

Document Details		
Title		Clinical Audit Policy
Trust Ref No		1538-73024
Main points this document covers		This policy details the responsibilities and processes associated with clinical audit activity within the Trust
Who is the document aimed at?		All staff who take part in clinical audit or who are responsible for staff who do so
Authors		Michelle Bramble, Quality Facilitator
Approval Process		
Approved by		Quality & Safety Delivery Group
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Other		HQUIP
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No	Date	Amendment
1	22/03/2018	Changes to: responsibilities forward audit plan process and audit actions reporting.
2	1/2/2022	Some changes to roles, responsibilities, job titles, group or meeting names and processes

1 National context

1.1 Statutory and mandatory requirements for clinical audit

When carried out in accordance with best practice standards, clinical audit:

- Improves the quality of care and patient outcomes
- Provides assurance of compliance with clinical standards
- Identifies and minimises risk, waste and inefficiencies

Participation in both national and local clinical audit is a statutory and contractual requirement for healthcare providers. The NHS Standard Contract forms the agreement between commissioners and providers of NHS-funded services, who must:

- Participate in national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to their services.
- Implement and/or respond to all relevant recommendations of any relevant clinical audit.
- Implement an ongoing, proportionate programme of clinical audit of their services in accordance with good practice
- Provide to the coordinating commissioner, upon request, the findings of any audits carried out, in particularly locally-agreed requirements such as Commissioning for Quality and Innovation (CQUIN) audits.

In addition, the regulatory framework of the Care Quality Commission (CQC) requires registered healthcare providers to monitor the quality of their services. The CQC Fundamental Standards describe the care patients should expect and provide prompts for providers to consider when aiming to meet requirements for governance and audit, set out in Regulation 17: Good governance, of the Health and Social Care Act 2008 , whereby:

“To meet this regulation, providers must have effective governance, including assurance and auditing systems or processes. These must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service. The systems and processes must also assess, monitor and mitigate any risks relating to the health, safety and welfare of people using services and others. Providers must continually evaluate and seek to improve their governance and auditing practice.”

Providers must use the findings from clinical audits and other quality improvement initiatives, including those undertaken at a national level – such as national confidential enquiries and inquiries and national service reviews – to ensure that action is taken to protect people who use services. They must also ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of their relevant professional bodies (for example, for revalidation and professional development).

Under the Health Act 2009, the Trust is required to produce an annual Quality Account, which must include information on participation in national and local clinical audits and the actions that have been taken as a consequence to improve the services provided.

The statutory and mandatory frameworks that regulate clinical audit within the NHS in England continue to evolve, and are detailed within HQIP's publication, Statutory and mandatory requirements in clinical audit.

2 Purpose of this policy

2.1 Purpose of this policy

The purpose of this policy is to set out the rationale for clinical audit and provide a framework for such activity, including standards, guidance and procedures, as well as details of the support available from the Quality Team:

- For registering and approving clinical audit project proposals
- For developing and designing clinical audit projects

This policy aims to support a culture of best practice in the management and delivery of clinical audit, and to clarify the roles and responsibilities of all staff involved.

2.2 Improvement and assurance

Quality in the NHS was defined in High quality care for all: NHS next stage review, led by Lord Darzi, and enshrined in legislation through the Health and Social Care Act 2012. This set out three dimensions, seen in Figure 1, which must all be present to provide a high-quality service.

Figure 1. Definition of quality



- **Patient experience:** quality care is delivered for a positive experience, including being treated according to individual wants or needs, and with compassion, dignity and respect
- **Clinical effectiveness:** quality care is delivered according to the best evidence regarding what is clinically effective in improving an individual's health outcome
- **Patient safety:** quality care is delivered to prevent all avoidable harm and risks to an individual's safety

Quality improvement in healthcare is a process that seeks to enhance patient experience and individual health outcomes, through measuring and improving the effectiveness and safety of clinical services.

Quality assurance in healthcare is the planned and systematic monitoring of activity to ensure that the requirements for safe, clinically effective services and positive patient experience are met. Quality assurance aims to provide confidence and certainty in the quality of services.

While clinical audit is fundamentally a quality improvement process that provides the opportunity for ongoing review and service development, it also plays an important role in providing assurance on the quality of services.

HQIP's A guide to quality improvement methods offers an overview of a range of quality improvement techniques that might be combined with clinical audit activity:

[Click here](#)

The prime responsibility for auditing clinical care lies with the clinicians who provide that care. Support from appropriately trained and experienced clinical audit staff, which includes training in processes and practice, is provided for clinicians who carry out clinical audit, and for non-clinical staff, patients and members of the public who may be involved in clinical audit projects.

The Trust is committed to ensuring:

- Participation in all national clinical audits, national confidential enquiries and national service reviews relevant to the services provided.
- All clinical audit activity within the Trust, or conducted in partnership with external bodies, is registered both locally and nationally as appropriate, and conforms to nationally agreed best practice standards.
- The annual programme of clinical audit activity meets Board Assurance Framework objectives and includes all of the clinical audits necessary to meet the requirements of regulators and commissioners.
- Records of reviews of the annual programme of clinical audit, individual clinical audit projects, as well as the results of national clinical audits, national confidential enquiries and inquiries and national service reviews, are maintained, to:

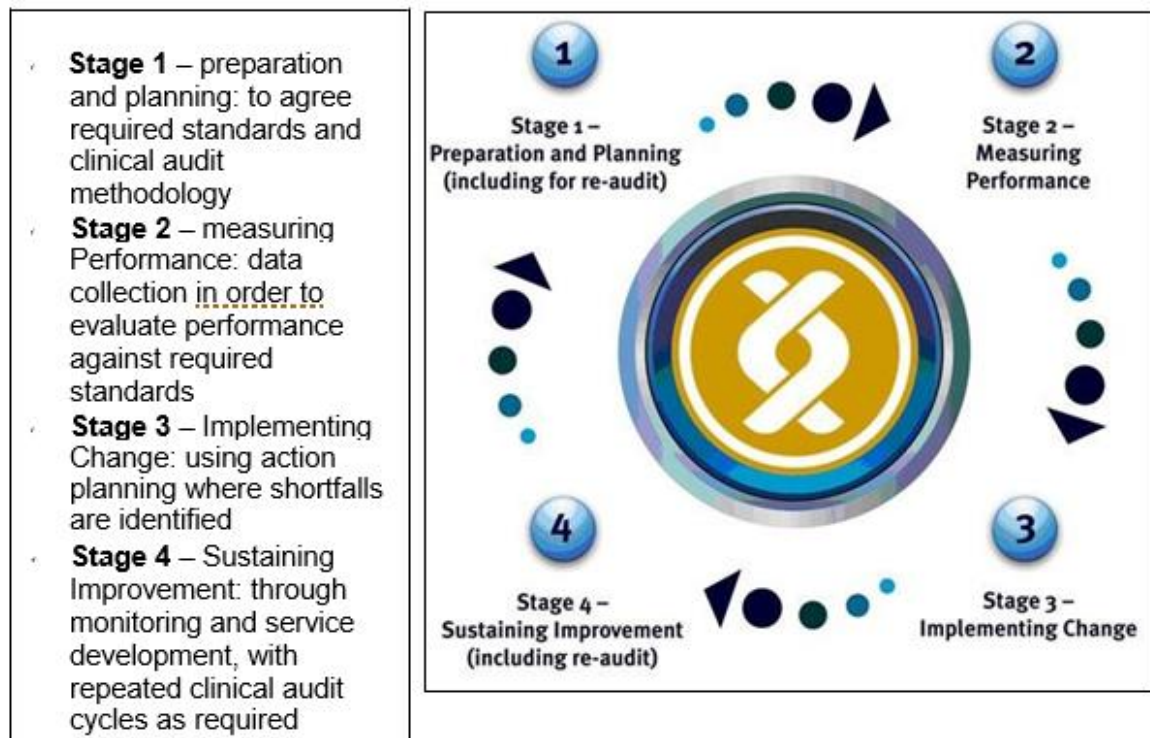
- Help facilitate effective clinical audit activity through robust governance systems
- Demonstrate compliance with requirements of regulators and commissioners

3 Definitions

3.1 Definition of clinical audit

Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.

Figure 2: the clinical audit cycle:



4 Scope

4.1 Target audience

This policy applies to anyone engaged in the clinical audit process within the Trust, including:

- All staff, both clinical and non-clinical, and those on short-term or honorary contracts
- Students and trainees in any discipline
- Patients, carers, volunteers, and members of the public

This policy also applies when clinical audit is undertaken jointly across organisational boundaries.

4.2 Multidisciplinary and multi-professional audit, and partnership working with other organisations

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

The Trust also supports collaboration on multi-professional clinical audits of interest to other parts of the local health and care economy, both within the outside of the NHS, e.g. primary/secondary care, local authorities, independent health and social care providers etc.

4.3 Involving patients and the public

The Trust promotes a commitment to involving patients, carers, and members of the public in the clinical audit process, either indirectly through the use of patient surveys and questionnaires, or directly through participation of patients, carers, and members of the public on clinical audit project steering groups or quality improvement patient panels. The draft forward audit programme must be circulated to the Patient and Carer Volunteer Group at the start of each financial year for review and to provide the opportunity for additional project suggestions. Clinical audit project leads are required to complete the Patient and Public Involvement section of the Trust clinical audit proposal form in order to identify opportunities for involvement, for example, in the governance of the project, the development of action plans and dissemination of audit findings and recommendations.

5 Duties, roles and responsibilities

Chief Executive

The Chief Executive is responsible overall for the statutory duty of providing a good quality of care which is the principal aim of this policy.

Trust Board

The Trust Board is responsible for setting Trust priorities and requirements in relation to clinical audit. Its roles and responsibilities are set out in HQIP's guidance: A guide for NHS boards and partners. [Click here](#)

Audit Committee

The Audit Committee maintains an overview of the audit process within the Trust to ensure that it is comprehensive and fit for purpose. The Audit Committee will receive a biannual update on progress in implementing the agreed Clinical Audit plan.

Quality and Safety Committee

The Quality and Safety Committee will receive biannual updates on progress in implementing the Clinical Audit plan and be made aware of quality and safety issues identified from clinical audit.

Quality and Safety Delivery Group

The Quality and Safety Delivery Group will receive biannual updates on progress in implementing the Clinical Audit plan and be made aware of quality and safety issues identified from clinical audit.

SDG Quality and Safety Groups

The SDG Quality and Safety Groups are tasked with oversight and scrutiny of the Trust's clinical audit activity, prioritisation of participation in national clinical audit, decisions about local clinical audit, the review of audit proposals and audit reports, including progress through repeated clinical audit cycles.

Medical Director

The executive/Board lead for clinical audit is the Medical Director. His/her responsibilities in respect of clinical audit are:

- To ensure that the Trust's annual programme of audit work is aligned to the Board's strategic interests and concerns
- To ensure that clinical audit is used appropriately to support the Board Assurance Framework
- To ensure this policy is implemented across all clinical areas
- To ensure that any serious concerns regarding the Trust's policy and practice clinical audit, or regarding the results and outcomes of national and local clinical audits, are brought to the attention of the Board
- To take responsibility for ensuring effective prioritisation is undertaken to participate in national clinical audit, and for decisions about local clinical audit

Senior Managers/Managers

Managers are responsible for ensuring that service development and delivery is underpinned by an effective programme of clinical audit, which forms part of the Continuing Professional Development regime for their team(s). Service managers must ensure that all clinical audit activity within their respective areas is registered.

Clinical Leads for Quality

The Clinical Leads for Quality will work collaboratively with the Quality Facilitator in relation to implementation of the Clinical Audit plan within their respective SDGs. They will quality-check audit proposals and audit project reports prior to submission to SDG Quality and Safety Group and assist in identifying priorities for inclusion on the annual Clinical Audit plan.

Quality Facilitator

The Quality Facilitator is responsible for compiling the annual clinical audit plan in collaboration with senior clinical and managerial staff, implementation of the agreed plan of work, facilitation of individual audit projects and ensuring that the processes outlined within this policy are adhered to within the Trust

SCHT Staff

All staff employed by the Trust have a responsibility for the continual improvement of the quality of the service they provide, and all clinical staff are individually accountable for ensuring they audit their own practice in accordance with the professional codes of conduct and in line with the standards set out within this document

6 Conduct of clinical audit

The process for undertaking clinical audit within the Trust is outlined below and shown as a process map, which can be found at Appendix 1 to this policy.

6.1 Agreeing an annual programme of audit activity

Prior to the start of every financial year, the Trust will agree an appropriate planned programme of clinical audit activity. This programme should meet the Trust's corporate requirements for assurance, but must be owned by clinical services and be reflective of both national and local priorities. The prioritisation of audits on the programme is based on the model developed by the Healthcare Quality Improvement Partnership (HQIP).

External 'must do' audits (Priority 1)

The first step in developing a comprehensive annual programme is the identification of all the clinical audit projects which must be undertaken by the Trust in order to meet external regulatory requirements. It is essential to ensure that these projects are treated as priority and that appropriate resources are provided to support them. Failure to participate or deliver on these externally driven audits may carry a penalty for the Trust, either financial or in the form of a failed target or non-compliance. They will form the core of the annual clinical audit programme.

The list of 'must do' audits may include:

- NCAPOP (National clinical audit and Patient Outcomes Programme) and other national clinical audits which are relevant to the services provided and where participation must be reported in Quality Accounts
- Audits demonstrating compliance with regulatory requirements e.g. audits with the aim of providing evidence of implementation of NICE guidance, NSFs (National Service Frameworks), and other national guidance such as that coming from the Clinical Outcomes Review Programme (former National Confidential Enquiries)
- Audits required by external accreditation schemes e.g. NHSLA Risk Management Standards and associated indemnity schemes, cancer peer review audits etc.
- Audits which must be undertaken in order to comply with provider policies which are themselves subject to external review
- Commissioner priorities including national and regional CQUIN audits

Internal 'must do' audits (Priority 2)

The Trust must also compile a list of internal 'must do' clinical audits, based on the classic criteria of high risk or high profile. Many of these projects will emanate from governance issues or high-profile local initiatives and may include national initiatives with local relevance but no penalties for non-participation. They may include:

- Priorities reflective of organisational objectives for clinical audit
- Clinical risk issues
- Audits undertaken in response to serious untoward incidents/adverse incidents/complaints
- Organisational clinical priorities
- Priorities identified via Patient and Public Involvement initiatives

Local priority audits (Priority 3)

Once the 'must do' audits have been identified, staff and stakeholders should be asked to propose projects they believe will be of benefit to the Trust and its patients and service users. Any member of staff who wants to propose an audit **must** complete an audit proposal form, which should be downloaded directly from the Resources section of the Clinical Audit SharePoint site: [Click here](#) and submit it to their service manager or lead in the first instance for approval. This will ensure that the project is aligned to service or team objectives and priorities and that it can be assigned a priority score. This should then be emailed to the Quality Facilitator prior to the start of the new financial year. All proposals will be reviewed against agreed criteria by the Quality Facilitator and the relevant Clinical Lead for Quality prior to inclusion on the audit plan.

Factors to take into account when considering project proposals for inclusion on the Audit Plan are:

- Is the topic concerned with high cost, high volume or high risk to staff, or to patients/service users?
- Is there evidence of a quality problem, e.g. patient complaints, high complication rates, adverse outcomes or poor symptom control?
- Is there evidence of wide variation in practice?
- Is good evidence available to inform audit standards, e.g. systematic reviews or national clinical guidelines?
- Is the problem measurable against relevant standards?
- Is auditing the problem likely to improve healthcare outcomes as well as process improvements?
- Is auditing the problem likely to have economic and efficiency benefits?
- Is the topic a key professional or clinical interest?
- Are reliable sources of data readily available for data collection purposes?
- Can data be collected within a reasonable time frame?
- Is the problem concerned amenable to change?
- Is the topic pertinent to national or local initiatives or priorities?
- Does the topic lend itself to the process of audit, or is a different process more appropriate e.g. root cause analysis, activity or workload analysis?
- How much scope is there for improvement, and what are the potential benefits of undertaking this audit?

Review and approval of the draft clinical Audit Plan

The process for review and approval of the draft Audit Plan is as follows:

- The draft Audit Plan will be reviewed initially by the Quality Facilitator and the two Clinical Leads for Quality and then by a group of senior clinical/managerial staff.
- The draft will then be submitted to SDG Quality and Safety Groups and accepted or amended accordingly.
- The final version will be submitted to Quality and Safety Delivery Group for approval.

The following issues will be considered as part of the review process:

- Is each project included on the plan definitely a clinical audit i.e. does it aim to improve patient care by implementing change, where quality of care under review falls short of defined standards and criteria?
- Are all projects of relevance to the Trust?
- Is the priority score assigned to each project appropriate?
- Is the Trust participating in all relevant national audits?

Additions to the programme

Audits will also be accepted onto the programme on an *ad hoc* basis as the year progresses. A proposal form will need to be completed for all such audits, quality-checked by the Quality Facilitator and the relevant Clinical Lead for Quality and then approved at SDG Quality and Safety Groups.

6.2 Working with commissioners

The Trust will consult and work collaboratively with commissioners in determining a programme of clinical audit activity. Where appropriate, the results of individual audits will be shared with commissioning bodies.

6.3 Systems for registering and approving audits

All clinical audit activity must be registered with the Quality Facilitator, irrespective of the level of facilitation required, to ensure project consistency, and to enable progress review and monitoring for quality assurance purposes.

6.4 Use of databases

Data provided on registration will be used to compile a database of all clinical audit activity undertaken throughout the Trust. The database will be updated regularly by the Quality Facilitator and will be used to report to Quality and Safety Delivery Group, Quality and Safety Committee, Audit Committee and the Board on implementation of the Clinical Audit plan. Each SDG will have its own clinical effectiveness programme spreadsheet stored on the Clinical Audit SharePoint site, which can be accessed via the following link: [Click here](#)

6.5 The use of standards (or criteria) in clinical audit

By definition, clinical audit involves measuring clinical practice against standards of best practice. Project leads and SDG Quality and Safety Groups when approving project proposals should ensure:

- Clinical audit standards are based upon the best available evidence, e.g. NICE guidance (or equivalent), National Service Frameworks, other national guidelines etc.
- The audit standards being used are valid i.e. they have the capability of giving a true picture of what is being audited and are sensitive (able to 'flag' all or almost all cases in the audit for which there is a problem) and specific (able to identify truly good care).

If in doubt, advice and guidance should be sought from the Quality Facilitator and/or HQIP's Guide to ensuring data quality in clinical audits consulted by project leads at the audit planning stage: [Click here](#)

6.6 Reporting

A project report must be completed for every clinical audit undertaken using the agreed Trust clinical audit report template. In the majority of cases, data analysis and report write-up will be carried out by the Quality Facilitator, in collaboration with the project lead/team. The clinical audit report template is available to download from the Clinical Audit SharePoint via the following link: [Click here](#). HQIP guidance on documenting local clinical audit should also be consulted: [Click here](#)

The completed audit report will be quality-checked by the Quality Facilitator and the relevant Clinical Lead for Quality prior to being submitted to SDG Quality and Safety Groups for review and approval of the findings and recommendations. The project lead may be invited to present the audit findings, but as a minimum, the relevant service representative must be present when the audit findings are reviewed.

A biannual summary of the findings and recommendations from audits will be submitted to Quality and Safety Delivery Group, Quality and Safety Committee, Audit Committee and the Board. The summary will also identify any delays in implementation of the Clinical Audit plan.

6.7 Dissemination

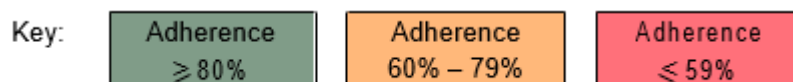
Once a round of data collection has been completed and the data has been analysed, the results and findings should be presented to relevant healthcare professionals, stakeholders and groups for discussion, agreement of action plans and a commitment to complete another audit cycle within a designed timeframe.

6.8 Action plans for improvement

Where areas of non-compliance have been identified by an audit, an action plan should be developed and included as part of the clinical audit report. This information will be recorded on the respective Clinical Effectiveness programmes stored on SharePoint and implementation monitored by the Quality Facilitator and the respective SDG Quality and Safety group.

The scoring mechanism below, developed by HQIP, should be used to interpret clinical audit results. This is a general guide only; results can also be weighted by the project team according to the importance of the aspect of care or treatment being audited.

Diagram 3: scoring mechanism for audit results



Actions should be SMART - specific, measurable, achievable, relevant and timely. They must have clear implementation timescales, with identified leads for each action.

Not all clinical audits will require an action plan, e.g. where an audit shows that standards are consistently and repeatedly being met, and practice is effective. For such audits there should be an explicit statement within the summary report that no further action is required, along with the reason(s) for this.

The SDG Quality and Safety Groups will monitor the implementation of action plans ensuring that any identified required changes are incorporated into practice and into relevant business plans and/or risk registers as appropriate.

If the failure to progress or complete a clinical audit, or the failure to implement an action plan, poses a risk to patients, staff or the healthcare provider as a whole (e.g. a financial risk due to failure to meet standards), appropriate entries must be made on the Trust's risk register.

6.9 Repeating audit cycles

The clinical audit cycle is not complete until agreed actions are implemented according to the corresponding action plan, and evidence is obtained of the impact of the action plan on compliance with standards. Repeated cycles of audit may be carried out to ensure standards and criteria are consistently and repeatedly met, and practice is effective.

As a general rule, re-audits should be carried out within a 6-month timescale following completion of the initial audit. The re-audit may be targeted at those areas of clinical practice where non-compliance was identified in the initial audit so as to minimise the time and resources involved.

7 Governance and ethics

7.1 Ethics and consent

By definition, clinical audit projects should not require formal approval from a Research Ethics Committee. However, one of the principles underpinning clinical audit is that the process should do good and should not do harm. Clinical

audit must always be conducted within an ethical framework and should consider the following four principles:

- There is a benefit to existing or future patients or others that outweighs potential burdens or risks
- Each patient's right to self-determination is respected
- Each patient's privacy and confidentiality are preserved
- The activity is fairly distributed across patient groups

See HQIP's Guide to managing ethical issues in quality improvement or clinical audit projects for more information [Click here.](#)

The clinical audit programme is managed efficiently to make best use of resources, and The SDG Quality and Safety Groups are responsible for the ethical oversight of clinical audit across the organisation and any person who has concerns regarding the ethics of clinical audit should refer them to the Chairs of these groups. This ethical oversight will ensure that:

- Performance management issues associated with poor audit design, poor execution or failure to deliver improvements in patient care, are addressed.
- Any ethical concerns that arise during the design and planning of individual clinical audits are addressed.
- Any instances of serious shortcomings in patient care that come to light through clinical audit are communicated to the manager of the service involved at the earliest opportunity, and that appropriate steps are taken to address them.
- Risk management issues identified through clinical audit results are addressed in clinical audit action plans, and that those plans are implemented effectively.

7.2 Equality and diversity

The Trust aims to ensure that its healthcare services and facilities are not discriminatory and attend to the physical, psychological, spiritual, social, and communication needs of any patient or visitor, showing no discrimination on the grounds of ethnic origin or nationality, disability, gender, gender reassignment, marital status, age sexual orientation, race, trade union activity, or political or religious beliefs.

The process for determining choice of clinical audit projects, and the manner in which project patient samples are drawn up, should not inadvertently discriminate against any groups in society based on their race, disability, gender, age, sexual orientation, religion and belief. Any person who has concerns regarding the ethics of clinical audit activity within the Trust should refer them in the first instance to the SDG Quality and Safety Groups, who may require equality impact assessments to be undertaken and/or equality data to be collected as part of

clinical audit activity, in order to determine whether any particular groups of patients are experiencing variations in practice.

7.3 Information governance: collection, storage and retention of data and confidentiality

All clinical audits must adhere to NHS Information Governance policies and standards, paying special attention to the Data Protection Act and the Caldicott Principles, whereby data should be:

- Adequate
- Accurate
- Processed for limited purposes
- Held securely
- Not kept for longer than is necessary

8 Training and development

8.1 Overall organisational approach

Some aspects of clinical audit activity require specialist skills, for example, using the correct clinical audit methodology. This policy sets out how the trust will ensure that all clinicians and other relevant staff and patients conducting and/or managing clinical audits are given the appropriate time, knowledge and skills to facilitate the successful completion of clinical audit cycles. Clinical audit education and training are key to the delivery of this policy, in order to promote activity led by healthcare professionals.

Training raises the profile of clinical audit and best practice standards, builds up the capacity and capability for reflective practice of all those involved, and acts as a driver for quality improvement

8.2 Provision of clinical audit training

The Trust will make available suitable training, awareness and support programmes to staff regarding the systems and arrangements for participating in clinical audit. This will ensure:

- Training for local, regional and national clinical audit activities, and bespoke training, will be given to groups and individuals upon request.
- Appropriate training is available to any patients and other members of the public who participate in clinical audit activities.
- Educational resources and links to HQIP guidance will be made available on the Clinical Audit SharePoint site which can be accessed via the following link: [Click here.](#)

9 Consultation

Dr Jane Povey – Medical Director

Dr Emily Peer – GPwSI DAART and Associate Medical Director

Samantha Young – Deputy Director of Nursing, Quality and Infection Prevention and Control

Angela Cook – Head of Nursing and Quality (Adult Service Delivery Group)

Vickie Clayton – Clinical Lead for Quality

Sharon Simkin – Clinical Lead for Quality

10 Dissemination and implementation

The Policy will be made available to all staff via the Trust's website, staff zone in the policies section.

All service managers/leads will be informed about the policy via SDG Quality and Safety groups. Managers and leads will be asked to make staff working within their respective areas aware of the policy.

11 Monitoring compliance

Compliance with this policy will be monitored via the routine check-and-challenge process in place for reviewing audit project proposals and reports.

An audit of compliance with key aspects of the policy will be undertaken annually.

12 Associated documents

Consent To Examination and Treatment Policy

Risk Management Policy

Information Governance Policy

Clinical Record Keeping Policy

13 References

Good governance. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17

Statutory and mandatory requirements in clinical audit guidance, HQIP 2019

High quality care for all. Department of Health, 2008

A guide to quality improvement methods, HQIP 2015

Clinical audit: a guide for NHS Boards and partners, HQIP 2021

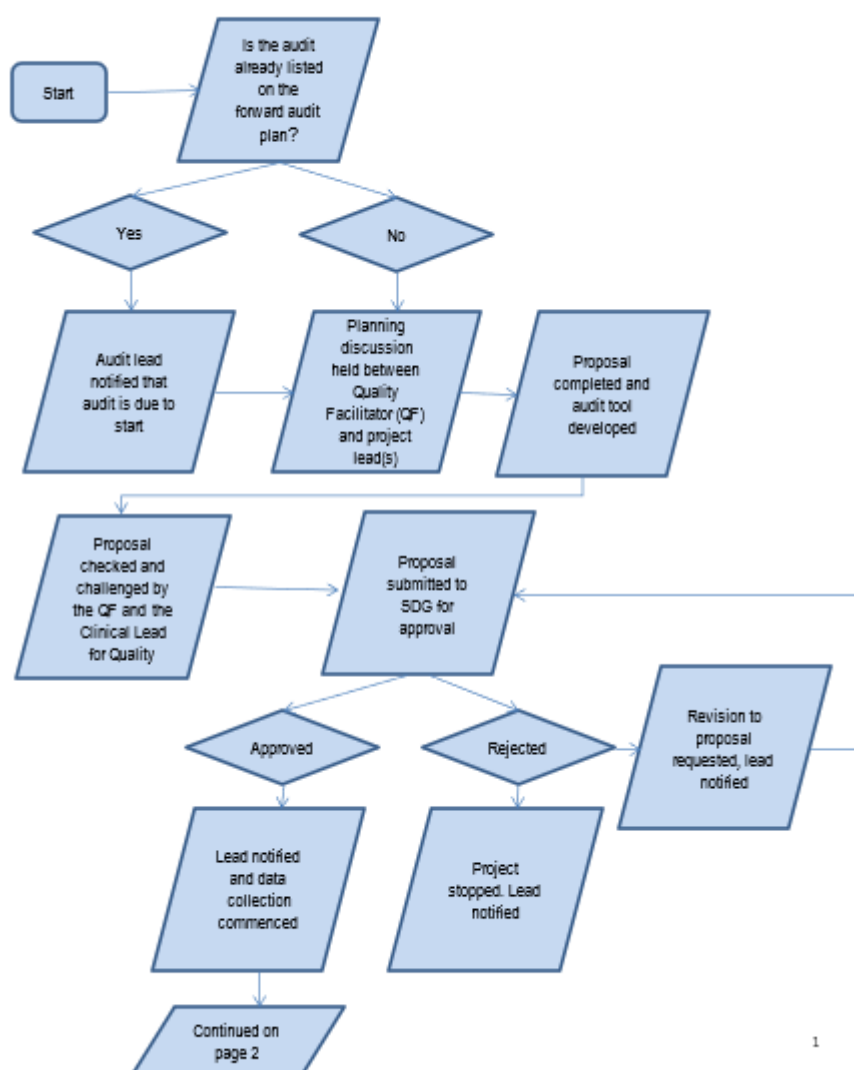
Documenting local clinical audit – a guide to reporting and recording, HQIP 2020

Guide to ensuring data quality in clinical audits, HQIP 2011

Guide to managing ethical issues in quality improvement or clinical audit projects, HQIP 2021

Developing a clinical audit programme, HQIP 2016

PROCESS FOR UNDERTAKING A CLINICAL AUDIT PROJECT



1

