Sheffield Health and Social Care NHS Foundation Trust

Policy:

Clinical Audit and Service Evaluation

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Policy Owner	Clinical Effectiveness Manager
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Summary of policy
Provide a summary description of the policy

Target audience	N/A

Keywords	N/A

Storage & Version Control
Version 5 of this policy is stored and available through the SHSC intranet/internet. This version of the policy supersedes the previous version (V4 2019). Any copies of the previous policy held separately should be destroyed and replaced with this version.

Version Control and Amendment Log

Version No.	Type of Change	Date	Description of change(s)
1	New policy	03/2011	Original policy ratified
1.1	Review	03/2013	Policy reviewed to reflect revised governance structures

1.2	Review	03/2015	Policy reviewed to reflect revised governance structures
2	Review	02/2016	Revised policy ratified Feb 2016
3	Review	05/2017	Full review and revision of policy
4	Review	05/2019	Policy reviewed to reflect revised governance structures and other minor updates
5	Review	11/2022	Full review and revision of policy

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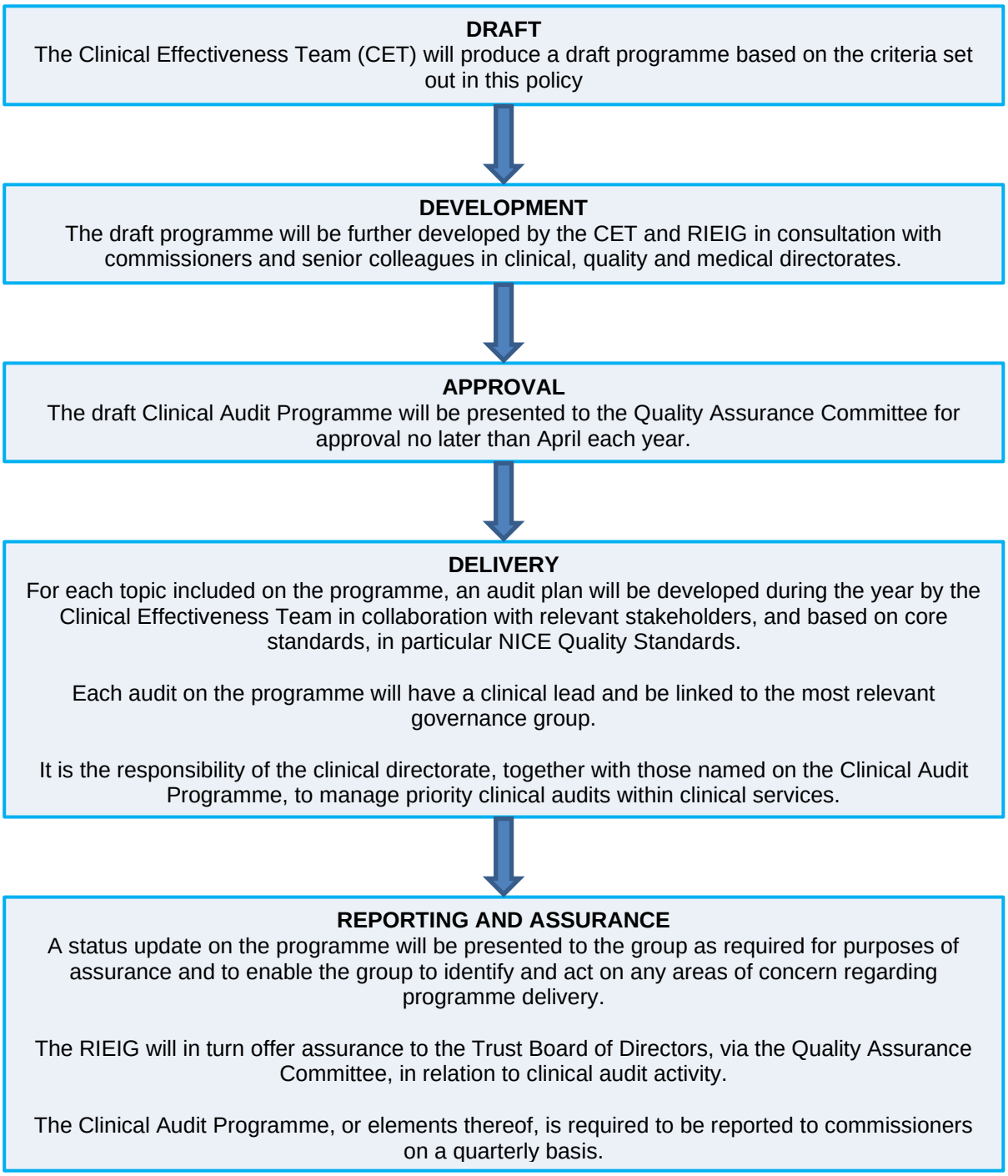
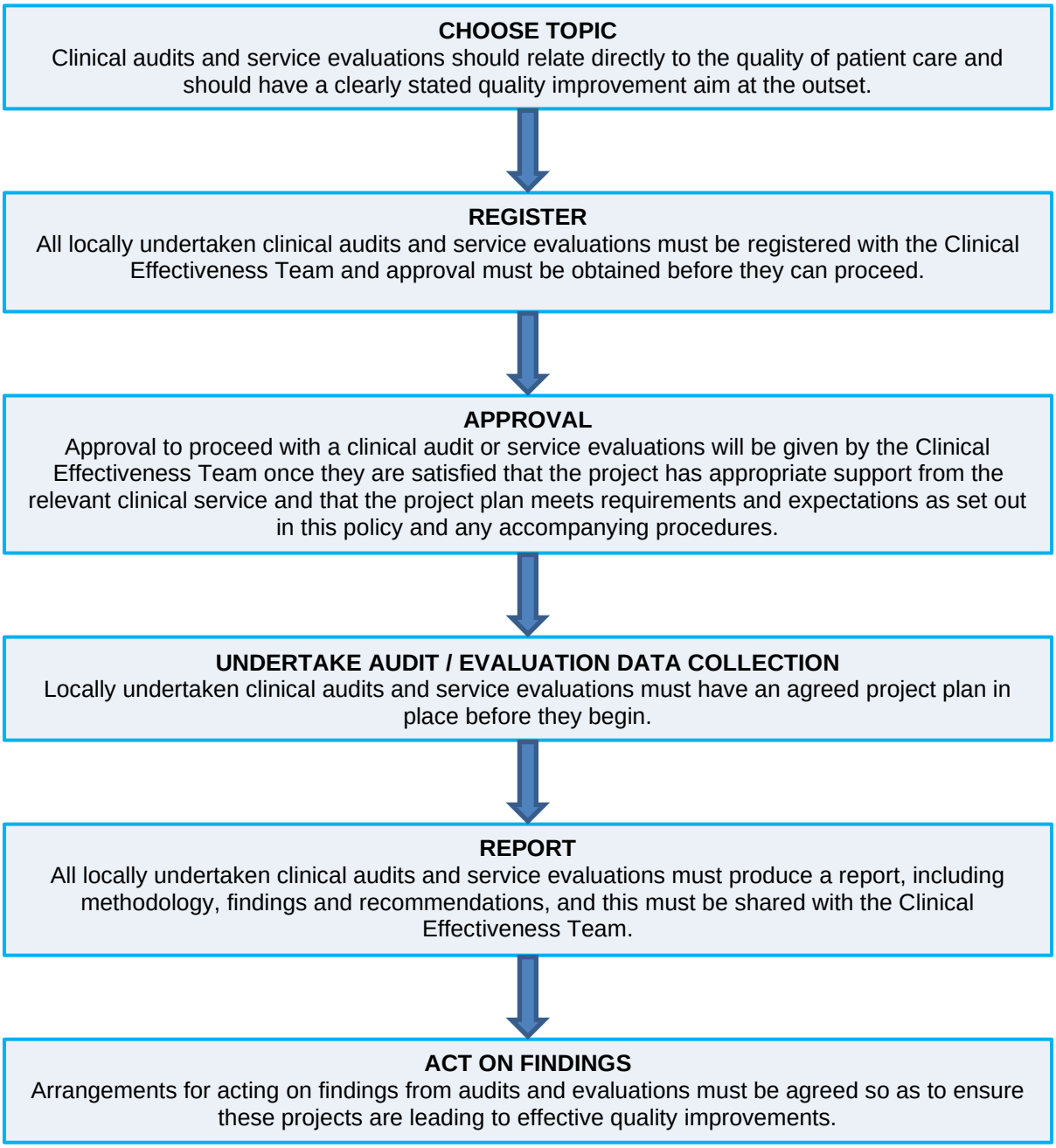


Process for Local Audits and Service Evaluations



1. Introduction

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. The three dimensions which must all be present to provide a high quality service are:

- Clinical effectiveness: quality care is care which is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes
- Patient safety: quality care is care which is delivered so as to avoid all avoidable harm and risks to the individual's safety
- Patient experience: quality care is care which looks to give the individual as positive an experience of receiving and recovering from the care as possible, including being treated according to what that individual wants or needs and with compassion, dignity and respect.

Clinical audit and service evaluation are key elements in clinical effectiveness, in assessing, assuring and improving the quality of care and treatment, and in supporting evidence-led care.

The Clinical and Social Care Strategy has identified being evidence-led as one of the four pillars of care. Being evidence-led means generating, appraising, and using evidence, taking an evaluative approach to the services and care we deliver, and using data and digital innovation to support us in improving outcomes for service users. The Research, Innovation and Effectiveness strategy speaks directly to this ambition: we cannot be evidence-led, and deliver on our commitment, without research, innovation and clinical effectiveness being an integral part of the services we deliver. Research helps us find out what works best, when, where and for whom, and clinical effectiveness supports the use of evidence to improve the effectiveness of clinical practice and service delivery.

One of the priorities of the Research, Innovation and Effectiveness Strategy is that 'we will work with teams to monitor service outcomes through evaluation and continuous improvement, to evidence the benefits and impact associated with clinical service delivery. We will support service-level 'action' research, including clinical audit, service evaluation and continuous improvement, as an effective way for services to collaborate with service users to develop learning and improve outcomes.'

<u>Statutory and Mandatory requirements</u>

The NHS Standard contract states that healthcare providers must participate in relevant national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP), any other national clinical audit or clinical outcome review programme managed or commissioned by HQIP; and any national programme included within the NHS England Quality Accounts List for the relevant Contract Year. (NHS Standard Contract).

Healthcare providers "must have systems and processes such as regular audits of the service provided and must assess, monitor and improve the quality and safety of the service" (CQC guidance on Health and Social Care Act 2008 regulations). The systems and processes must "enable the provider to identify where quality and/or safety are being compromised and to respond appropriately and without delay".

The National Health Service (Quality Account) Regulations 2017 requires healthcare providers to produce an annual Quality Account, which must include information on participation in national and local audits, and the actions that have been taken to improve services, as a result of the audit.

The overarching aim of clinical audit and service evaluation is to improve service user outcomes by improving professional practice and the quality of services delivered.

The prime responsibility for auditing clinical care lies with the clinicians who provide that care. Clinical staff are expected to take part in clinical audits and service evaluations as part of their professional practice. For some, for example medical practitioners, this may be a requirement of their post or a necessary part of their training.

Support for clinical audit and service evaluation is provided by the Clinical Effectiveness Team.

2. Scope

This is a Trust–wide policy which applies to all services without any exceptions. This policy also applies to staff that work in Sheffield Health and Social Care NHS Foundation Trust services but are not employed by the Trust. Where staff employed by the Trust work in services provided by other organisations, they have a duty to follow the policies of the organisation they are working in, and comply with their process. This policy also applies to employees of partner organisations conducting clinical audit, evaluation or quality improvement with staff, patients or data from this trust.

3. Purpose

The purpose of this policy is to set out the Trust's approach to clinical audit and service evaluation and to provide a framework for such activity, including clear processes.

Clinical Audit
Clinical audit measures the quality of care and services against agreed standards, making improvements where necessary.

Service Evaluation
Service evaluations consider if existing or newly implemented services are effective. This process explores what is happening in a service as well as outcomes and experience for patients.

4. Definitions

Clinical audit
Clinical audit is defined as 'measuring the quality of care and services against agreed standards and making improvements where necessary' (Healthcare Quality Improvement Partnership (HQIP), 2009).

Clinical audit is not just a data collection exercise:

- It involves measuring current patient care and outcomes against explicit audit criteria (standards).
- There is an expectation from the outset that practice will be improved. Further clinical audit may be required to confirm that practice has improved.

The process of clinical audit is sometimes called the Audit Cycle and includes: agreeing standards of best practice (audit criteria); collecting data; analysing data against standards; feeding back results; agreeing and implementing changes; allowing time for changes to embed and then re-auditing to assess improvement.

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.

Service evaluation
Service evaluations explore what is happening in a service, as well as outcomes and experience for patients, to consider if existing or newly implemented services are effective. There are many different approaches to service evaluation. Whichever method is used, the process should provide practical information which helps to inform the future development of a service.

Clinical Effectiveness
Clinical effectiveness is best understood as a cycle of informing, changing, and monitoring clinical practice. It is 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" (Promoting clinical effectiveness: a framework for action in and through the NHS, Department of Health,1996).

National clinical audit
A national clinical audit is a clinical audit which has been set up across Trusts in England and Wales, enabling a large dataset to be created and comparisons to be made between Trusts. The NHS Standard contract states that healthcare providers must participate in relevant national clinical audits. Trusts are expected to report on their participation in national audits in their Annual Quality Accounts.

Clinical Audit Programme
A priority clinical audit programme is developed each year for approval by the Quality Assurance Committee. The Clinical Audit Programme ensures that the clinical audit activity meets key SHSC priorities in relation to delivering evidence-led care in line with the Clinical and Social Care Strategy. The programme helps ensure that clinical audit is used to audit against key clinical standards and to support improvements to the quality of care and treatment.

Local (or team-level) clinical audits and service evaluations
A local audit/evaluation is a more ‘bottom up’ and often smaller scale project designed to meet a Trust or service priority or as part of a quality improvement initiative in a team or on a ward. Local audits and service evaluations are not included on the Clinical Audit Programme.

Other types of audit
‘Audit’ has a range of meanings and whilst people might want to ‘audit’ something it does not necessarily mean that they are doing or want to do a clinical audit project.
The word ‘audit’ is often used when we talk about measuring or examining something. That might include: routine data monitoring, performance monitoring, or monitoring routine processes.

Internal audit
An internal mechanism that traces non-clinical activities and systems along 'audit paths' to see if things happened the way they should have. For example, tracing a patient complaint from the initial letter of complaint through to resolution to establish whether Trust guidelines were followed appropriately

Research
Research is designed and conducted to generate new knowledge and identify best practice.

Best practice
A best practice is a technique or methodology that, through experience and research, has proven to reliably lead to a desired result. A commitment to using the best practices in any field is a commitment to using all the knowledge and technology at one's disposal to ensure success.

NICE guidance
National Institute of Health and Care Excellence publishes evidence-based guidance for health and social care practitioners based on independent reviews of evidence for clinical and cost effectiveness of interventions.

Quality improvement
Quality Improvement (QI) is a systematic process using QI theory and methods to continually make small changes that lead to measurable improvements. "Quality improvement is about giving the people closest to issues affecting care quality the time, permission, skills and resources they need to solve them. It involves a systematic and coordinated approach to solving a problem using specific methods and tools with the aim of bringing about a measurable improvement" Quality improvement made simple, London: The Health Foundation, 2021.

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

Quality accounts
A Quality Account is a report about the quality of services by an NHS healthcare provider. The reports are published annually by each provider.

5 Detail of the policy

Clinical Audit Programme
A priority clinical audit programme is developed each year for approval by the Quality Assurance Committee. The clinical audit programme identifies topics for audit during the financial year. It focuses on SHSC's priorities and national audits, and includes audits requested from NHS Sheffield Clinical Commissioning Group (CCG), and audits that are expected to be reported as part of SHSC's annual Quality Account.

The Clinical Audit Programme ensures that the clinical audit activity meets key SHSC priorities in relation to delivering evidence-led care in line with the Clinical and Social Care

Strategy. The programme helps ensure that clinical audit is used to audit against key clinical standards and to support improvements to the quality of care and treatment.

In addition to national clinical audits, the inclusion of other audit topics on the programme will be influenced by:

- National Institute for Health and Clinical Excellence (NICE) guidance
- Key areas of Quality where greater levels of assurance or improvement is known to be required. This includes consideration of safety, effectiveness and service user experience.
- Priorities associated with Care Quality Commission (CQC) reviews and recommendations, or address recommendations from other regulators.
- Serious incidents or complaints (e.g. to provide assurance that an action plan following a serious incident has been implemented and has had the desired impact in improving safety).
- Implementation of the Trust's quality objectives and areas for improvement as described in the annual quality accounts or annual plans.
- Previous clinical audit topics that require continuation or previous 'local' clinical audit topics that are appropriate for a Trust-wide clinical audit.
- Internal audits. Linkages between clinical and internal audit programmes will enable colleagues to highlight key areas of assurance or weakness, and potentially provide recommendations to SHSC as to the most effective means of auditing key priorities

Local (team-level) clinical audits and service evaluations

The Trust is committed to supporting locally determined clinical audit and service evaluation activity to significantly contribute to the process of continuous service quality improvement. Local clinical audit and service evaluations should be determined via clinical service leadership teams in order to ensure that such activity supports key priorities.

Individual clinicians may initiate a clinical audit/service evaluation project on the basis of professional interest, professional development, or as part of an educational or training programme. All local audits/service evaluations should align with Trust or service priorities for improvement. Audits and service evaluations are more likely to lead to improvements when local leadership teams are involved in all stages of the audit cycle.

It is important that all locally driven clinical audits and service evaluations are registered as detailed in this policy and reported through governance structures to maximise organisational learning.

Clinical Audit, Service Evaluation and other Trust activity

It is recognised that a number of Quality Improvement projects or activities undertaken by the Trust contain clinical audit and may contain activities that can be defined as service evaluation. All clinical audit and service evaluation activity must be undertaken in line with this policy.

A variety of quality improvement activities are undertaken by and within the Trust that are not covered by this policy. These may be investigations, research, 'microsystems' or other quality improvement methods, or other types of audits. It is recognised that there is significant benefit to be gained from coordinating and linking these activities, both in terms of the activity undertaken and the actions and quality improvements that result. To that end,

the processes associated with clinical audit/service evaluation activities covered by this policy will aim to work in conjunction with other types of quality improvement activity.

6. **Duties**

Individual/Group	Duties
Chief Executive	The Chief Executive is ultimately responsible for the quality and safety of services provided by the Trust.
Medical Director	The Medical Director has lead executive responsibility for clinical effectiveness activity in the Trust and acts as a champion for quality improvement and evidence-based best practice. The Medical Director is responsible for providing assurance to the Board of Directors that an effective system exists to ensure the Trust complies with its obligations and expectations regarding priority clinical audits and that clinical audit and service evaluation are being utilised within the Trust to underpin improvements to clinical care. The Medical Director will ensure that any serious concerns regarding the Trust's policy and practice in clinical audit and service evaluation, or regarding the results and outcomes of national and local clinical audits, are brought to the attention of the Board. The Medical Director chairs the Research, Innovation, Effectiveness and Improvement Group (or may delegate this responsibility).
Trust Board	The Trust Board of Directors is responsible for ensuring good quality care is delivered and best practice is followed. The Trust Board has responsibility for oversight and scrutiny of clinical audit and service evaluation activity and findings. The Trust Board is ultimately responsible for ensuring the Trust meets its Statutory and Mandatory requirements with regard to clinical audit. The Trust Board is encouraged to use clinical audit as a tool in strategic management as part of the broader quality improvement programme; obtain assurance that the strategy for clinical audit is aligned to broader interests and targets that the board needs to address. The Trust Board may choose to delegate these responsibilities to Board Committees, in particular the Quality Assurance Committee.
Quality Assurance Committee (QAC)	Delegated responsibilities from Trust Board in relation to oversight of clinical audit and service evaluation activity. Receives reports related to clinical audit activity from the Research, Innovation, Effectiveness and Improvement Group and offers assurance to the Trust Board of Directors in relation to this.
Research, Innovation,	The RIEIG directs and oversees clinical effectiveness across the Trust and provides assurance to the Board.

Effectiveness and Improvement Group (RIEIG)	The Group oversees and monitors clinical quality improvement across the Trust via the use of clinical audit or other quality improvement methods. RIEIG will establish an annual priority clinical audit programme, combining national and local priorities, ensuring that it delivers quality improvements, and report progress to the QAC. It will ensure that this programme is aligned to the Trust's strategic interests and concerns. RIEIG will ensure that clinical audit and service evaluation are used appropriately to support the board assurance framework and other key priorities. RIEIG will ensure this policy is implemented across all clinical areas. RIEIG will provide reports to the Quality Assurance Committee (QAC) on clinical audit activity and resulting quality improvements or assurances, and whether the process outlined in this policy is being followed.
Clinical Directors and Clinical Directorate leadership teams	Provide clinical direction to clinical audit activity to ensure that the system and activity provide assurances on and improvements to clinical care. To ensure that this policy is implemented throughout their directorate. To ensure that all clinical audit/service evaluation activity within their directorate is registered on the Trust database and complies with nationally accepted best practice standards. To ensure that their directorate participates in all national clinical audits, national confidential enquiries and inquiries, and national service reviews that are relevant to the services provided. Clinical Directors, along with their respective directorate leadership teams, are responsible for ensuring that the annual priority clinical audit programme is delivered within their service areas and to ensure that clinical audit/service evaluation activity is undertaken within those services in such a way as to result in quality improvements to, or assurances regarding, clinical care. Clinical Directors have a role in acting as champions for clinical audits/service evaluations within their areas of responsibility. They will ensure that staff within their areas of responsibility comply with the requirement to lead, participate or contribute information to clinical audits/service evaluations. Clinical Directors, along with their respective directorate leadership teams, will ensure that, through their governance structures, the results of clinical audits/service evaluations are reviewed and any improvements required are identified and action taken accordingly.
Director of Research	The Director of Research is responsible for overseeing the work of the Clinical Effectiveness Team and ensuring they provide the support needed for the implementation of this policy and clinical audit/service evaluation processes in the Trust.

Clinical Effectiveness Manager	Responsible for writing and overseeing the implementation of this policy. To ensure that the Clinical Effectiveness Team fulfils its roles and responsibilities in relation to clinical audit/service evaluation, and that these are aligned to Trust strategies and priorities.
Clinical Effectiveness Team	Day to day management of clinical audit/service evaluation processes outlined in this policy and associated procedures. Manage a process of registering and approval of local/team-level clinical audits/service evaluations. Maintain a database of clinical audits and service evaluations undertaken within the Trust. Support clinical teams to ensure required audit/evaluation is prioritised. Work with other members of staff to support the completion of clinical audits/service evaluations and associated improvements. Provide advice for staff undertaking clinical audits/service evaluations to support these projects to be of good quality. Monitor and report the progress of clinical audit/service evaluation activity through reports to RIEIG. Prepare and recommend to RIEIG the required annual priority clinical audit programme. Co-ordinate the inclusion of compliance with NICE guidance into clinical audits being undertaken. To work with clinicians, service managers, directorate to ensure that the clinical audit programme meets all clinical, statutory, regulatory, commissioning, and Trust requirements.
Senior managers, clinical leads and service leadership teams	Senior managers and clinical leads, and their respective service leadership teams, are responsible for working with clinical directors and the Clinical Effectiveness Team to ensure that the annual priority clinical audit programme is delivered within their service areas and to ensure that clinical audit/service evaluation activity is undertaken within those areas in such a way as to resulting in quality improvements to or assurances on clinical care. This will include: ensuring that staff within their services comply with the requirement to lead, participate or contribute information to clinical audits/service evaluations; identify audit and evaluation priorities in their service areas; work with the Clinical Effectiveness Team to agree audit and evaluation projects at service level; ensuring that, through their governance structures, the results of clinical audits/service evaluations are reviewed and any actions required are identified and action taken accordingly; ensuring they have due oversight of clinical audit/service evaluation activity undertaken within their service areas.

	Managers are responsible for ensuring that service development and delivery is underpinned by an effective programme of audit and evaluation so as to support continuous improvement. Senior clinicians may be responsible for supervising clinical audit/service evaluation activity as required.
All staff undertaking or participating in clinical audits/service evaluations	Those taking part in clinical audit/service evaluation activities are responsible for doing so in accordance with this policy and associated processes. All staff undertaking clinical audits/service evaluations are required to ensure that this activity is registered and approved as set out in this policy and associated processes. In addition they are also expected to ensure the clinical audit/service evaluation activity is of good quality, as described in this policy and associated processes, so as to provide expected assurances or lead to quality improvements.
All staff providing care and treatment	All staff providing care and treatment have a fundamental responsibility to provide care and treatment that is safe and effective. They must therefore comply with Trust policies and procedures. 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 and evaluate their own practice in accordance with their professional codes of conduct and in line with the standards set out within this policy. All clinical staff are expected to learn from the results of clinical audits/service evaluations and make any necessary improvements to their practice that may be required as a result.

7. **Procedure**

Details of procedures may vary slightly over time according to organisational need. More detail on procedures concerning clinical audit and service evaluation will be made available by the Clinical Effectiveness Team.

Clinical Audit Programme

Development

A priority clinical audit programme is developed each year by the Research, Innovation, Effectiveness and Improvement Group (RIEIG) and approved by the Quality Assurance Committee.

The Clinical Effectiveness Team (CET) will produce a draft programme based on the criteria set out in this policy. The draft programme will be further developed by the CET and RIEIG in consultation with commissioners and senior colleagues in clinical, quality and medical directorates. The draft Clinical Audit Programme will be presented to the Quality Assurance Committee for approval no later than April each year.

The RIEIG may make changes to the Clinical Audit Programme during the year so as to ensure it accurately reflects national audit programmes and remains responsive to organisational need.

Delivery

The Clinical Audit Programme will set out key expectations and timescales associated with each audit (where these are known). For each topic included on the programme, an audit plan will be developed during the year by the Clinical Effectiveness Team in collaboration with relevant stakeholders, and based on core standards, in particular NICE Quality Standards. The aim of each audit project is to evaluate and provide assurance, but also to establish an ongoing system of audit and evaluation so as to provide continuity of assurance. Some audit projects may last more than one year.

Each audit on the programme will have a clinical lead and be linked to the most relevant governance group. The use of clinical leads and governance groups help to ensure that priority clinical audits are embedded in SHSC priorities and processes. This will in turn help ensure that audits support improvement.

It is the responsibility of the clinical directorate, together with those named on the Clinical Audit Programme, to manage priority clinical audits within clinical services. Where audits cross service areas the clinical directors (knowing their local priorities) must liaise to ensure audits are managed in a timely and coherent manner.

Reporting and assurance

The RIEI Group has oversight of the Clinical Audit Programme. A status update on the programme will be presented to the group as required for purposes of assurance and to enable the group to identify and act on any areas of concern regarding programme delivery. The RIEIG will in turn offer assurance to the Trust Board of Directors, via the Quality Assurance Committee, in relation to clinical audit activity.

Following the completion of a clinical audit on the Clinical Audit Programme, a copy of the completed audit report will be shared with the RIEIG who may direct the clinical effectiveness team to share reports with other appropriate governance groups. For a number of audit projects on the programme the report may be a nationally produced report that may only be available a significant time after the data collection was carried out. Sharing of findings and wider dissemination of reports for all audits on the programme will normally be determined by the clinical effectiveness team, though may be directed by the RIEIG.

The Clinical Audit Programme, or elements thereof, is required to be reported to commissioners on a quarterly basis.

Where the results of a clinical audit suggest that practice is below the required standard, actions must be taken to ensure improvement. Such actions will be undertaken by the clinical areas the audit concerns, together with relevant clinical and managerial leadership. The RIEIG may seek assurance that action has been taken and improvements are made.

Local, or team-level, clinical audits and service evaluations
All locally undertaken clinical audits and service evaluations must be registered with the Clinical Effectiveness Team and approval must be obtained before they can proceed.

In order to register a project for approval, the Clinical Effectiveness Team should be contacted and the appropriate proposal or registration form completed.

Approval to proceed with a clinical audit or service evaluations will be given by the Clinical Effectiveness Team once they are satisfied that the project has appropriate support from the relevant clinical service and that the project plan meets requirements and expectations as set out in this policy and any accompanying procedures.

In cases where approval is not given the CET will give advice to the registrant as to what needs to be changed for approval to be given. It is hoped that such instances would be rare: the CET will aim to provide advice and support so as to help audit project plans to be of good quality prior to their submission.

Locally undertaken clinical audits and service evaluations must have an agreed project plan in place before they begin.

All locally undertaken clinical audits and service evaluations must produce a report, including methodology, findings and recommendations, and this must be shared with the Clinical Effectiveness Team.

Arrangements for acting findings from audits and evaluations must be agreed so as to ensure these projects are leading to effective quality improvements.

The processes associated with overseeing local clinical audits and service evaluations are managed by the Clinical Effectiveness Team.

Determining priorities for local audits
Team-level or ‘local’ clinical audits and service evaluations are encouraged in order to provide assurances in certain areas/services or to aid quality improvement. The choice of topic for a local clinical audit/service evaluation is important: such projects take time and resources so the topic should be an area of priority for a service and of potential benefit to the service or service users. Clinical audits and service evaluations should relate directly to the quality of patient care and should have a clearly stated quality improvement aim at the outset.

Clinical services are encouraged to carefully consider the areas of their care or service delivery that would benefit from the closer attention involved in a clinical audit or service evaluation project. This may be to evaluate new interventions or changes to the delivery of care, or to audit the quality of regular aspects of care and treatment. Clinical audits and service evaluations should only be undertaken if they are the most suitable methodology. Consideration should be given to whether findings are more easily determined via data reporting, or improvements are more effectively made by way of other quality improvement methods.

In deciding which clinical audits and service evaluations should be undertaken, the following factors should be considered:

- Clinical priorities, including clinical risks, adverse incidents, near-misses, and patient safety

- Organisational priorities, including service redesign and development
- Patient and service user priorities
- Commissioner priorities and specifications, including Commissioning for Quality and Innovation frameworks (CQUINs), National policies such as the NHS Long Term Plan, and NHS Standard Contract requirements
- Outputs from the National Clinical Audit and Patient Outcomes Programme (NCAPOP), and other national clinical audits

Clinical audits and service evaluations may be undertaken by individuals but it is recommended that a team/service are involved in determining the appropriate topic to be audited/evaluated. This is more likely to focus the topic on an area of priority (in terms of assurance required or improvements needed) and lead to sustained quality improvements. Care should be taken to ensure the management of the clinical service concerned is committed to making improvements in care if the audit or evaluation findings show the need for improvement.

It may be appropriate for the Clinical Effectiveness Team to work with the member of staff registering the audit/evaluation to ensure the choice of topic is suitable before further steps can be taken.

Involving students, researchers and other partners
Students or external partners may be involved in clinical audit, service evaluation or QI as part of or a condition of their training. Researchers may also be involved in one of these projects to inform a future piece of research. Where students of any profession, researchers or members of partner organisations are involved in a clinical audit or service evaluation project, this should be undertaken in line with guidance in this policy.

Every clinical audit should be carried out under the supervision of a senior clinician, especially where the project lead is undertaking the project as part of their training. Clinical services have a responsibility to ensure that anyone with access to their service, service users, data or other information has the appropriate authorisations to do so. All clinical audits and service evaluations must be undertaken in accordance with relevant data protection policies and legislation. If there is any doubt, advice should be sought from senior managers, information governance colleagues or the clinical effectiveness team.

Projects undertaken as part of education and training connected to university may be subject to the processes and requirements of that institution. In such cases, project leads should work closely with the Clinical Effectiveness Team to ensure that there are no conflicting requirements or expectations between SHSC policy and policies from other institutions. Particular attention should be paid to information governance where there is a possibility of service user information being transferred or stored outside of SHSC.

Supporting local audit activity
The Clinical Effectiveness Team will work with project leads and others involved in clinical audits and service evaluations to support their completion to a good standard and within timeframes. However, it is recognised that the Clinical Effectiveness Team can only offer limited guidance and support and that the completion and quality of a clinical audit/service evaluation project is the responsibility of those undertaking the project.

Monitoring local clinical audit/service evaluation activity
The ongoing processes associated with local clinical audit/service evaluation audits and will be monitored by the Clinical Effectiveness Team. The Clinical Effectiveness Team will

maintain a database of all clinical audit and service evaluation projects registered with the team. This database will be used to monitor the progress of projects, and may be used to report on this activity as required.

The Clinical Effectiveness Team may also wish to report on the detail of individual projects with appropriate governance groups or stakeholders to share good practice or highlight areas of concern. This may be in relation to the topic or methodology of the project or in relation to its findings.

Reporting, sharing of findings, and making improvements

A final audit/evaluation report / findings should be shared appropriately so as to inform relevant staff of its findings, with a view to leading to quality improvements being made. Sharing of a local clinical audit/service evaluation may be done via a presentation or via dissemination of the audit report.

A copy of the audit/service evaluation report / findings should be sent to the Clinical Effectiveness Team, who may share it with relevant staff members to inform future audits/service evaluations, quality improvement projects, and service development.

The main purpose of clinical audits and service evaluations is to deliver improvements in clinical practice and service delivery for the benefit of service users. Responsibility for acting on the findings of audit and evaluation projects lies with the clinical service the findings relate to. It is up to the relevant service to determine how best to act on the findings. Use of quality improvement methodologies is encouraged, though a simple action plan may be all that is required in some instances. It is important that consideration is given to how changes and improvements will be evaluated and how the topic will be monitored in future. An effective way of doing this is through repeated cycles of audit (or re-audit).

Where the project or findings relate to more than one service/team, it may be necessary or appropriate to coordinate improvements across services. Where findings may be of interest to a large number of teams/services the Clinical Effectiveness Team should be made aware of this. They may in turn inform relevant governance groups and support the coordination of improvement actions.

Ethics and consent

Clinical audit and service evaluation projects should not require formal approval from a research ethics committee. However one of the principles underpinning such projects is that the process should do good and should not do harm.

Clinical audits and service evaluations must always be conducted within an ethical framework. The ethical framework should consider the following four principles:

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

Any ethical concerns that arise during the design and planning of individual clinical audits/service evaluations should be addressed by the project leads, the Clinical Effectiveness Team and key stakeholders.

Any instances of serious shortcomings in patient care that come to light through clinical audits/service evaluations must be communicated to the clinical director of the service involved at the earliest opportunity, and appropriate steps are taken to address them.

Equality and diversity

SHSC aims to ensure that its healthcare services and facilities are not discriminatory and, wherever possible, 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. Clinical audit and service evaluation practices must take account of equality and diversity issues. The process for determining choice of projects, and the manner in which patient samples are selected, should not inadvertently discriminate against any groups in society based on their race, disability, gender, age, sexual orientation, religion, or belief. It is recommended that equality data is collected as part of clinical audits and service evaluations, to determine whether any particular groups of service users are experiencing variations in practice.

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

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

- Adequate, relevant, and not excessive
- Accurate
- Processed for limited purposes
- Held securely
- Not kept for longer than is necessary

Clinical audit activity must comply with 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.'*

It is standard practice for clinical audit reports to be anonymous and confidential i.e. not mentioning the names of service users or clinicians.

All clinical audit data must be stored securely, and anonymous and confidential.

The Trust has a set of policies relating to information governance, records management, data security, confidentiality etc which are available to all staff via the Trust website. Further advice and support can be sought from the Clinical Effectiveness Team or from the Trust's information governance officers.

Publication and external presentation

There may be instances where staff wish to share clinical audit or service evaluation findings and reports external to SHSC. In such instances it is essential that the information governance standards are adhered to. It is also normal practice when sharing findings outside of the organisation that the service the information is gathered from is not identified in the report or presentation.

Anyone wishing to publish clinical audit or service evaluation findings, or to share such findings external to the Trust, should seek senior approval.

The Clinical Effectiveness Team can provide advice and support if necessary.

8 Development, Consultation and Approval

- This policy version builds on and develops from previous versions.
- The revision of the policy and associated processes takes account of Healthcare Quality Improvement Partnership (HQIP) guidance on best practice in clinical audit, Care Quality Commission expectations, and commissioner expectations.
- Current review to bring policy in-line with SHSC's Research, Innovation and Effectiveness Strategy, and to reflect changes in governance arrangements.
- Consultation on policy drafts undertaken with Research Innovation Effectiveness and Improvement Group, Research Innovation and Effectiveness Strategy Steering Group.
- Updates to policy also made in response to ongoing feedback received by the Clinical Effectiveness Team from staff undertaking audits and evaluations, in particular concerning the processes involved in registering and undertaking local clinical audits and service evaluations.

9. Audit, monitoring and review

Monitoring Compliance Template						
Minimum Requirement	Process for Monitoring	Responsible Individual/ group/committee	Frequency of Monitoring	Review of Results process (e.g. who does this?)	Responsible Individual/group/ committee for action plan development	Responsible Individual/group/ committee for action plan monitoring and implementation
A) Delivery of annual Clinical Audit Programme	Review	Quality Assurance Committee and Research Innovation Effectiveness and Improvement Group	Annual	Quality Assurance Committee	Research Innovation Effectiveness and Improvement Group	Research Innovation Effectiveness and Improvement Group
B) Priority clinical audits are delivered in line with policy	Review	Research Innovation Effectiveness and Improvement Group	Quarterly	Research Innovation Effectiveness and Improvement Group	Research Innovation Effectiveness and Improvement Group	Research Innovation Effectiveness and Improvement Group
C) Local clinical audits and service evaluations are carried out in line with policy	Review	Clinical Effectiveness Team	Bi-annually	Research Innovation Effectiveness and Improvement Group	Research Innovation Effectiveness and Improvement Group and Clinical Effectiveness Team	Research Innovation Effectiveness and Improvement Group and Clinical Effectiveness Team

This policy is to be developed and updated alongside the delivery of the Research, Innovation and Effectiveness Strategy, and reviewed no later than November 2025.

10. Implementation plan

Action / Task	Responsible Person	Deadline	Progress update
Upload revised policy onto intranet and remove old version	Director of Corporate Governance		
Awareness raising of revised policy with Clinical Directorate management team and key staff	Clinical Effectiveness Manager	Within 6 weeks of policy ratification	
Review effectiveness of policy and processes	Clinical Effectiveness Manager	1 year after policy ratification	

11. Dissemination, storage and archiving (Control)

The Corporate Governance Team is responsible for the storage and dissemination of this policy.

This policy will be disseminated via the Sheffield Health and Social Care NHS Foundation Trust intranet and be made available to all staff.

The Director of Corporate Governance is responsible for making sure the new policy is inserted on the Trust intranet in the policies section.

Clinical and Service Directors are responsible for ensuring that all staff in their directorates are aware of new policies and know where to find them.

Some teams have paper policy files or archives for easy reference. It is the responsibility of the locality team manager to ensure that paper policy files are kept up to date and comprehensive, and that staff are made aware of new or revised policies. Older versions should be destroyed to avoid confusion. It is the responsibility of the team manager to make sure the latest version of a policy is available to all staff in the team.

It is the responsibility of the Director of Corporate Governance to maintain an archive of previous versions of policies, and to make sure that the latest version is the one which is posted on the Trust intranet. They will circulate a list of all Sheffield Health and Social Care NHS Foundation Trust policies at least annually to team managers and directors throughout the Trust.

Version	**Date added to intranet**	**Date added to internet**	**Date of inclusion in Connect**	**Any other promotion/ dissemination (include dates)**
5.0	November 2022	November 2022	November 2022	N/A

12. Training and other resource implications

There are no specific training implications with regards to this policy. The majority of tasks described within this policy fall within the skills, knowledge and job descriptions of senior managers and clinicians in the Trust.

The Clinical Effectiveness Team will provide informal training and support for staff on clinical audit and service evaluation and guide them through the processes described in this policy.

It is anticipated that the requirements of this policy can be met within current resources.

13. Links to other policies and standards (associated documents)

Clinical and Social Care Strategy
Research, Innovation and Effectiveness Strategy
Quality Strategy
Policy on Implementation of NICE Guidance
Confidentiality Code of Conduct Policy
Data and Information Acceptable Use Policy
Data and Information Governance Policy
Data and Information Sharing Policy
Records Management Policy

13.1 References

Best Practice in Clinical Audit, Healthcare Quality Improvement Partnership (HQIP), 2020

Caldicott Report, Caldicott Committee, Department of Health, 2013.

Clinical audit - A guide for NHS Boards and partners, Healthcare Quality Improvement Partnership (HQIP), 2021.

CQC Fundamental standards (CQC): https://www.cqc.org.uk/what-we-do/how-we-do-our-job/fundamental-standards

Data Protection Act, HMSO, 2018.

Developing a clinical audit policy, Healthcare Quality Improvement Partnership (HQIP), 2020.

Developing a clinical audit programme, Healthcare Quality Improvement Partnership (HQIP), 2020.

Documenting local clinical audit – a guide to reporting and recording, Healthcare Quality Improvement Partnership (HQIP), 2020.

Guidance for Providers, Care Quality Commission, 2015.

Guide to Ensuring Data Quality in Clinical Audit, Healthcare Quality Improvement Partnership (HQIP), 2010.

General Data Protection Regulation, (EU) 2016/679, 2016.

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

Promoting clinical effectiveness: a framework for action in and through the NHS, Department of Health,1996

Quality Accounts toolkit, Department of Health, 2010.

Quality improvement made simple, London: The Health Foundation, 2021

Strategic quality improvement: An action learning approach, The Kings Fund, 2016.

14. Contact details

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Appendix A

Equality Impact Assessment Process and Record for Written Policies

Stage 1 – **Relevance** - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? This should be considered as part of the Case of Need for new policies.

NO – No further action is required – please sign and date the following statement. **I confirm that this policy does not impact on staff, patients or the public.**	***I confirm that this policy does not impact on staff, patients or the public.*** Name/Date:	**YES,** Go to **Stage 2**

Stage 2 Policy Screening and Drafting Policy - Public authorities are legally required to have 'due regard' to eliminating discrimination, advancing equal opportunity and fostering good relations in relation to people who share certain 'protected characteristics' and those that do not. The following table should be used to consider this and inform changes to the policy (indicate yes/no/ don't know and note reasons). Please see the SHSC Guidance and Flow Chart.

Stage 3 – **Policy Revision** - Make amendments to the policy or identify any remedial action required and record any action planned in the policy implementation plan section

SCREENING RECORD	Does any aspect of this policy or potentially discriminate against this group?	Can equality of opportunity for this group be improved through this policy or changes to this policy?	Can this policy be amended so that it works to enhance relations between people in this group and people not in this group?
Age	**No**	**Yes**	**No**
Disability	**No**	**Yes**	**No**
Gender Reassignment	**No**	**Yes**	**No**
Pregnancy and Maternity	**No**	**Yes**	**No**

Race	**No**	**Yes**	**No**
Religion or Belief	**No**	**Yes**	**No**
Sex	**No**	**Yes**	**No**
Sexual Orientation	**No**	**Yes**	**No**
Marriage or Civil Partnership	**No**		

Please delete as appropriate: - ~~Policy Amended / Action Identified~~ (see Implementation Plan) / no changes made.

Impact Assessment Completed by: Clinical Effectiveness Manager
Name /Date October 2022