)
Each Clinical Directorate has an identified lead clinician for clinical audit who has responsibility for:
• Ensuring that clinical audit is embedded within the culture of the Directorate
• Ensuring that the Trust is updated on the clinical audits being carried out, primarily by providing an annual clinical effectiveness report to the Clinical Effectiveness, Audit and Guidelines Committee. More frequent attendance may be required.
• Ensuring that there is a clinical audit programme for the directorate. This includes providing an annual ‘forward programme’ which includes non-compliant or high risk NICE guidelines, national clinical audits, and trust-wide clinical audits which are relevant to the directorate. Additional audits will be required in response to local issues which have been found eg via Datix, or local interest.
• Ensuring audit projects are logged on the Trust’s clinical effectiveness register with all appropriate outcomes recorded on completion of audit projects
• Allowing time for regular multidisciplinary meetings to discuss audit projects and the status of non-compliant NICE guidelines, with records of attendance, topics considered and actions agreed (with responsibility for action). Directorates should support this by explicitly allocating time for staff to attend multidisciplinary audit meetings
• Providing advice, support and/or training for colleagues who are carrying out clinical audits in conjunction with CGARD
• Facilitating the implementation of actions resulting from audit to produce improvements in the quality of patient care
• Ensuring that junior doctors and junior dentists are participating in the clinical audit programme
• Encouraging a multi-professional approach and teamwork to carrying out clinical audit
• Encouraging the inclusion of the patient experience in clinical audits and the inclusion of patients or patient representatives as appropriate.

Liaising as needed with the clinical director and business manager about the clinical audit programme and any support needed for the programme including support for the implementation of actions needed to improve services.

4.9 Clinicians
The Trust is committed to ensuring all clinicians are actively involved in the audit process. Professional staff are individually accountable for ensuring they audit their own practice as defined by their codes of conduct.

5 Definitions

It is important to distinguish clinical audit from data collection exercises and research projects.

*Review*  
Where does my practice stand at the moment? (No comparison with a standard). Project seeks to inform decision-making; it can also be referred to as Service Evaluation or Benchmarking. It does not necessarily involve a change of outcome for patients or the service (projects designed to produce change of outcome can be deemed to be audit or research).

*Satisfaction Survey*  
Asking for patient preferences, staff opinions, etc., when not measuring against a standard or guideline.

*Research*  
What should I be doing? (To establish best practice). Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. (Research Governance Framework for Health and Social Care, DoH 2005)

*Clinical Audit*  
Am I doing what I should be doing? (Comparison with best practice standard or target, e.g. to determine the level of compliance against the standard; the areas of non-compliance; recommendations for change.)

See [NRES definitions of Research, Audit and Service Evaluation](#) for further clarification.

6 Clinical Audit

6.1 Commitment to Stakeholder Engagement, Collaboration and Partnership

6.1.1 Involving Patients and the Public
The Trust is committed to involving patients/carers in the clinical audit process either indirectly through the use of patient surveys/questionnaires or directly through participation of identified individuals on project steering groups or patient forums.

6.1.2 Multi-disciplinary and multi-professional audit, and partnership working with other organisations

The Trust encourages clinical audit undertaken jointly across professions and across organisational boundaries. Partnership working with other local and regional organisations will be encouraged where improvements to the patient journey may be identified through shared clinical audit activity.

6.1.3 Involving medical students and F1 / F2 doctors

The Trust has established an annual award for F1 and F2 doctors which recognises good clinical audit practice through longitudinal projects.

6.2 Prioritising Clinical Audit Projects

6.2.1 Trust Programme

The Trust will audit projects against the most appropriate standards of performance. Consequently, the Trust programme will consist of two key components i.e. mandatory and discretionary audit.

6.2.2 Mandatory Audits

These are audits that are compulsory for the Trust to demonstrate compliance for example,

- National clinical audits
- NICE Guidance for example Quality standards (QS)
- National Confidential Enquiries’ recommendations (see Trust Policy on Implementation of National Confidential Enquiries, Strategies and High Level Enquiries)
- Sign up to Safety
- National Clinical Audits included in the Quality Account and National Clinical Audit Patient Outcome Programme
- Care Quality Commission
- CQUIN indicators.

6.2.3 Discretionary Audits

These are audits which are not necessarily national priorities, but are important to the Trust / directorate in delivering patient care. All audit projects must contribute to the overall objectives of the audit programme and look to improve patient care / service delivery.
In terms of support for clinical audit, CGARD will focus on assisting with mandatory requirements.

6.2.4 Local Audit

This can be undertaken when a directorate has completed its mandatory and discretionary audit. It may involve particular risk or patient safety issues which may affect some groups of individuals within the Trust.

6.3 Approved process for audit (see Appendix 1)

6.3.1 When undertaking an audit project, the lead clinician for the project should register the project on the Trust’s Clinical Effectiveness Register.

6.3.2 Each audit project undertaken should ideally have a topic, a supervisor, a coherent plan and a timescale. The supervisor is responsible for overseeing the data collection, dissemination of findings, acting on recommendations including agreement of local action for performance development and reaudit. There are six key stages within an audit project which are referred to as the audit cycle (these are outlined in Appendix 2) and each project should reflect “Criteria for Good Audit” (Appendix 3).

6.3.3 Wherever possible, prospective clinical audit should be the norm as it allows for accurate real time accrual of data that reflects current rather than historical practice. Data collection should therefore be 100% accurate both in volume and detail. Retrospective clinical audit can however act as an historical benchmark, but is of most use if a critical incident arises be this a complaint, litigation, adverse event or serious adverse outcome and a review of practice is required urgently.

6.3.4 Clinical audit involves collecting information about patient care and treatment, but more than that it is about ensuring quality i.e. making sure that we are doing the things we should be doing. Standards are written to state explicitly what those things are. Once a topic has been selected to audit, the next stage of the audit cycle is to set the standards to measure performance.

A standard is an explicit statement describing the quality of care to be achieved, which is **definable** and **measurable**. In order to effectively measure performance, the standards developed need to be SMART (HQIP, 2009b):

- **Specific** – clear and unambiguous
- **Measurable** – easy to evaluate
- **Achievable** – within your resources
- **Realistic** – within service constraints
- **Timely** – not out-of-date or inaccurate
The Trust takes the view that, wherever possible, registration of audit projects should include the adoption of credible evidence based standards but notes that standards do not always exist in relation to local projects in particular.

6.3.5 Clinical audits should be multidisciplinary wherever possible and there should be a commitment to reaudit to ensure that an evaluation is undertaken of any changes in practice to determine whether they have yielded improvements to patient care or service delivery.

6.4 Making audit effective

An audit may provide reassurance that a standard of clinical care is being achieved, or identify areas where improvements are thought to be needed. Audit is only an effective tool when the results are:

- Believed and acknowledged
- Discussed by senior clinicians
- Owned, by the department / directorate
- Taken forward to a forum with the power to approve action plan and implement changes for example a Governance Committee.

Belief, acknowledgement and discussion of audit findings may best be achieved by presentation of the audit at a directorate audit meeting. One of the outputs from the meeting may also be agreement about ownership. There needs to be clear arrangements within each directorate for ensuring that findings and recommendations can be fed into the appropriate forums where changes can be mandated.

In addition:

6.4.1 Each completed audit must have a final report which should follow the structure and format outlined in Appendix 4.

6.4.2 When the final report has been produced the Clinical Effectiveness register must be updated with the main outcomes.

6.4.3 The results of audit should be disseminated to those unable to participate in the audit meeting; for example in newsletters, by email, by saving audits to an accessible shared drive, by posters and other alternatives.

6.4.4 Where issues of significant risk are identified, these should be placed on the directorate’s risk register. It is for the governance structures of the directorate to determine whether any further escalation is appropriate.

6.4.5 The Clinical Audit Lead must provide a clinical effectiveness report to the Clinical Effectiveness, Audit and Guidelines Committee indicating
elements of good practice and where improvements can be made and confirm that such improvements have been achieved.

6.4.6 Reaudit must feature within action plans where the need for improvements has been made to ensure that any interventions / changes in practice have resulted in improved practice.

6.4.7 The Directorate Governance Committee must ensure that all appropriate reaudits are reported in the Directorate’s annual report to the Clinical Effectiveness, Audit and Guidelines Committee.

6.5 Ethics and Consent

Improving clinical care, maximising quality and minimising harm should be regarded as an ethical imperative for all clinical staff; audit is a key tool for clinical improvement. Audits are not “research” and do not require Research Ethics Committee approval. However, they should bear in mind patients’ rights, dignity, privacy and confidentiality.

Guidance can be found in “Ethics and clinical audit and quality improvement – a guide for NHS organisations” (HQIP, 2009c)

7 Training

7.1 The Trust will ensure that all clinicians within the organisation have the skills and knowledge to undertake clinical audit through the provision of training for staff. In particular, a training programme, which is an e-Learning package held on the National Learning Management System within ESR on clinical audit has been developed which enables staff to either develop / refresh their knowledge and skills and provides an assessment to determine whether participants have learnt the key aspects relating to clinical audit.

7.2 Clinical staff who have particular projects can request advice and guidance from CGARD on a 1:1 basis.

8 Equality and Diversity

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This policy has been appropriately assessed.

9 Monitoring

A key role of the CEAGC is to monitor the clinical audit activity and effectiveness in each Directorate by scrutinising the annual clinical audit reports. CEAGC can also provide support and advice to directorate audit leads. Where issues of importance have been identified, or where directorates have identified issues for which
resolution has proved difficult, CEAGC may be able to assist with escalating these through Trust governance mechanisms.

<table>
<thead>
<tr>
<th>Standard/ Process/ Issue</th>
<th>Monitoring and Audit</th>
<th>Method</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
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</thead>
<tbody>
<tr>
<td>To scrutinise and feedback to directorates following their annual presentations to the Committee.</td>
<td></td>
<td>Letter to clinical audit lead</td>
<td>Chairman, Clinical Effectiveness, Audit and Guidelines Committee (CEAGC)</td>
<td>CEAGC</td>
<td>Following directorate annual presentation</td>
</tr>
<tr>
<td>To assess compliance with NICE Quality Standards.</td>
<td></td>
<td>Audit against NICE guidelines discussed</td>
<td>CGARD</td>
<td>CEAGC</td>
<td>Annual</td>
</tr>
<tr>
<td>To assess Trust compliance with NICE Technology Appraisal Guidelines.</td>
<td></td>
<td>Audit against NICE guidelines discussed</td>
<td>CGARD</td>
<td>CEAGC</td>
<td>Annual</td>
</tr>
<tr>
<td>To oversee Trust contribution to National Clinical Audits</td>
<td></td>
<td>Report</td>
<td>CGARD</td>
<td>CEAGC</td>
<td>Annual</td>
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10 Consultation and Review

The processes in this policy have been reviewed and agreed by the Clinical Effectiveness, Audit and Guidelines Committee.

11 Implementation of Policy

Information about Clinical Audit, the implementation processes and the forms to be completed are available on the Trust’s intranet pages.

12 References

• DH (2006). *Good Doctors, Safer Patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients. A report by the Chief Medical Officer*. London: Department of health.
Appendix 1

Approved Process for Audit

Register project → Clinical Effectiveness Register

Final Report

Record → Clinical Effectiveness Register

Action Plans
- corrective action → Monitored by Directorate Clinical Governance Committee /
  - lead
  - timescale → - Annual Clinical Governance Report

Audit results disseminated

Significant areas Non-compliance → Risk Register

Reaudit → Clinical Effectiveness Register
The Audit Cycle

**Stage One: Selecting a topic**
There can be many reasons for undertaking an audit project however the main reasons are perceived as being high risk, high cost, high volume, wide variation in practice or local concern. Topics for audit may originate from:

- NICE guidelines
- Confidential Enquiries
- National Audits / Royal Colleges
- Requirements of National Health Services Litigation Authority (formerly CNST)
- Reaudits
- Incidents captured by risk management process
- Complaints & Claims
- Risk assessments
- Case reviews
- Local guidelines and protocols.

**Stage Two: Set standards**
Clinical audit measures current practice against guidelines or performance criteria. Consequently, explicit evidence-based standards should be identified for each project.

**Stage Three: Data collection**
Numerous methods are available for both quantitative and qualitative data collection to determine whether current practice complies with the agreed standards. In addition, where appropriate, projects should recognise the need for active patient, carer and public involvement, and the involvement of other organisations in the local Health Economy. Where an area does not interact directly with the public they should ensure the involvement of service users.

Audit is primarily a snapshot in time of current practice. The sample should be small enough to allow for rapid data acquisition, but large enough to be representative. It is recommended that small-scale pilot projects are undertaken initially to identify any potential problems with the data collection method before embarking on the main study.

**Stage Four: Analysis and reporting**
Data analysis and reports should be produced which focus on all the key areas of the audit including recommendations and changes to practice as appropriate. Reports must be presented within a suitable timeframe and to a suitable standard (please see Advice on Best Practice below). When the final report has been produced the project results must be logged on the Trust’s Clinical Effectiveness Register.

**Stage Five: Implementing Change / Making Improvements**
The implementation of change is a key stage of effective audit and all affected parties must be informed of the results and understand the need for change and the changes recommended. A systematic approach should be adopted with each recommendation identifying the date by which it should be implemented and the person responsible for making it happen.
Stage Six: Reaudit
Once sufficient time has elapsed for changes to become implemented into practice, it is essential that a reaudit is undertaken to "close the loop" and demonstrate that improvements have been achieved, to patient care/service delivery. It cannot be merely assumed that changes will always result in positive outcomes.

Reaudit will need to address whether standards remain realistic and appropriate. Data should be collected by the same method as previous and compared accordingly.

The clinical audit process is a continuous quality improvement process and is often referred to as an "audit spiral" with opportunities for change becoming less as practice improves.

General Information

Ethical Responsibilities
Whilst audit projects do not routinely require ethical approval, project leads should be mindful of potential ethical concerns and seek advice as appropriate, in addition to paying appropriate recognition to the Caldicott recommendations. (recommendations available from, Trust Intranet homepage, Clinical Governance, Audit Registration Forms, Caldicott Principles).

Advice on Best Practice
The Clinical Governance and Risk Department publish a series of “How To” leaflets on their intranet website containing advice on best practice for planning and undertaking audit projects, devising questionnaires, running Focus Groups and writing audit reports.
Appendix 3

Criteria for “Good Audit”

1. Should be part of a structured programme.

2. Topics chosen should in the main be high risk, high volume or high cost or reflect National requirements e.g. NICE guidelines, NSFs, National Clinical Audit Programme and Confidential Enquiries.

3. Service users should be part of the clinical audit process.

4. Should be multidisciplinary in nature.

5. Clinical audit should include assessment of process and outcome of care.

6. Standards should be derived from good quality guidelines.

7. The sample size chosen should be adequate to produce credible results.

8. Managers should be actively involved in audit and in particular in the development of action plans from audit enquiry.

9. Action plans should address the local barriers to change and identify those responsible for service improvement

10. Reaudit should be applied to ascertain whether improvements in care have been implemented as a result of clinical audit.

11. Systems, structures and specific mechanisms should be made available to monitor service improvements once the audit cycle has been completed.

12. Each audit should have a local lead.

(Taken from Practical Clinical Audit Handbook, NHS, 2005)
Clinical Audit Report Writing
Structure and Format

A Clinical Audit Report template is available which highlights that audit reports should contain the following headings and contents:

**Title Page**
This will include the title of the report, who has written it and the date it was written. Trust logo should be on the top right hand corner.

**Contents Page**
This lists the headings in the report together with the page numbers to which they refer.

**Executive Summary**
This should contain an overview of the message in the report, with a clear summary of the recommendations.

**Introduction/Background**
These can be two separate sections or combined. It should set the context of the report and define the scope and any limitations of the study.

**Aims and Objectives**
This should clearly identify what you want to achieve.

**Standards**
This section documents any standards which are being used to measure current practice against. It should include the relevant evidence base from which the standards are taken.

**Methodology**
This section details how the study was undertaken. It should include how the information was collected, when project was undertaken, where it was taken from and how much e.g. if a survey was used – how was the survey carried out, how was the target population determined, how many were surveyed and how they were surveyed (by interview or questionnaire).

**Results**
This is the main body of the report from which the author’s ideas are developed. It should include the main findings in a logical and progressive manner interspersed with graphs to assist understanding. It should contain the requisite information to justify the conclusions and recommendations which follow.

**Conclusions**
These are derived from the results section and should also link back to the aims and objectives. No new information should be included. Bullet points are a recommended way for emphasising the key points.

**Recommendations**
This section highlights the actions which need to be taken to follow on from the project. As with the conclusion section, recommendations should be derived from the main body of the report and should not include new information.
**Action Plan**
All reports must include an action plan where recommendations have been made. It should include the action required, who has responsibility for doing it and the date it should be completed by, if necessary date and plan for re-audit.

**References**
All items referred to in a report should be appropriately referenced using the Harvard system.