

Clinical Audit Policy

This policy describes the process for undertaking and reporting clinical audits and for monitoring the implementation of action plans that arise from clinical audits.

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Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
Version 12	July 2019	<ul style="list-style-type: none"> • Updates to reflect current structures and terminology
Version 11	July 2017	<ul style="list-style-type: none"> • Reflected change in management structure. • Emphasised data protection and governance. • Strengthened process for approval of reports. • Changed frequency of process monitoring to annual.
Version 10	August 2015	<ul style="list-style-type: none"> • More detail on the process for monitoring the implementation of clinical audit actions • Streamlined the process for preparing and submitting an audit proposal form • Better signposting of help available from the Clinical Audit Team • The supporting documentation for proposals and report writing has been refreshed
Version 9E	December 2012	Version sent to the Policy Group for agreement.
Version 9D	November 2012	Version sent to December's SCQG for agreement.
Version 9C	October 2012	Draft circulated among the Clinical Audit Team for comments & corrections.
Version 9B	October 2012	Draft circulated for the second round of comments about the revised version.
Version 9A	August 2012	Policy sent for comments as coming up to 6 monthly review
Version 8	April 2012	Policy ratified at Quality Assurance Committee
Version 8	March 2012	Draft Clinical Audit policy approved at the Senior Clinical Quality Group (SCQG) subject to minor amendments.
Version 7 Draft	March 2012	Additional comments incorporated with TORs from QAC and SCQG
Version 6 Draft	March 2012	Comments incorporated
Version 5 Draft	February 2012	Comments incorporated
Version 4 Draft	February 2012	Harmonised – Leicestershire Partnership NHS Trust, Leicester City Community Health Service, Leicestershire County & Rutland Community Health Service
Version 3 Draft 4	January 2012	Document reorganised and reclassified to map NHSLA requirements
Version 2 Draft 3	November 2011	Version 3 developed to follow the organisation-wide Document for Undertaking and Learning from Clinical Audit

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Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. It takes into account the provisions of the Equality Act 2010 and promotes equal opportunities for all. This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, sex (gender), gender reassignment, sexual orientation, marriage and civil partnership, race, religion or belief, pregnancy and maternity.

Due Regard

LPT will ensure that Due regard for equality is taken and as such will undertake an analysis of equality (assessment of impact) on existing and new policies in line with the Equality Act 2010. This process will help to ensure that:

- Strategies, policies and services are free from discrimination;
- LPT complies with current equality legislation;
- Due regard is given to equality in decision making and subsequent processes;
- Opportunities for promoting equality are identified.

Please refer to due regard assessment (Appendix 5) of this policy.

Abbreviations within this document

AIMS – Accreditation for Inpatient Mental Health Services
BAF – Board Assurance Framework
CANQI – Clinical Audit and NICE: A Quality Improvement Team
CEG – Clinical Effectiveness Group
CEMACH - Confidential Enquiry into Maternal and Child Health
CQC – Care Quality Commission
CQEL – Clinical Quality and Effectiveness Trust Lead
CQUIN – Commissioning for Quality and Innovation
DH – Department of Health
ECTAS – Electroconvulsive Therapy Accreditation Service
HQIP – Healthcare Quality Improvement Partnership
IQPR – Integrated Quality & Performance Report
LPT – Leicestershire Partnership Trust
NCAPOP – National Clinical Audit and Patient Outcomes Programme
NCE – National Confidential Enquiry
NCEPOD - National Confidential Enquiry into Patient Outcome and Death
NCISH – National Confidential Inquiry into Suicide and Homicide
PDSA – Plan, Do, Study, Act
NICE – National Institute for Health and Care Excellence
QC – Quality Committee
QI – Quality Improvement
QDA – Quality and Data Analyst

Definitions that apply to this Policy

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 is used to confirm improvement in healthcare delivery
Clinical audit cycle	A conceptual diagram of the stages of clinical audit, by which, in turn, clinical best practice is defined, the project is planned, performance measured, change implemented and improvement is monitored through further cycles of the clinical audit.
Research	Research can be defined as the attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods. This is about creating new knowledge about what works and what doesn't.
Clinical Governance	Clinical governance is a term used to describe a systematic approach to maintaining and improving the quality of patient care within a health system. It can be defined as a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.
Clinical Effectiveness	The application of the best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients.
Due Regard	Having due regard for advancing equality involves: <ul style="list-style-type: none"> • Removing or minimising disadvantages suffered by people due to their protected characteristics. • Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. • Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low.
Quality Improvement	Improving quality is about making healthcare safe, effective, patient-centred, timely, efficient and equitable. Quality Improvement is a systematic approach that uses specific techniques to improve quality
PDSA	The PDSA cycle is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act).

1.0. Purpose of the Policy

The purpose of this policy is to set out a governance and ethical framework for the conduct of clinical audit. This will ensure clinical audit is embedded as an activity across the Trust and ensure current approaches to clinical practice are reviewed against pre-determined standards, leading to improvements and enhancements in care provision. Clinical audit is fundamentally about quality improvement. However it also plays an important role in providing Board assurances regarding the quality of services.

This policy sets out the responsibilities for all staff carrying out clinical audit and outlines the Trust's expectations in relation to training of staff, registering, developing, carrying out and monitoring of clinical audit projects.

This policy provides:

- Expectations in relation to conduct, and participation in clinical audit.
- The procedures and expectations for approving clinical audit project proposals.
- Guidance for all staff in clinical audit activities/ processes including dissemination of results and sharing lessons learnt.
- The procedures that should be followed in order to make changes and sustain them.
- An outline of support available from the LPT clinical audit & NICE: a quality improvement (CANQI) team.

The CANQI team is committed to ensuring that clinical audits are carried out in accordance with the principles of best practice in clinical audit.

This policy aims to:

- Improve outcomes for patients.
- Encourage patient, carer and public involvement in the clinical audit process.
- Ensure that clinical audit projects are relevant to Trust business.
- Drive and monitor clinical improvement and implement changes to practice.
- Reduce variation in the quality of healthcare.
- Maximise the effective use of limited resources.
- Ensure that all staff are supported and encouraged to participate in clinical audit.
- Encourage multidisciplinary clinical audit and closer working relationships within multidisciplinary teams.
- Contribute to the continued professional development of staff.
- Provide assurance that our services are safe, of a high quality and meet local, regional and national standards.
- Provide assurance against relevant indicators which are monitored through the Integrated Quality & Performance Report (IQPR).

2.0 Summary and Key Points

This policy outlines the system and processes for undertaking and reporting clinical audits and for monitoring the implementation of action plans that arise from clinical audits.

3.0 Introduction

This policy provides a framework for overseeing clinical audit activity within Leicestershire Partnership NHS Trust (LPT). LPT is committed to continual improvement in patient care, robust clinical audit systems and processes required in order to meet NHS Improvement's requirements.

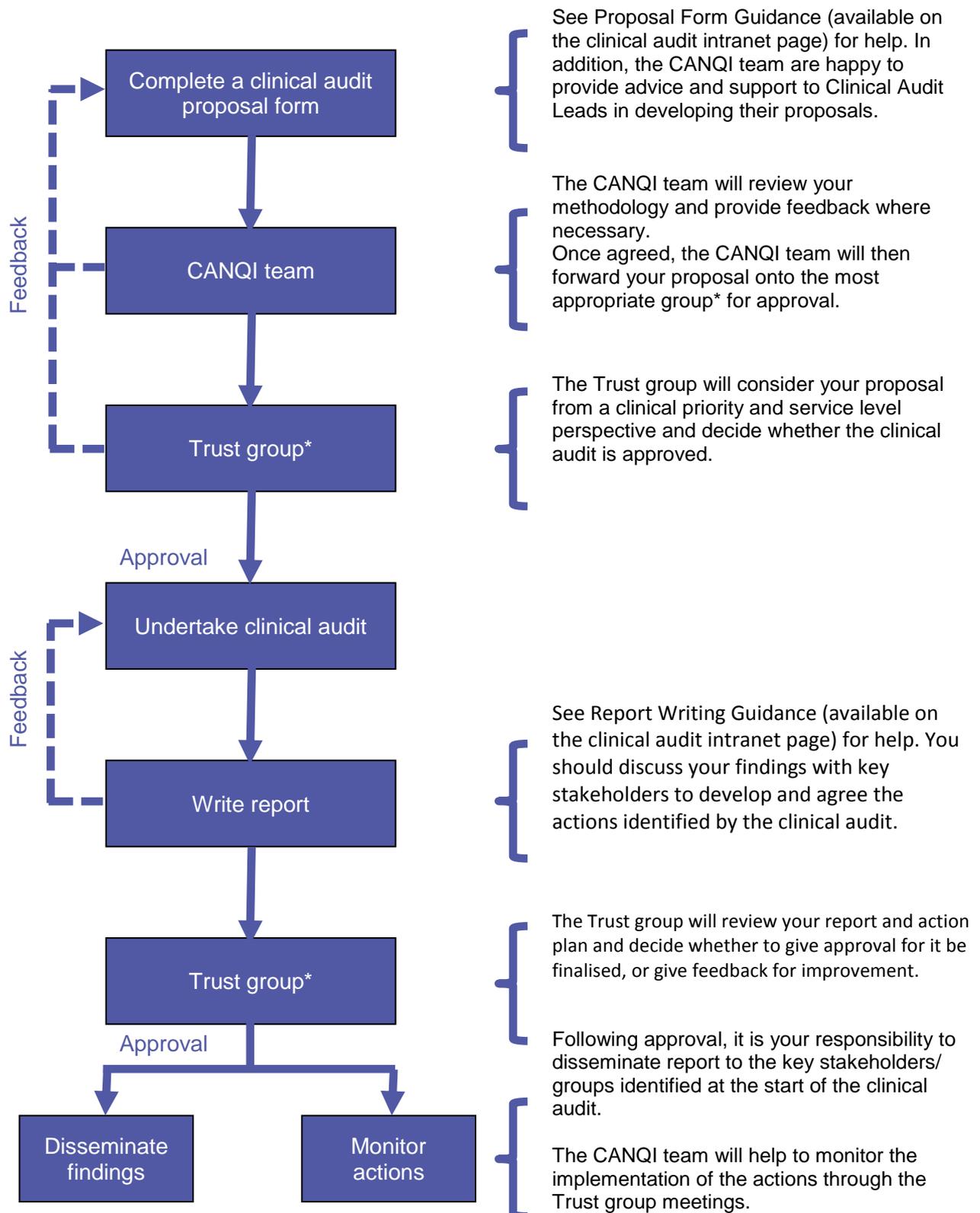
The expectation for healthcare professionals to participate in regular clinical audit was first established in the 1989 Government White Paper, 'Working for Patients'. This has been reinforced and extended by a succession of key national publications¹.

All clinical staff working in LPT are expected to participate in the clinical audit programme and to accept responsibility for carrying out and/ or acting on individual clinical audits and their findings, and to make the necessary changes to improve patient experience and outcomes.

LPT reports key achievements and quality improvements as a result of clinical audit in the LPT Clinical Audit Annual Report, the Department of Health Quality Account and the Board Assurance Framework (BAF).

¹ These publications include: Good Doctors Safer Patients (Department of Health, 2006), Trust Assurance & Safety (Department of Health, 2007), The NHS Next Stage Review Final Report, High Quality Care For All [the 'Darzi Report'], (Department of Health, 2008), Essential Standards of Quality and Safety (DH, 2010) Equity and Excellence: Liberating the NHS (DH, 2010)

4.0 Flowchart/ process chart



* Trust groups. For priority level 1 & 2 clinical audits, this will likely be one of the subgroups of the Quality Assurance Committee (e.g. CEG and PSG). For priority level 3 & 4 clinical audits, the group will likely be the relevant service level clinical audit group/ CHS equivalents. There may be exceptions to this rule, however.

5.0 Definitions

5.1 Clinical Audit

The National Institute for Health and Care Excellence, Principles for Best Practice in Clinical Audit (NICE: 2010) state that:

“Clinical audit is 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 is used to confirm improvement in healthcare delivery.”

5.2 Clinical Audit Cycle

Clinical audit is an essential component of Clinical Governance. There are four main stages of the clinical audit cycle:

- | | |
|---------|--|
| Stage 1 | Preparation and planning (organisation arrangements, stake- holder engagement, patient engagement and planning for re-audit) |
| Stage 2 | Measuring performance (clinical audit methodology, data collection process, data analysis and reporting) |
| Stage 3 | Implementing change (recommendations and action plan development) |
| Stage 4 | Achieving and sustaining improvement (re-audit where required and continuous improvement). |



Figure 1 - Healthcare Quality Improvement Partnership. Criteria and indicator of best practice in clinical audit, September 2009

5.3 Other quality improvement processes – research

Research can be defined as the attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods. This is about creating new knowledge about what works and what doesn't.

This methodology is distinct from clinical audit and not undertaken by the CANQI team.

5.4 Clinical Governance

Clinical governance is a term used to describe a systematic approach to maintaining and improving the quality of patient care within a health system. It can be defined as a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (Sally and Donaldson, 1998).

5.5 Clinical Effectiveness

Defined as “the application of the best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients, the process involves a framework of informing, changing and monitoring practice” Department of Health (DH) (1996).

5.6 National Institute of Health and Care Excellence (NICE)

NICE is the independent organisation responsible for providing national guidance on treatments and care for people using the NHS in England and Wales.

5.7 Care Quality Commission (CQC)

The CQC is a national organisation to check if care services meet government standards. Clinical audit can support the assurance process relating to registration standards and indicators such as Regulation 9 (Person Centred Care).

5.8 National Clinical Audit and Patient Outcomes Programme (NCAPOP)

NCAPOP specifies the key national audits that NHS Trusts should be participating in.

5.9 Healthcare Quality Improvement Partnership (HQIP)

HQIP was established in April 2008 to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. It is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices (formerly the Long-term Conditions Alliance).

6.0 Duties within the Organisation

All staff have a responsibility for ensuring that the principles outlined within this document are universally applied. Specific organisational duties are identified as follows:

6.1 Chief Executive

The Chief Executive is accountable for the implementation of this policy and ensuring that adequate resources are available.

6.2 Medical Director

The Medical Director is the Executive Lead for Clinical Audit and is responsible for providing leadership for the delivery of the clinical audit programme. Where appropriate the Medical Director informs the Trust Board of clinical audit activities that provide assurance on clinical effectiveness and for the mitigation of risks recorded on the Board Assurance Framework (BAF).

6.3 Deputy Chief Nurse

The Deputy Chief Nurse is responsible for coordinating the Trust's corporate and clinical governance assurance agenda. This includes developing and implementing strategies, policies and systems and performance measurements to deliver the requirements of independent regulators such as the Care Quality Commission and NHS Improvement.

6.4 Governance Leads

Each of the Services has a Governance Lead who is responsible for facilitating the delivery of service level clinical audit programmes, with clinical leadership from the Clinical Directors.

This includes:

- Ensuring that the results of clinical audit activity inform and influence clinical practice and staff training needs within the Services.
- Ensuring each Services Clinical Audit Group (a sub group of the Clinical Governance Groups) (where convened) has effective representation from all Service areas.
- Identifying priority level one and two audits (see section 8.1 for priority levels) to be approved by subgroups of the Quality Committee (QC) e.g. outcomes of CQC visits.
- Assisting in the identification of service leads for relevant priority level one and two clinical audits.
- Working with the Clinical Audit Officers to ensure priority level three and four clinical audits are logged on the Trust's clinical audit database.
- Identifying priority level three clinical audits (see section 8.1 for definition of priority levels).
- Ensuring there is a system in place for the dissemination of results.
- Ensuring the monitoring of clinical audit actions.
- Working with the Clinical Audit Officers to ensure that all appropriate actions arising from clinical audit projects are recorded on the Trust clinical audit database.
- Ensuring that actions are followed up and the clinical audit loop closed in terms of changes implemented and embedded.

6.5 Trust Clinical Quality and Effectiveness Lead

The Trust Clinical Quality and Effectiveness Lead (CQEL) has the responsibility to strategically manage the clinical audit forward plan and maintain an overview of the Trust's Clinical Audit Policy and related structures and processes.

In conjunction with the Clinical Effectiveness Group (CEG), Clinical Directors, Clinical Governance Leads and the Deputy Chief Nurse, the CQEL is responsible for ensuring that the clinical audit forward plan is relevant, supports service delivery and includes clinical audits specified within national, regional and local guidelines and performance targets.

6.6 Quality and Data Analyst

The QDA maintains a Trust wide clinical audit database which includes a log of proposal forms, completed reports and outcomes for all clinical audit activity.

Working with the Clinical Audit Officers, the QDA will ensure that regular reports on clinical audit activity are provided to the CEG, other subgroups of the QC and the Services Clinical Audit Groups (or equivalent). These reports include progress against the annual forward plan and reports on the implementation of actions arising from clinical audit.

The QDA ensures the appropriate planning, delivery and communication for projects which cross services/ pathways, and retains an overview of all clinical audits in each of the services and promotes consistency and assures quality through the use of the clinical audit quality control pro forma.

The role of the QDA also involves identifying and prioritising topics for inclusion in the annual forward plan of priority clinical audits.

6.7 Clinical Audit Officer

A Clinical Audit Officer is aligned to each of the Services. They support Clinical Audit Leads to facilitate the delivery of clinical audit reports for identified priority level one, two and three clinical audits (see section 9.1 re: priority levels).

Their duties include:

- Ensuring that all clinical audits compare practice to agreed standards of best practice.
- Reviewing proposal forms and reports for all level clinical audits.
- Ensuring that all level clinical audit reports are reviewed by two members of the CANQI team before being submitted to the relevant meetings.
- Advising on the development of and reviewing action plans to ensure they are effective.
- Working with the Patient and Carer Experience team to promote patient, carer and Member involvement in clinical audit.
- Encouraging Clinical Audit Leads to engage in multidisciplinary and interface clinical audits where appropriate.
- Providing Clinical Audit Leads for priority clinical audits with practical support (see section 9.1 for definition of priority audits).
- Supporting the QDA to maintain the Trust clinical audit database and forward plan.

6.8 Clinical Audit Assistant

Clinical Audit Assistants support the Clinical Audit Officers to facilitate the delivery for priority level one, two and three audits.

6.9 Clinical Audit Leads

Clinical Audit Leads are responsible for:

- Writing the clinical audit proposal form in consultation with key stakeholders, including service users where appropriate.
- Acquiring approval from the identified Trust-wide or Service level group.
- Carrying out the clinical audit in line with this policy.
- Completing the clinical audit within agreed timescales.
- Writing the clinical audit report.
- Devising action plans in conjunction with the key stakeholders to address areas of non-compliance and advising regarding re-audit
- Ensuring final reports are sent to the Clinical Audit Officer for logging on the Trust Clinical Audit database.
- Presenting results at the identified Trust-wide and/ or Service Groups (e.g. CEG or the related QC subgroup, Service Clinical Audit Groups/ CHS Clinical Networks).
- Liaising with the CANQI team at the start of projects and providing regular updates on progress

6.10 Managers

- To support staff in undertaking clinical audits and support leads in developing and implementing action plans.
- Ensure all clinical audit activity within their directorate is registered.

6.11 Members of the Service Clinical Audit Groups/ CHS Clinical Networks

Disseminate the results of clinical audits to front line staff. Key results and areas requiring action should be highlighted.

6.12 All LPT Clinical Staff

All staff will participate in clinical audit either through leading, collecting data and/ or implementing actions resulting from the findings of clinical audit. Professional staff are individually accountable for ensuring they audit their own practice as defined by their respective professional codes of conduct.

6.13 Trust Board

The Trust Board has a role in driving quality through checks on compliance to care delivery standards. The Trust Board has the responsibility to use clinical audit activities as an

assurance tool including for the mitigation of risks related to clinical effectiveness recorded on the Board Assurance Framework (BAF).

6.14 Quality Committee

The QC is authorised by the Trust Board to monitor the Trust's quality strategies and to provide the Trust Board with assurance on quality Key Performance Indicators (KPIs) and deliverables which includes quality improvement and effectiveness.

6.15 Clinical Effectiveness Group (CEG) and other subgroups of the QC

The subgroups of the QC promote effective clinical audit using evidence based criteria. They also assess the quality of new clinical audit proposals for level one and two audits, and ensure that they are conducted within an ethical framework.

The CEG is a sub group of the QC and is chaired by the Medical Director. The CEG has responsibility for developing a strategy for clinical audit and effectiveness, which includes setting priorities, participation in national, regional and local clinical audit and establishing a clinical audit forward plan (a system for recording clinical audit activity) for priority clinical audits (level one and two). The CEG maintains an overview of all priority clinical audits. The CEG receives level one and two reports that are not considered by the other subgroups of the QC (i.e. Safeguarding Committee, Infection Prevention & Control Committee, Health & Safety Committee, Patient Safety Improvement Group and the Patient & Carer Experience Group).

Some clinical audits will be considered by specialist groups that report to the sub-groups of the QC. For example:

- Electroconvulsive Therapy (ECT) Steering Group
- Medicines Risk Reduction Group

For more information contact the CANQI team on: LPTClinicalAudit@leicspart.nhs.uk

6.16 Service Clinical Audit Groups

- Promote effective clinical audit based on evidence-based criteria.
- Encourage multidisciplinary clinical audit and interface clinical audits with partner organisations where appropriate.
- Promote patient and carer involvement in clinical audit.
- Assess the quality of new clinical audit proposals for level three and four clinical audits and their value in delivering improvements to patient care.
- Ensure that clinical audits are conducted within an ethical framework and in line with this policy.
- Receive clinical audit reports and agree a re-audit date or other appropriate quality improvement work.
- Review, approve and monitor the implementation of action plans.
- Provide the CANQI team with updates on the status of actions monitored by the group, providing evidence of implementation where possible.
- Promote re-audit where there is a need to improve care and agree a rationale

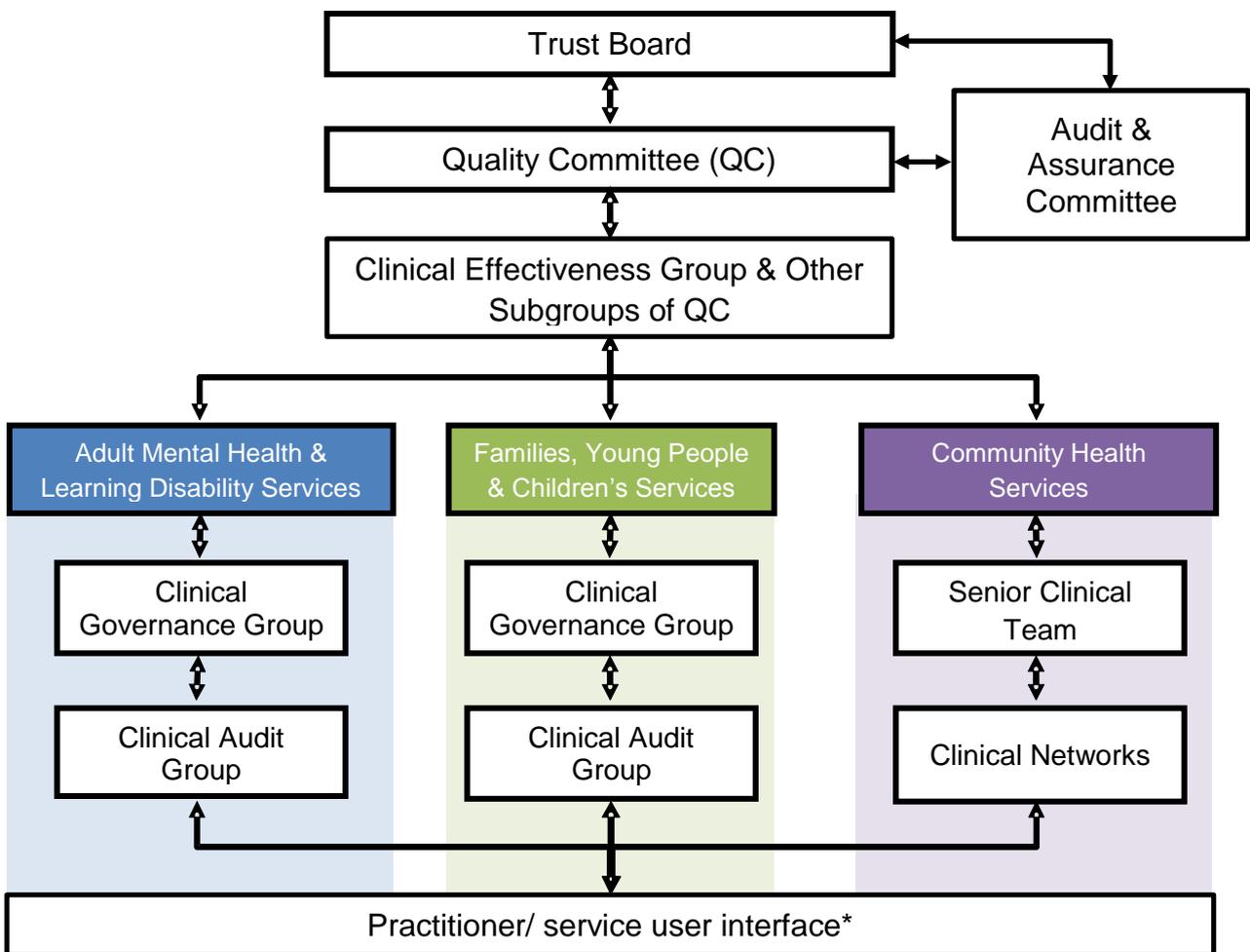
where re-audit is not required (to be recorded in the minutes and the Trust clinical audit database).

- Review progress against the annual clinical audit forward plan.
- Promote the clinical audit web link on the Trust intranet (see section 12).
- Promote associated training and support (see section 17).

6.17 Learning and Development Team

The Learning and Development Team is required to respond to additional training needs as identified by clinical audits.

7.0 Organisation for Clinical Audit



*The results of clinical audit are disseminated to frontline staff by Service Clinical Audit Group/ CHS Clinical Network representatives

8.0 Commitment to stakeholder engagement, collaboration and partnership

8.1 Patient and Public Involvement

The Healthcare Quality Improvement Partnership (HQIP) have identified patients and carers as being key stakeholders in the clinical audit process and recommends that “if appropriate and feasible, patients, patient representatives and relevant patient organisations, should be involved at all stages of the audit cycle as equal members of the audit team.”

The Trust promotes the involvement of Members and 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.

8.2 Multidisciplinary clinical audit and partnership working with other organisations

The Trust encourages clinical audit that is undertaken jointly across professions and across organisational boundaries where improvements to the patient journey may be identified through shared clinical audit activity.

8.3 Working with Commissioners

LPT is committed to collaborative working with its Commissioners. The Trust clinical audit forward plan will include clinical audit activity that reports against the clinical quality performance indicators specified within the Quality Schedule and those related to the Commissioning for Quality and Innovation (CQUIN) scheme.

9.0 Process for setting priorities for a clinical audit programme

9.1 Clinical Audit Forward Plan of Priority Clinical Audits

At the start of the financial year the CEG approve an annual clinical audit forward plan of priority clinical audit activity for the Trust. This takes account of national, regional and local requirements. The National Healthcare Quality Improvement Partnership ‘Developing a Clinical Audit Programme’ guidance (HQIP, 2016) is used to prioritise clinical audits.

The guidance consists of four levels:

- Priority level one – External ‘must do’ clinical audits
- Priority level two – Internal ‘must do’ clinical audits
- Priority level three – Service priorities
- Priority level four – Clinician interest

The Medical Director will provide clarity regarding the priority levels of clinical audits when required.

9.1.1 Priority level one – External ‘must do’ clinical audits

Failure to participate in or deliver on these externally driven clinical audits may carry a penalty for the Trust (either financial or in the form of a failed target or non-compliance – hence “must-do” priority). These are externally monitored and assessed by the CQC and Commissioners.

Priority level one clinical audits include:

- Commissioner priorities including CQUINS and Quality Schedule
- Clinical audits required as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP)
- Projects required for external accreditation schemes e.g. ECTAS, AIMS

9.1.2 Priority level two – Internal ‘must do’ clinical audits

These clinical audits are based on high risk, high cost or high profile topics. They may include national initiatives with Trust-wide relevance but no penalties exist for non-participation. Many of these projects will emanate from Trust governance issues or high profile local initiatives.

Priority level two clinical audits include:

- Issues raised from the Patient Safety Improvement Group and other sub-groups of the QC to meet Trust strategic and clinical priorities and objectives.
- Priorities identified by patient and public involvement initiatives
- Issues raised from Serious Incident investigation/ adverse incidents/ complaints.
- National Institute for Health and Care Excellence (NICE) guidance.
- National Confidential Enquiries (NCEs) – NCEPOD, CEMACH, and NCISH – clinical audits which derive from these.

9.1.3 Priority level three – Service Level priorities

Priority level three clinical audits are identified at a service level; they may include DH initiatives such as Essence of Care and national audits that are not part of NCAPOP where no penalties exist for non-participation. Alternatively the clinical audits may be a response to persistent/ local concerns or a trend analysis of complaints and adverse incidents.

9.1.4 Priority level four – clinician interest

These clinical audits are generated from innovative ideas by individual clinicians or professional group and do not fit into any of the above priority levels. Some of these clinical audits may be identified at the start of the year though most are likely to emerge as the year progresses and so will be added to the clinical audit programme on a rolling basis.

Undertaking these audits can provide valuable educational experience for staff. As a teaching Trust LPT has an obligation to support students and trainees to undertake clinical audit projects that are linked to educational competencies. Wherever possible, clinical audits should link with Trust priorities and Service Level Clinical Audit Groups/ CHS Senior Clinical Team should consider the following:

- If the problem is amenable to change.

- If the issue poses a risk to patient experience and safety.
- The requirement to prioritise re-audits.
- If the issue is of high cost to the trust, high volume or high risk to staff or to patients/ service users.
- There is evidence of a quality problem.

9.2 Clinical Audit Programme

The QDA will produce an annual clinical audit forward plan for clinical audits approved by the CEG or relevant subgroup of the QC, or the Service Clinical Audit Groups/ CHS Senior Clinical Team. Progress against the plan and any areas of concern are reported to the CEG (or other relevant subgroup of the QC) and Service Clinical Audit Groups/ CHS Senior Clinical Team.

10.0 Process for ensuring the quality of clinical audits

It is expected that, unless indicated otherwise, Clinical Audit Leads will follow the process below to receive approval for all their clinical audits. Clinical audits not following these procedures will not have complied with formal governance requirements and therefore will be in breach of the Data Protection Act if they access patient information.

The key steps to receiving approval to start a clinical audit and to have the final report approved by the Trust are summarised in the flowchart shown in Section 4, and are explored further here.

10.1 Complete a clinical audit proposal form

A clinical audit proposal form (available on the clinical audit intranet page) must be completed before commencing any clinical audit project (the only exception are national audits). This document requests key information about why, where and how a clinical audit is to be carried out. This document is used to assess whether the topic is a priority, indicate the quality of the methodology and identify the potential of the project to improve quality of care.

10.2 Submit for assessment

Once completed, the form must be emailed to the CANQI team at, LPTClinicalAudit@leicspart.nhs.uk, who will then assess the quality of methodology and appropriateness of the data to be collected using the clinical audit assessment form. Based on the review, the CANQI team may provide feedback to the Clinical Audit Lead on ways the proposal could be improved. The CANQI team will also provide a view on the priority level of the clinical audit (see section 9, for details of the priority levels).

Clinical audits must be registered with the CANQI team to count towards revalidation.

The CANQI team will refer the proposal form to the most appropriate Trust group for a decision regarding approval.

The following factors will be taken into consideration when deciding which Trust group to send the proposal for approval; the priority level of the clinical audit, the topic under consideration², representation on the group³, and whether the clinical audit is focused around a specific service⁴.

Advice will be sought from the Medical Director regarding cases where either the priority level or appropriate Trust group is unclear.

10.4 Write a report and action plan

All clinical audits, with the exception of those derived from CQUINs⁵ and National Audits (e.g. NCAPOP)⁶, are to be written up using the clinical audit report template (available on the clinical audit intranet page). This template provides a standardised structure to reports, making it easier to write and for staff across the Trust to pick out the relevant information.

All clinical audit reports must contain an action plan⁷. The responsibility for producing the report, including action plan, rests with the Clinical Audit Lead, however the action plan must be developed in collaboration with key service leads.

The action plan must address areas that require improvement within the clinical audit.

The Clinical Audit Lead should ensure that the findings from the clinical audit are discussed at the relevant team meetings (as part of action planning)

The results of clinical audits should be disseminated by the Clinical Audit Lead to all key stakeholders identified in the clinical audit proposal.

The actions must be recorded on the action plan template within the clinical audit report.

10.5 Submit for assessment

Once completed, the report must be emailed to the CANQI team at, LPTClinicalAudit@leicspart.nhs.uk. The overseeing Clinical Audit Officer will review the report for quality, using the clinical audit report assessment form. Based on the review, the Clinical Audit Officer may provide feedback to the Clinical Audit Lead on ways the report and action plan could be improved.

The CANQI team will refer the report to the relevant Trust group for a decision regarding approval.

² To provide the most appropriate expertise in the subject, e.g. safeguarding clinical audits to the Safeguarding Committee, medicines clinical audits to the LPT Prescribing Group (a sub-group of CEG), infection control topics to the IP&C subgroup.

³ To ensure that all stakeholders, especially service and clinical representation, have the opportunity to comment on the proposal.

⁴ It may be appropriate to authorise a priority level one and two clinical audit proposal at a Service level clinical audit group if its scope is contained to one Service.

⁵ CQUIN audit reports for Q1-4 can be provided in the standard CQUIN report format. A final annual report should be produced using the clinical audit report template which summarises the findings for the year.

⁶ LPT has no influence over the production of reports from nationally coordinated clinical audits.

⁷ Unless 100% compliance has been achieved and no changes are indicated.

10.6 Approving the report

The relevant Trust group will decide whether to approve the report and associated action plan and will also agree a re-audit date (or other appropriate quality improvement work).

The group can also request changes to the report or action plan, for example:

- A breakdown of compliance by Service,
- Recommend changes to the content which will make it easier to identify how the findings relate to the services involved,
- To clarify the findings when presented as evidence for the Commissioners or other regulatory body,
- To add or remove actions.

By giving approval the relevant Trust group is authorising the actions identified in the action plan to be carried out, and for the allocation of resources identified to carry out the actions.

The group should escalate the report in cases where an action is valid but the resources to carry it out are beyond the capacity of the service to deliver. Where the action is identified as a risk it should be logged by the appropriate individual onto the Trust risk register.

The appropriate group will ensure that all agreed actions have been implemented. Any problems in doing this will be escalated to the relevant group.

10.7 Discontinued clinical audits

The discontinuation of any clinical audit will be in consultation with the relevant sub-group of the QC or Service Level group. The rationale for discontinuation will be reported to the relevant group for noting.

11.0 Standard Templates

Only Trust approved standard templates should be used during clinical audit activity. The approved forms are listed below and can be accessed electronically through the clinical audit page on the Trust intranet

<http://www.leicspart.nhs.uk/SupportServices-ClinicalAudit.aspx>

11.1 Proposal form

- Clinical Audit Proposal Form
- Guidance notes on completing the audit proposal form

11.2 Report Template

- Report Writing Template which includes a summary pro forma and action plan template
- Guidance notes on completing the report template.

Clinical audit proposals and reports will not be accepted if standard templates are not used.

12.0 Process for disseminating clinical audit results and actions

It is important that the findings from clinical audit are shared among all relevant staff to ensure actions are taken to improve care. As a minimum requirement each clinical audit should be written up into a report with an action plan.

12.1 Clinical Audit Lead

The Clinical Audit Lead should ensure that the findings from the clinical audit are disseminated to all key stakeholders. This includes the staff and services who took part in the clinical audit, related or similar teams in other services, and patients/ carers where appropriate.

The report should be disseminated using appropriate media including by publication through the Trust intranet, newsletters and posters. Presentations can be given locally within care settings where relevant findings should be discussed or displayed via posters and action plans highlighted.

The Clinical Audit Lead should be willing to present their findings at any clinical audit feedback events.

12.2 Subgroups of the QC and Service Level Clinical Audit Groups/ CHS Clinical Networks

Members of the receiving groups are expected to disseminate the findings of clinical audits relevant to their services and teams via discussion at service level and team meetings, or sharing the clinical audit report by any other appropriate route.

Clinical audit reports cannot be disseminated externally until permission has been granted by the CANQI team and the Service Governance process.

12.3 Trust Intranet

All approved clinical audit reports will be uploaded to the LPT intranet by the CANQI team.

All LPT staff have access to the intranet and can access the reports through the document library search or via the clinical audit page.

12.4 Clinical Audit Annual Report

At the end of each financial year a Clinical Audit Annual Report is produced. This includes a summary of clinical audit activity and key examples of audits that have been carried out that have shown improvements in clinical practice and the patient experience. The annual report will be published on the LPT website.

12.5 Trust Quality Account

The LPT Quality Account provides an overview of national and local clinical audits undertaken and evidence of specific outcomes as a result of the clinical audit programme.

12.6 Sharing of Results Events

There will be a Trust wide event to present findings and share learning from clinical audits.

13.0 Process for making improvements

13.1 Action Plans

The CANQI team log all actions from completed clinical audit projects on the clinical audit database. The database contains the identified actions, responsible clinicians for overseeing improvements, and timescales for making improvements and which groups are assigned to monitor improvement.

The CANQI team will provide regular reports to the Trust groups with responsibility for monitoring the implementation of actions. In turn, these groups will update the CANQI team with the status of each action and provide evidence of implementation (where possible).

13.2 Non-compliance

Where findings fall significantly below expected standards and there are implications to patient safety or the reputation of the Trust, then the relevant Trust group should decide on what actions or controls should be put in place to manage the risk.

If actions and controls are unable to be implemented then these should be recorded on the service/ corporate risk register and reported to the appropriate subgroup of the QC by exception.

14.0 Process for monitoring effectiveness of action plans

14.1 Re-audit

The CANQI team will schedule re-audits following consultation with the relevant subgroups of the QC or Service Clinical Audit Groups/ CHS Clinical Networks, either at the point of approving the clinical audit report or when actions are signed off as complete. Where appropriate, a re-audit should allow at least six months after the completion of the last action to be embedded.

14.2 Other quality improvement methods

The relevant Trust group may agree other quality improvement work would be appropriate, as an alternative to re-audit. These alternatives may include run charts or PDSA (Plan, Do,

Study Act). In such circumstances this will be recorded in the clinical audit report and undertaken as per the Trust guidance on conducting such projects.

15.0 Process for Monitoring Compliance with this Policy

15.1 Compliance with policy

Compliance with this policy will be monitored by the CEG. The QDA will produce a report yearly which will monitor performance against this policy using the Clinical Audit Quality Control Pro forma.

15.2 Policy Review

This Policy will be reviewed after two years by the Quality & Effectiveness – Trust Lead.

16.0 Ethics and Consent

16.1 Ethical Framework

In general clinical audit projects do not require Research Ethics Committee approval. However clinical audit projects should maintain patients' rights, dignity, privacy and confidentiality. Further guidance can be found in the booklets "HQIP Guide to managing ethical issues in QI or CA projects" (HQIP 2017) and "HQIP Information Governance in local quality improvement" (HQIP 2017).

The chair of the relevant subgroup of the QC and the Service Clinical Audit Groups/ CHS Senior Clinical Team will be responsible for ensuring that any proposed clinical audit projects are conducted within an ethical framework. If ethical concerns are identified which are not judged to be adequately addressed in the proposal, advice should be sought from the Operational Lead (Research and Development).

Any areas of concern identified during data collection e.g. poor patient care or missing equipment must be reported to the relevant managers immediately.

16.2 Data Protection

Clinical audit involves accessing and recording sensitive patient information. All clinical audit activity must take account of the Data Protection Act (2018) and the Caldicott Principles (1997). Please refer to the HQIP Information Governance in local quality improvement guide (HQIP, 2017). This means that the data collected should be adequate, relevant and not excessive, accurate, processed for limited purposes, held securely and not kept for longer than is necessary.

Person identifiable information is defined as any item that may lead to the disclosure of someone's identity. This includes name, address, postcode, date of birth or other dates, sex, GP Practice, NHS Number, Ethnic Group or Occupation.

Before conducting any clinical audit that is likely to involve patient identifiable data, Clinical Audit Leads must be aware of and comply with the following principles, as set out in the Data Protection Act 2018:

- All data is to be obtained and processed fairly and lawfully.
- Personal data shall be obtained only for one or more specified and lawful purposes and shall not be further processed in any matter incompatible with that purpose or purposes.
- Personal data shall be adequate, relevant and not excessive in relation to the purpose/s for which they are processed.
- Personal data, e.g. name and address, shall be accurate, relevant and not excessive.
- Personal data should not be kept for longer than necessary.
- Personal data shall be processed in accordance with the rights of data subjects under this act.
- Data must be kept secure.
- Personal data should not be transferred to a country or territory outside the EU economic area without adequate protection.
- Names, addresses and NHS numbers should not be recorded or collected on clinical audit forms, unless under exceptional circumstances.

16.3 Confidentiality

Clinical audit activity must conform to the requirements of the NHS Confidentiality Code of Practice (2003) which states that “Patients must be made aware that the information they give may be recorded, may be shared in order to provide them with care, and may be used to support local clinical audit”. This is done via a patient information leaflet “Your Healthcare, Your Records, Your Number”.

Section 60 of the Health and Social Care Act 2001 makes provision for the collection of patient identifiable data for the purposes of clinical audit. However, all data collected for clinical audit purposes will be anonymised. No patient or professional identifiable data will be reported for any clinical audit at any time. Clinical audit data (paper forms, electronic/ scanned) should be retained for a period of five years after completion of the clinical audit project after which time it should be destroyed.

16.4 Obtaining Patient Health Records

Clinical staff may access records from within their own caseloads without obtaining special permission in order to carry out a clinical audit.

Non-clinicians and clinicians wishing to access records outside their caseloads should first seek permission/ approval from the relevant consultant and Caldicott Guardian at the initial stage of the clinical audit. The process for seeking Caldicott approval is shown in the Caldicott Approval Process Flowchart (see Appendix 3, p.31). An application is made using the Caldicott Approvals Request Form (see Appendix 4, p.32).

When using electronic systems such as SystemOne/ RiO to access patient records, it is advisable to record activity in the record as ‘general clinical audit’.

17.0. Training needs

There is no training requirement identified within this policy

17.1 Introductory level

An introduction to clinical audit which is suitable for all LPT staff is available on the clinical audit web page of the Trust intranet.

17.2 Support from the CANQI team

Clinical Audit Leads and staff engaging in clinical audit can access training/ support through the CANQI team (LPTClinicalAudit@leicspart.nhs.uk).

This includes:

- Access to online surveys e.g. Survey Monkey
- Provision of Excel workbooks with preliminary breakdown of results.

17.3 Accredited training courses

Clinical Audit Leads can access the following training programmes designed to support the delivery of specific clinical audits:

Clinical Audit Skills – this programme is run in partnership with the National Clinical Audit Support Centre and includes clinical audit design support.

Clinical Audit for Quality Improvement – this programme is delivered by the CANQI team to provide the knowledge and skills required to plan and carry out clinical audits as part of a quality improvement process

For more information contact LPTClinicalAudit@leicspart.nhs.uk.

17.4 uLearn

All clinical audit training opportunities will be listed in the WelImprove section of the Trust uLearn system

17.5 Junior Doctors

Quality improvement including clinical audit is an essential part of training for junior doctors. The CANQI team will liaise with junior doctors at the beginning of their placement to inform them of the support and to enable them to expedite the quality improvement process.

18.0 Associated Documentation

This document should be read in conjunction with the following documents which give guidance on related activities

- Trust Procedure for the Implementation of NICE Guidance and other nationally agreed best practice (October 2018)
- Clinical Audit Strategy (2018)

19.0. Monitoring Compliance and Effectiveness

Ref	Minimum Requirements	Evidence for Self-assessment	Process for Monitoring	Responsible Individual / Group	Frequency of monitoring
16	The organisation sets priorities for clinical audit including local and national requirements	See section 9	Annual Clinical Audit forward plan of priority clinical audit activity	CEG	Annual
18	Clinical audits are conducted in line with the approved process for clinical audit	See section 10	Audit of Audits monitoring report	Quality & Data Analyst CEG	Annual
21	how clinical audit reports are shared	See section 12	Audit of Audits monitoring report	Quality & Data Analyst CEG	Annual
20	Format for all clinical audit reports	Approved templates including a report writing template (section 11)	Audit of Audits monitoring report	Quality & Data Analyst CEG	Annual
19 21 22	How the organisation makes improvements	See section 13, and also 12 and 10	Audit of Audits monitoring report	Quality & Data Analyst CEG	Annual
22	The organisation monitors action plans and carries out re-audits	See sections 13 and 14	Audit of Audits monitoring report	Quality & Data Analyst CEG	Annual

20.0. References and Bibliography

Listed below are some useful sources of reference material:

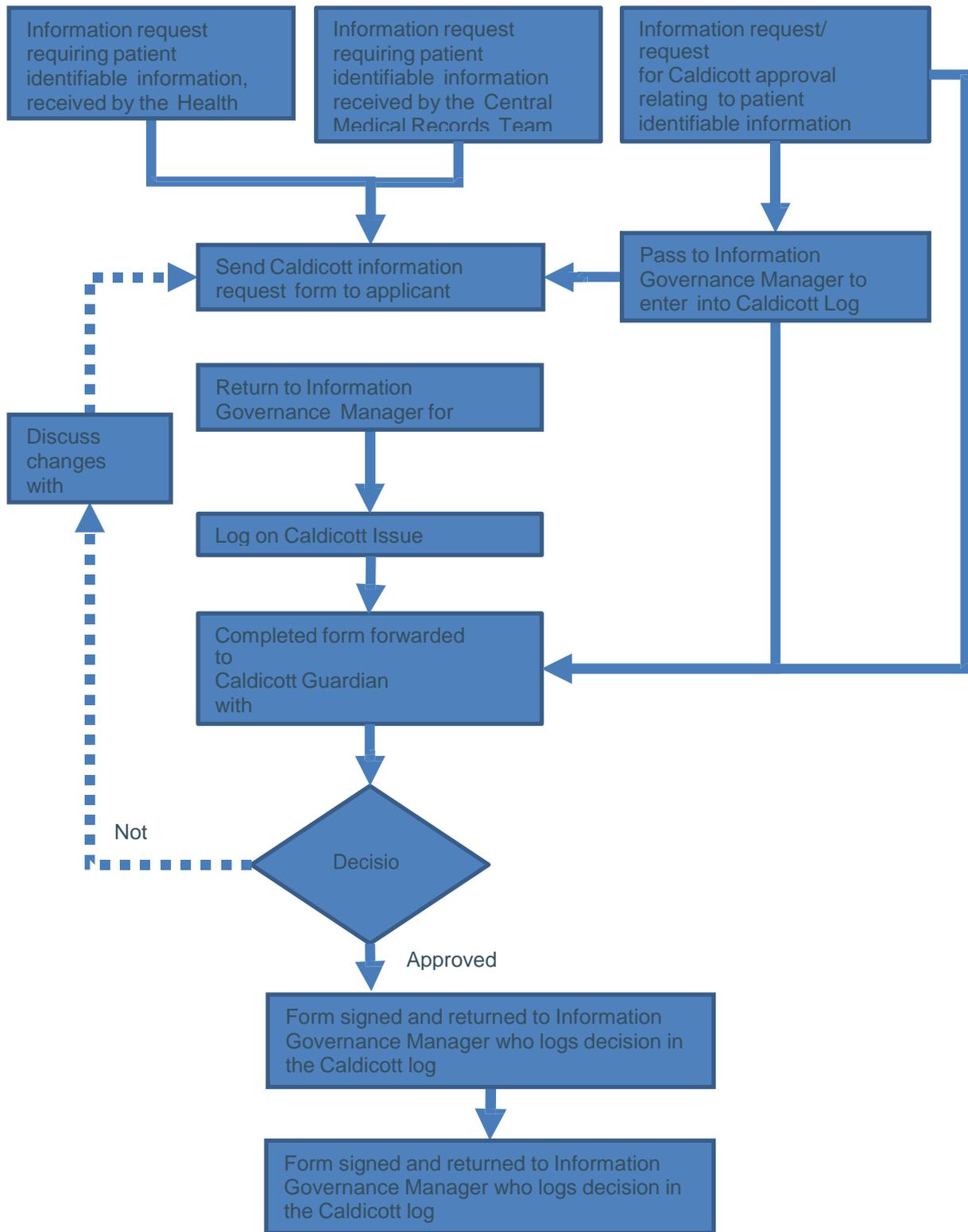
- Bristol Royal Infirmary Inquiry. (2002). *Learning from Bristol. The report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995*. London: The Stationery Office. Available at: https://webarchive.nationalarchives.gov.uk/20090811143822/http://www.bristol-inquiry.org.uk/final_report/the_report.pdf
- Darzi, Professor the Lord. (2008). *High Quality Care For All: NHS Next Stage Review Final Report*. London: Department of Health. Available at: www.gov.uk
- Department of Health. (2003). *NHS Confidentiality Code of Practice*. London: Department of Health. Available at: www.gov.uk
- Department of Health. (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. Available at: www.gov.uk
- NHS Digital. (2016). *Records Management Code of Practice for Health and Social Care*. Available at: digital.nhs.uk
- Healthcare Quality Improvement Partnership. *Criteria and indicators of best practice in clinical audit*, September 2009
- HQIP. Information Governance in local quality improvement. 2017.
- HQIP *New Principles for Best Practice in Clinical Audit*. 2011 (2nd Ed) London: Radcliffe Publishing.
- NHS Clinical Governance Support Team. (2005). *A Practical Handbook for Clinical Audit*. NHS Clinical Governance Team. Available at: <https://webarchive.nationalarchives.gov.uk>
- Parliament. Working for patients. Cm 555. London: HMSO, 1989.
- Scally G and Donaldson LJ (1998) Clinical governance and the drive for quality improvement in the new NHS in England. *British Medical Journal* 317(7150) 4th July 1998 pp61-65
- The Healthcare Quality Improvement Partnership (HQIP). (2009). *Ethics and Clinical Audit and Quality Improvement (QI) - A Guide for NHS Organisations*. Available: www.hqip.org.uk. Last accessed 22.02.2019

The NHS Constitution

The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services

Shape its services around the needs and preferences of individual patients, their families and their carers	✓
Respond to different needs of different sectors of the population	✓
Work continuously to improve quality services and to minimise errors	✓
Support and value its staff	✓
Work together with others to ensure a seamless service for patients	✓
Help keep people healthy and work to reduce health inequalities	✓
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	✓

Appendix 3 Caldicott Approval Process Flowchart



<p>Who else will have access to the data? (If data recipients are not employed by the NHS please state whether NHS honorary contracts are in place. If not – detail confidentiality agreements)</p>
<p>How will the service users be contacted?</p>
<p>How will service users consent be obtained?</p> <p>If no consent being obtained, please detail the reason why not e.g. exemption under section 60 of the Health and Social Care Act 2001</p>
<p>Where will the data be stored?</p> <p>How will the data be protected? (Please detail security measures to be taken)</p>
<p>If the data is on a computer is there access via a network?</p>
<p>How long will the data be stored?</p>
<p>At the end of this period, how will the data be disposed of?</p>

Who will be responsible for ensuring that the data is disposed of in a confidential manner?

You must address the 6 Caldicott Principles – please give a brief description under each of the following headings

Principle 1 – Justify the purpose(s)

Every proposed use or transfer of service user identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed, by an appropriate guardian.

Principle 2 – Don't use service user-identifiable information unless it is absolutely necessary

Service user-identifiable information items should not be included unless it is essential for the specified purpose(s) of that flow. The need for service users to be identified should be considered at each stage of satisfying the purpose(s).

Principle 3 – Use the minimum necessary service user-identifiable information

Where use of service user-identifiable information is considered to be essential, the inclusion of each individual item of information should be considered and justified so that the minimum amount of identifiable information is transferred or accessible as is necessary for a given function to be carried out.

Principle 4 – Access to service user-identifiable information should be on a strictly need-to-know basis

Only those individuals who need access to service user-identifiable information should have access to it, and they should have access to the information items that they need to see. This may mean introducing access controls or splitting information flows where one information flow is used for several purposes.

<p>Principle 5 – Everyone with access to service user-identifiable information should be aware of their responsibilities</p> <p>Action should be taken to ensure that those handling service user-identifiable information – both clinical and non-clinical staff – are made aware of their responsibilities and obligations to respect service user confidentiality</p>
<p>Principle 6 – Understand and comply with the law</p> <p>Every use of service user-identifiable information must be lawful. Someone in each organisation handling service user information should be responsible for ensuring that the organisation complies with legal requirements.</p>
<p>Other supporting information e.g. Ethics approval, correspondence etc.</p>

I confirm that the data will be held and used according to the condition and information given as described within this approval form.

Name.....

Title.....

...

Signature.....

Date.....

Please return to:
 Sam Kirkland, Records Transformation & Information Governance Manager
 Leicestershire Partnership NHS Trust
 Riverside House
 Bridge Park Plaza
 Bridge Park Road
 Thurmaston
 Leicester
 LE4 8PQ

For Office Use Only

The release and use of data as described above: **Approved / Not Approved**

Caldicott Guardian/Deputy.....

Date:.....

Appendix 5

Due Regard Screening Template

Section 1			
Name of activity/proposal		Clinical Audit Policy	
Date Screening commenced		19.07.2019	
Directorate / Service carrying out the assessment		Clinical Audit & NICE: A Quality Improvement team	
Name and role of person undertaking this Due Regard (Equality Analysis)		Carl Lomas, Quality and Data Analyst	
Give an overview of the aims, objectives and purpose of the proposal:			
AIMS: To update the clinical audit policy to better reflect best practice and the procedures used at LPT			
OBJECTIVES: A clinical audit policy that accurately reflects best practice and the procedures used at LPT			
Section 2			
Protected Characteristic	If the proposal/s have a positive or negative impact please give brief details		
Age	None		
Disability	None		
Gender reassignment	None		
Marriage & Civil Partnership	None		
Pregnancy & Maternity	None		
Race	None		
Religion and Belief	None		
Sex	None		
Sexual Orientation	None		
Other equality groups?	None		
Section 3			
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please <u>tick</u> appropriate box below.			
Yes		No	
High risk: Complete a full EIA starting click here to proceed to Part B		Low risk: Go to Section 4.	✓
Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
This policy covers the internal processes governing clinical audit, not the aspects of clinical audit that could affect protected characteristics, for example choice of audit topic			
Signed by reviewer/assessor	Carl Lomas	Date	19.07.2019
<i>Sign off that this proposal is low risk and does not require a full Equality Analysis</i>			
Head of Service Signed	Andrew Moonesinghe	Date	19.07.2019

Appendix 6

DATA PRIVACY IMPACT ASSESSMENT SCREENING

<p>Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy.</p> <p>The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.</p>		
Name of Document:	Clinical Audit Policy	
Completed by:	Carl Lomas	
Job title	Quality and Data Analyst	Date: 19.07.2019
Screening Questions	Yes / No	Explanatory Note
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	
<p>If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk</p> <p>In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.</p>		
Data Privacy approval name:		
Date of approval		

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust