Sheffield Health and Social Care NHS Foundation Trust

Policy:

MD 009 Clinical Audit

Executive or Associate Director lead	Executive Medical Director
Policy author/ lead	Clinical Effectiveness Manager Associate Medical Director for Quality and Governance
Feedback on implementation to	Head of Clinical Governance

Document type	Policy
Document status	Final
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Date of consultation	April 2019
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Ratified by	Executive Directors' Group
Date of issue	7 June 2019
Date for review	30/11/2022 (Extended from 30/05/2022 by PGG on 30/05/2022)

Target audience	Directors and Senior Clinical Staff for Cascade

Keywords	

Policy Version and advice on document history, availability and storage

The original policy was drafted March 2011 and reviewed in March 2013 and March 2015. Version 3 of the Clinical Audit Policy reflected changes in local and national guidance and practice. Version 4, drafted in April 2019, contains minor amendments in order to keep the policy up to date.

The policy is available through the Trust Intranet and website

Contents

1. Introduction

Clinical Audit is seen by Sheffield Health and Social Care NHS Foundation Trust (SHSC) (hereafter referred to as 'the Trust') as a key process for assessing, improving and assuring the quality of care and treatment. The Quality Improvement and Assurance Strategy 2016 describes the Trust's vision, systems and processes for quality, including making best use of clinical audit.

Clinical audit is a proven method of quality improvement. It gives staff a systematic way of looking at their practice and making improvements. Clinical audit:

- Identifies and promotes good practice
- Leads to improvements in patient care
- Provides information about the effectiveness of a service
- Highlights problems and helps with solutions

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

Clinical audit links into both clinical effectiveness and clinical governance. Clinical effectiveness aims to identify and appraise existing evidence of best practice. Once identified, if necessary, local practice may be amended to ensure that it is conforming to best practice. Secondly, concerns regarding clinical care are often identified through other clinical governance structures. These concerns can often be used to inform a clinical audit project.

Clinical staff are expected to take part in clinical audits as part of their professional practice; for medical practitioners this is a requirement of their post and a core part of their training. Support for clinical audit is provided by the Clinical Effectiveness Team.

There are a number of national clinical audits that Trusts are expected to participate in and a review of clinical audits forms a mandatory element of the Trust's review of quality in its annual Quality Accounts (Quality Accounts toolkit, Department of Health, 2010).

Clinical audit is a key source of assurance for the Board and forms a key part of the of the Trust's Quality Framework.

The Trust is commissioned by NHS Sheffield Clinical Commissioning Group to deliver a clinical audit programme annually. It reports to the commissioner quarterly and at year end on the delivery of the programme.

The regulatory framework of the Care Quality Commission (CQC) requires registered healthcare providers to monitor the quality of their services. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 state providers must:
"17(2)(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services).
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. The audits should be baselined against Regulations 4 to 20A of the Health and Social

Care Act 2008 (Regulated Activities) Regulations 2014 and should, where possible, include the experiences people who use the service. The systems and processes should be continually reviewed to make sure they remain fit for purpose. Fit for purpose means that:

o Systems and processes enable the provider to identify where quality and/or safety are being compromised and to respond appropriately and without delay.
o Providers have access to all necessary information."

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 for clinical audits.

3. 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 a quality improvement process that measures current patient care and outcomes against agreed standards of best practice.

- Not all 'audit' is clinical audit.
- There is a difference between:
  - Clinical audit - audit against agreed standards of best practice
  - Research - aims to create new knowledge
  - Service evaluation - assesses the effectiveness of a service
- Clinical audit is not just a data collection exercise:
  - It involves measuring current patient care and outcomes against explicit audit criteria (also termed 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.

Clinical audit can be seen as a three dimensional process comprising of the clinical audit cycle and the audit spiral in which having measured quality or practice our outcomes lead to on-going and measureable (by further audit) outcomes:

Diagram 1: The Clinical Audit Cycle

Observe current practice

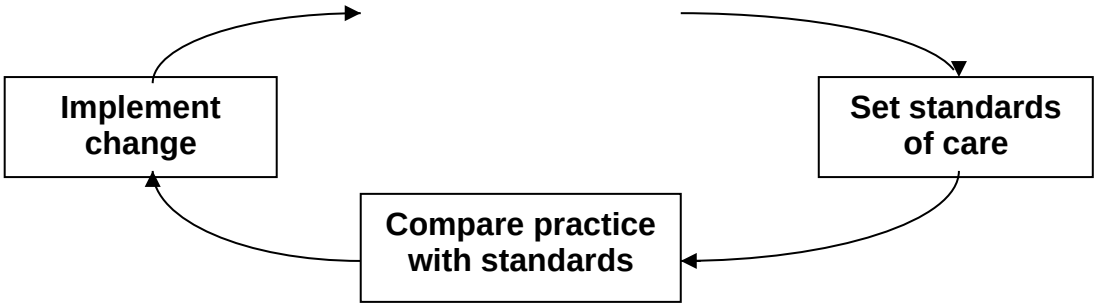
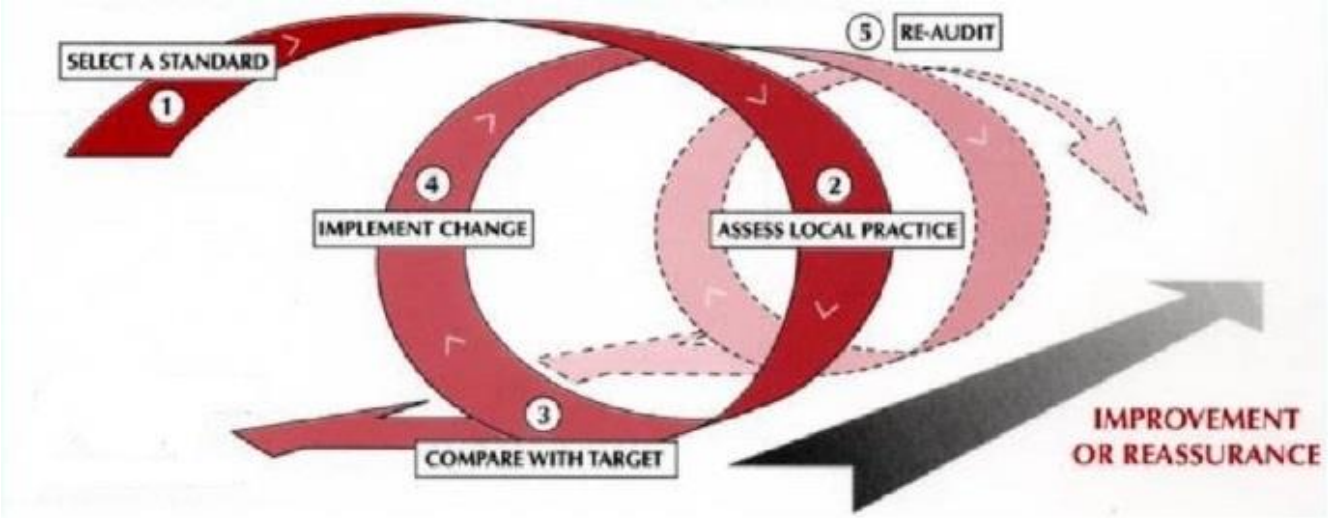

Implement change
Set standards of care
Compare practice with standards

Diagram 2: The Audit Spiral



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. Participation in national clinical audits is strongly encouraged by the Department of Health and Monitor: Trusts are expected to report on their participation in national audits in their Annual Quality Accounts (Quality Accounts toolkit, 2010).

Trust priority audits
The Trust has a Clinical Audit Programme that is approved each year. This focuses on Trust priorities including national audits, audits requested from NHS Sheffield Clinical Commissioning Group (CCG), and audits related to the Commissioning for Quality and Innovation programme (CQUINs). These audits are considered to be of particular importance and are likely to have findings that relate to a number of clinical areas.

Local (or team-level) clinical audits
A local audit is a more 'bottom up' and often smaller scale audit 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 are not included on the Clinical Audit Programme.

The difference between clinical audit and research
Research seeks new knowledge and identifies best practice and clinical audit ensures that existing knowledge is being put into practice and best practice is being carried out.

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 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.

CQUIN programme
The Commissioning for Quality and Innovation (CQUIN) framework is designed to support improvements in the quality of services and the creation of new, improved patterns of care through a programme of targets and improvements that the Trust is commissioned to achieve each year.

Quality improvement
'Quality improvement in health has many definitions, but it is commonly understood as an approach that enables an individual, team or organisation to improve performance by identifying and eliminating poor quality in any aspect of service delivery. Health organisations that adopt this approach commit to creating a culture in which constant evaluation and innovation thrives' (Strategic quality improvement: An action learning approach, The Kings Fund, 2016). Quality improvement involves designing and redesigning work processes and systems that deliver health care with better outcomes and lower cost, wherever this can be achieved.

Service evaluation
Service evaluation may be defined as: "A set of procedures to judge a service's merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes and costs" (NHS Executive, 1997). 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 audit may be one activity which takes place during a service evaluation, alongside other activities such as routine data gathering, incident reporting, and interviews with staff and service users.

Clinical effectiveness
'The extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are supposed to do, i.e., maintain and improve health and secure the greatest possible health gain from available resources' (Promoting Clinical Effectiveness: A Framework for Action In and Through the NHS, NHS Executive, 1996).

Clinical governance
'A framework through which the NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish' (A First Class Service: Quality in the New NHS, Department of Health, 1998).

4. Purpose

The purpose of this policy is to set out the Trust's approach to establishing clear structures and processes for clinical audit. It aims to ensure clinical audit fits into the Trust's governance and assurance systems and helps to improve the quality and safety of care.

5. 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 audit 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 is being utilised within the Trust to provide assurance on, and improvements to, clinical care. The Medical Director Chairs the Clinical Effectiveness Group (or may delegate this responsibility).
Associate Medical Director for Quality and Clinical Governance	Providing support and assistance to the Medical Director in respect of clinical audit processes. Chairs the Clinical Effectiveness Group (delegated authority from Medical Director). Provides clinical direction to clinical audit activity to ensure that the system and activity provide assurances on and improvements to clinical care.
Quality Assurance Committee (QAC)	Receives reports related to clinical audit activity from the Clinical Effectiveness Group (via the Executive Directors Group (EDG) as required) and offers assurance to the Trust Board of Directors in relation to this.
Executive Directors Group (EDG)	The Executive Directors Group is responsible for ensuring good quality care is delivered and best practice is followed by the staff within the clinical directorate, teams and services and professional groups they manage. The EDG receives reports from the Clinical Effectiveness Group related to clinical audit activity and provides assurance to Quality Assurance Committee as required.
Clinical Effectiveness Group (CEG)	The CEG directs and oversees clinical effectiveness across the Trust and provides assurance to the Board as to the effectiveness of clinical care and that quality improvements continue to be made. The Group oversees and monitors clinical quality improvement across the Trust via the use of clinical audit or other quality improvement methods. CEG will establish an annual priority clinical audit programme, ensuring that it delivers quality improvements, and report progress to the QAC. CEG will provide reports to the Executive Directors Group (EDG) and 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 Professional Leads	Clinical Directors are responsible for ensuring that the annual priority clinical audit programme is delivered within their service areas and to ensure that clinical audit activity is undertaken within those services in such a way as to result in quality improvements to, or assurances regarding, clinical care. Clinical Directors and Professional Leads have a role in acting as champions for clinical audit 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 They must also ensure that, through their governance structures, the results of clinical audits are reviewed and any actions required are identified and action taken accordingly. All Clinical Directors and Directors of clinical professional groups will be members of the CEG or included on the distribution list of the CEG.
Head of Clinical Governance	The Head of Clinical Governance 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 processes in the Trust.
Clinical Effectiveness Team	Day to day management of clinical audit processes outlined in this policy and appendices. Manage a process of registering and approval of local/team-level clinical audits. Maintain a database of clinical audits undertaken within the Trust. Support clinical teams to ensure required audit is prioritised. Work with other members of staff to support the completion of audits and action plans. Provide advice for staff undertaking clinical audits to support the completion of clinical audits that are of good quality. Support the implementation of action plans in order to demonstrate quality improvements made. Monitor and report the progress of all clinical audit activity through monthly reports to CEG. Prepare and recommend to CEG the required annual priority clinical audit programme. Prepare and recommend to CEG the required quarterly reports to EDG/QAC and to commissioners. Co-ordinate the inclusion of compliance with NICE guidance into clinical audits being undertaken. Co-ordinate and direct, with recommendations to CEG, clinical audit activity to ensure it addresses identified areas where assurance or quality improvement is required and so as to avoid where possible duplication with other quality improvement activities.

Senior Clinicians	Senior clinicians will be responsible for supervising clinical audit activity as required
Service Directors and clinical directorate management teams	Service directors and clinical directorate management 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 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; ensuring that, through their governance structures, the results of clinical audits are reviewed and any actions required are identified and action taken accordingly; ensuring they have due oversight of clinical audit activity undertaken within their directorates; ensuring that any local clinical audits that involve more than one team are approved by the appropriate governance group and that this governance group is responsible for any action planning resulting from the audit.
Team managers, clinical leads, team governance groups	Team managers, clinical leads and team governance groups are responsible for working with Clinical Directors, Professional Leads and the Clinical Effectiveness Team to ensure that the annual priority clinical audit programme is delivered within their teams and to ensure that clinical audit activity is undertaken within their teams in such a way as to resulting in quality improvements to or assurances on clinical care. This will include: ensuring that staff within their teams comply with the requirement to lead, participate or contribute information to clinical audits; ensuring that, through appropriate governance structures, the results of clinical audits are reviewed and any actions required are identified and action taken accordingly; ensuring they have due oversight of clinical audit activity undertaken within their teams; identifying the need for clinical audits within their teams; agreeing to and approving local clinical audits to be conducted within their teams; ensuring that any recommendations and findings of team-level audits conducted within their teams are reported back and that the appropriate governance groups are involved in any resulting action planning.
All staff undertaking or	Those taking part in clinical audit activities are responsible for doing so in accordance with this policy and associated processes.

participating in clinical audits	All staff undertaking clinical audits 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 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 clinical staff are expected to be aware of the priority clinical audit programme, as well as any local audits being undertaken in their area of work, and to contribute as appropriate to their job role and as required by their managers and professional bodies. They are expected to learn from the results of clinical audits and make any necessary improvements to their practice that may be required as a result.

6. Process

Clinical Audit Programme

The Trust has an annual process for prioritising topics in relation to clinical audit. This includes both national and local audits and is in line with Healthcare Quality Improvement Partnership guidance (2016) that annual audit plans should prioritise (required) national audits and local audits from stakeholders (e.g. NHS Sheffield Clinical Commissioning Group and Care Quality Commission) over local ad hoc audit.

A priority clinical audit programme is developed each year by the Clinical Effectiveness Group and approved by the Quality Assurance Committee. This focuses on Trust priorities including national audits, audits requested from NHS Sheffield Clinical Commissioning Group (CCG), and audits related to the Commissioning for Quality and Innovation programme (CQUINs). This clinical audit programme will include audits national clinical audits that are expected to be reported as part of the Trust's annual Quality Account.

A process for how the priority clinical audit programme is developed, monitored and reported will be attached to this policy. The detail of this process may change over time according to organisational need.

Local or team-level clinical audits

In addition to the Clinical Audit Programme, 'local' or team-level clinical audits are encouraged. These tend to be smaller scale and will be carried out as part of a quality improvement initiative in a team or on a ward.

All local audits must be registered with the Clinical Effectiveness Team and approval must be obtained before they can proceed. Local audit projects must have an agreed project plan in place before they begin.

All local audits must produce a report, including methodology, findings and recommendations, and this must be shared with the Clinical Effectiveness Team.

Arrangements for action planning and sharing findings from local audits must be agreed so as to ensure clinical audits are leading to effective quality improvements.

The Clinical Effectiveness Team will maintain a database of all local audits. Amongst other uses, this will be used to help direct the appropriateness of audit topics and to ensure oversight of the completion of clinical audits. Monitoring and reporting arrangements will be in place via the Clinical Effectiveness Group.

The processes associated with overseeing local clinical audits will be attached to this policy. This includes detail of monitoring and reporting arrangements. The detail of these processes may change over time according to organisational need.

Clinical Audit and other Trust activity

It is recognised that a number of Quality Improvement projects or activities undertaken by the Trust contain clinical audit. It is important that this clinical audit is still undertaken and managed robustly to ensure that the output from it can be used to provide assurance against the Trust's priorities and objectives. All Clinical Audit activity undertaken by or within the Trust must follow the processes outlined above for 'priority' or 'local' clinical audits.

A variety of quality improvement activities are undertaken by and within the Trust that are not clinical audit. These may be service evaluations, 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 activities covered by this policy will aim to work in conjunction with other types of quality improvement activity.

7. 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.

An 'All SHSCT staff' email alert should be sent to all staff telling them of the new policy and where to find it. 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.

Additional promotion of the policy will take place through further publicity such as articles in Sheffield Health and Social Care NHS Foundation Trust newsletters and other staff briefings.

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.

8. 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 guide them through the processes described in this policy.

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

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 Clinical Effectiveness Group	Annual	Quality Assurance Committee	Clinical Effectiveness Group	Clinical Effectiveness Group
B) Priority clinical audits are delivered in line with policy	Review	Clinical Effectiveness Group	Monthly	Clinical Effectiveness Group	Clinical Effectiveness Group	Clinical Effectiveness Group
C) Local clinical audits are carried out in line with policy	Review	Clinical Effectiveness Group	Monthly	Clinical Effectiveness Group	Clinical Effectiveness Group and Clinical Effectiveness Team	Clinical Effectiveness Group and Clinical Effectiveness Team

10. Implementation plan

Action / Task	Responsible Person	Deadline	Progress update
Upload revised policy onto intranet and remove old version	Director of Corporate Governance		
Email to ‘all SHSC staff’ to alert them to the revised policy	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	
Make available the resources outlined within this policy and process	Clinical Effectiveness Manager	Within 3 months of policy ratification	
Review effectiveness of policy and processes	Clinical Effectiveness Manager	1 year after policy ratification	

11. Links to other policies, standards and legislation (associated documents)

Trust Annual Plan
Quality Improvement and Assurance Strategy
Policy on Responding to National Confidential Inquiries and Other National Inquiries and Reviews
Policy on Implementation of NICE Guidance
Policy on Data and Information Governance
Policy on Data and Information Quality Management
Policy on Records Management

12. Contact details

Title	***Name***	***Phone***	***Email***
Medical Director	Mike Hunter	64838	Mike.Hunter@shsc.nhs.uk
Associate Clinical Director	Jonathan Mitchell	50720	Jonathan.Mitchell@shsc.nhs.uk
Head of Clinical Governance	Tania Baxter	63279	Tania.Baxter@shsc.nhs.uk
Clinical Effectiveness Manager (Clinical Effectiveness Team)	Jonathan Burleigh	18540	Jonathan.Burleigh@shsc.nhs.uk
Clinical Audit Facilitator (Clinical Effectiveness Team)	Philip Jonas	18950	Philip.Jonas@shsc.nhs.uk

13. References

Clinical audit - A simple guide for NHS Boards and partners, Healthcare Quality Improvement Partnership (HQIP), 2010.

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

Ethics and Clinical Audit and Quality Improvement, Healthcare Quality Improvement Partnership (HQIP), 2010.

NHSLA Risk Management Standards Standard 2 – Criterion 2.1

Quality Accounts toolkit, Department of Health, 2010.

Essential Standards of Quality and Safety, Care Quality Commission, 2010.

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

Data Protection Act, HMSO, 2018.

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

Criteria and Indicators of Best Practice in Clinical Audit, Healthcare Quality Improvement Partnership (HQIP), 2009.

Developing a clinical audit programme, Healthcare Quality Improvement Partnership (HQIP), 2016.

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

Promoting Clinical Effectiveness: A Framework for Action In and Through the NHS, NHS Executive, 1996.

A First Class Service: Quality in the New NHS, Department of Health, HMSO, London, 1998.

Appendix A – Version Control and Amendment Log

Version No.	Type of Change	Date	Description of change(s)
1.0	Original policy ratified	March 2011	
1.1	Reviewed policy	March 2013	Policy reviewed to reflect revised governance structures
1.2	Reviewed policy	March 2015	Policy reviewed to reflect revised governance structures
2.0	Revised policy	Feb 2016	Revised policy ratified
3.0	Draft of revised policy created	Feb 2017	Full review and revision of policy
3.0	Revised policy ratified and issued	May 2017	Minor redrafting following consultation. Policy verified by Clinical Effectiveness Group in March 2017.
4.0	Reviewed policy	May 2019	Policy reviewed to reflect revised governance structures and other minor updates

Appendix B – Dissemination Record

Version	Date on website (intranet and internet)	Date of "all SHSC staff" email	Any other promotion/ dissemination (include dates)

Appendix C – Stage One Equality Impact Assessment Form

Equality Impact Assessment Process for Policies Developed Under the Policy on Policies

Stage 1 – Complete draft policy

Stage 2 – **Relevance** - Is the policy potentially relevant to equality i.e. will this policy potentially impact on staff, patients or the public? If **NO** – No further action required – please sign and date the following statement. If **YES –** proceed to stage 3

This policy does not impact on staff, patients or the public (insert name and date) Jonathan Burleigh. March 2017

Stage 3 – **Policy Screening** - 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 on equality impact assessment for examples and detailed advice. This is available by logging-on to the Intranet first and then following this link https://nww.xct.nhs.uk/widget.php?wdg=wdg_general_info&page=464

	Does any aspect of this policy actually 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			
DISABILITY			
GENDER REASSIGNMENT			
PREGNANCY AND MATERNITY			
RACE			
RELIGION OR BELIEF			
SEX			
SEXUAL ORIENTATION			

Stage 4 – **Policy Revision** - Make amendments to the policy or identify any remedial action required (action should be noted in the policy implementation plan section) Please delete as appropriate: Policy Amended / Action Identified / no changes made.

Impact Assessment Completed by (insert name and date)

Appendix D - Human Rights Act Assessment Form and Flowchart

You need to be confident that no aspect of this policy breaches a person's Human Rights. You can assume that if a policy is directly based on a law or national policy it will not therefore breach Human Rights.

If the policy or any procedures in the policy, are based on a local decision which impact on individuals, then you will need to make sure their human rights are not breached. To do this, you will need to refer to the more detailed guidance that is available on the SHSC web site
http://www.justice.gov.uk/downloads/human-rights/act-studyguide.pdf
(relevant sections numbers are referenced in grey boxes on diagram) and work through the flow chart on the next page.

1. Is your policy based on and in line with the current law (including case law) or policy?

✓ **Yes. No further action needed.**

☐ **No. Work through the flow diagram over the page and then answer questions 2 and 3 below.**

2. On completion of flow diagram – is further action needed?

☐ **No, no further action needed.**

☐ **Yes, go to question 3**

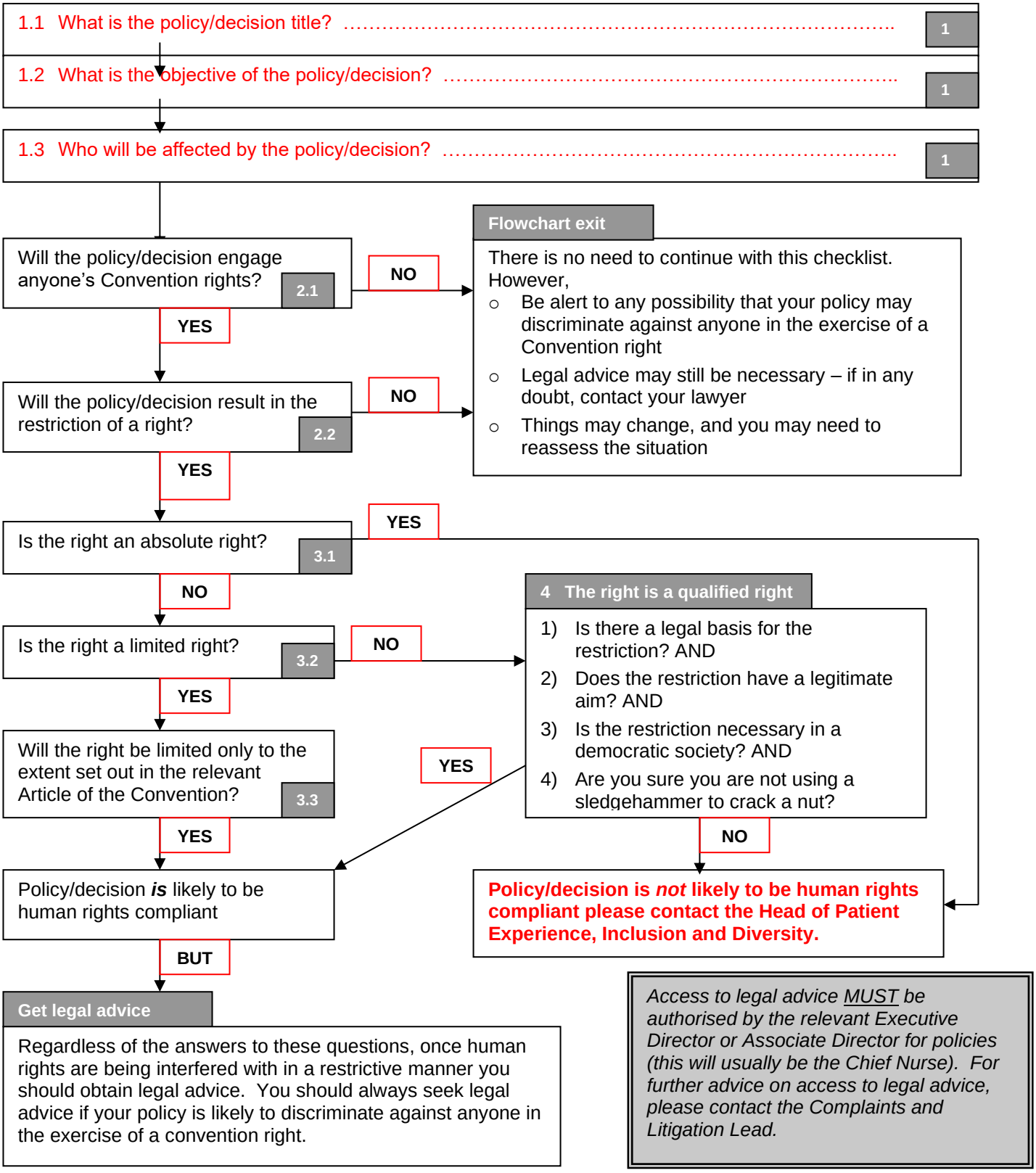
3. Complete the table below to provide details of the actions required

Action required	By what date	Responsible Person

Human Rights Assessment Flow Chart

Complete text answers in boxes 1.1 – 1.3 and highlight your path through the flowchart by filling the YES/NO boxes red (do this by clicking on the YES/NO text boxes and then from the Format menu on the toolbar, choose 'Format Text Box' and choose red from the Fill colour option).

Once the flowchart is completed, return to the previous page to complete the Human Rights Act Assessment Form.



Appendix E – Development, Consultation and Verification

The revision of the clinical audit policy was prompted by discussion at the Quality Assurance Committee as well as the Care Quality Commission report resulting from the inspection in May 2016 of the 'Well Led' domain.

The processes associated with clinical audit have been developed and altered under the oversight of the Clinical Effectiveness Group since it was established in 2015. The policy required revision to bring policy and practice in line.

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. It has also been revised in line with the Internal Audit review of clinical audit conducted in 2016/17.

Feedback on the draft revised policy was sought from Directorate Management Teams, professional leads, senior clinical staff, the care standards team, and others known to have an interest in this policy.

The policy was discussed at, and verified by, the Clinical Effectiveness Group in their role of overseeing clinical audit within the Trust.

The policy was revised in accordance with governance processes in April 2019, making minor changes in order to keep the policy up to date. The revised policy was verified by the Clinical Effectiveness Group in April 2019.

Appendix F –Policies Checklist

Please use this as a checklist for policy completion. The style and format of policies should follow the Policy template which can be downloaded on the intranet (also shown at Appendix G within the Policy).

1. Cover sheet ☐

All policies must have a cover sheet which includes:

- The Trust name and logo ☐
- The title of the policy (in large font size as detailed in the template) ☐
- Executive or Associate Director lead for the policy ☐
- The policy author and lead ☐
- The implementation lead (to receive feedback on the implementation) ☐
- Date of initial draft policy ☐
- Date of consultation ☐
- Date of verification ☐
- Date of ratification ☐
- Date of issue ☐
- Ratifying body ☐
- Date for review ☐
- Target audience ☐
- Document type ☐
- Document status ☐
- Keywords ☐
- Policy version and advice on availability and storage ☐

2. Contents page

3. Flowchart ☐

4. Introduction ☐

5. Scope ☐

6. Definitions ☐

7. Purpose ☐

8. Duties ☐

9. Process ☐

10. Dissemination, storage and archiving (control) ☐

11. Training and other resource implications ☐

12. Audit, monitoring and review ☐

This section should describe how the implementation and impact of the policy will be monitored and audited and when it will be reviewed. It should include timescales and frequency of audits. It must include the monitoring template as shown in the policy template (example below).

Monitoring Compliance Template						
Minimum Require-ment	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) Describe which aspect this is monitoring?	e.g. Review, audit	e.g. Education & Training Steering Group	e.g. Annual	e.g. Quality Assurance Committee	e.g. Education & Training Steering Group	e.g. Quality Assurance Committee

13. Implementation plan ☐

14. Links to other policies (associated documents) ☐

15. Contact details ☐

16. References ☐

17. Version control and amendment log (Appendix A) ☐

18. Dissemination Record (Appendix B) ☐

19. Equality Impact Assessment Form (Appendix C) ☐

20. Human Rights Act Assessment Checklist (Appendix D) ☐

21. Policy development and consultation process (Appendix E) ☐

22. Policy Checklist (Appendix F) ☐

Appendix G

Processes Associated with Clinical Audits

Annual Priority Clinical Audit Programme

Setting priorities for the annual priority Clinical Audit Programme
The criteria for selecting priorities for clinical audit in the Trust are as follows:

All audits on the annual priority Clinical Audit Programme must all be relevant to the Trust and to assessing, improving and assuring the quality of care and treatment.

A number of clinical audits that are included on the Clinical Audit Programme will be determined by expectations and obligations the Trust must deliver. They will fall within the following categories:

- National Audits (list obtainable from the Healthcare Quality Improvement Partnership (HQIP))
- National Institute for Health and Clinical Excellence (NICE) guidance, including commissioner expectations for 'deep dives' into particular pieces of guidance
- Audits linked to the Trust CQUIN programme
- Other key Trust priority topics.

Other clinical audits included on the Clinical Audit Programme will be determined according to Trust priorities. Priority topics will be selected by the Clinical Effectiveness Group, and will be influenced by:

- 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.

Developing the Clinical Audit Programme
The Clinical Effectiveness Team (CET) are responsible for drafting the annual priority Clinical Audit Programme. This will be done using the priorities set out above. It will, in part, be drafted in consultation with commissioners so as to ensure that commissioner expectations are incorporated.

The draft Clinical Audit Programme will be presented to the Clinical Effectiveness Group (CEG) no later than March each year. Further consultation and development of the draft programme may then take place. Members of the CEG are responsible for ensuring that priority topics from within their areas of responsibility are incorporated into the programme as appropriate. The CEG are responsible for agreeing the Clinical Audit Programme and recommending it to the Quality Assurance Committee for approval. The Quality Assurance Committee will approve the programme no later than the end of April each year.

Once approved, the Clinical Audit Programme will be disseminated across the Trust.

Delivery of the Clinical Audit Programme
The Clinical Effectiveness Team (CET) will support the Clinical Effectiveness Group (CEG) in ensuring that, for all audits on the programme, the clinical services responsible for delivering the audit are identified, a senior managerial lead is identified and a member of staff is identified for leading the conducting of the audit. This information will be added to the programme.

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.

The Clinical Audit Programme will set out key expectations and timescales associated with each audit (where these are known).

Following the completion of a clinical audit on the Clinical Audit Programme, a copy of the completed audit report will be shared with the CET who will in turn ensure this is shared with the CEG. 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. It is recognised that on occasion such national reports are not readily available.

For all audits on the programme requiring submission of data to a third party (e.g. national audits), the CET will keep a copy of results in order to facilitate local analysis. Where appropriate this data will be analysed and reported prior to, or in addition to, national data reporting.

Sharing of findings and wider dissemination of reports for all audits on the programme will be determined by the CEG.

Where the results of a clinical audit suggest that practice is below the required standard, an action plan should be produced, implemented and monitored. The CEG will seek assurance that an action plan is developed and improvements are made. Where appropriate the CEG may determine arrangements for developing, monitoring and reporting progress against each action plan.

Monitoring and reporting on the delivery of the Clinical Audit Programme
The processes associated with clinical audit are overseen within the Trust by the Clinical Effectiveness Group (CEG) which reports to the Executive Directors Group (EDG) and Quality Assurance Committee (QAC).

The Clinical Audit Programme will be monitored by Clinical Effectiveness Team (CET) by use of a database or spreadsheet. This will be used to track progress on:

- Identifying responsibilities and lead staff for each audit
- Data collection, including where appropriate: development of methodologies, data collection tools, identification of staff to complete data collection, submission of data, analysis of data
- Arrangements for audit reports, including sharing with CEG
- Arrangements for sharing audits, as determined by CEG
- Arrangements for audit action plans, as determined by CEG
- Arrangements for re-audits where appropriate/known.

All of the above will be monitored against any known timeframes.

Each (monthly) meeting of the CEG will receive and update and exception report based on the information outlined above.

Exception reporting will identify all instances where expected timeframes have been exceeded together with other areas of concern that may affect the delivery of an audit.

Where these reports to CEG identify that individuals/groups have not complied with the expected processes and timeframes outlined for an audit, the Chair of CEG will contact the individual/chair of the group to request explanation and agree a method of getting the process back on track.

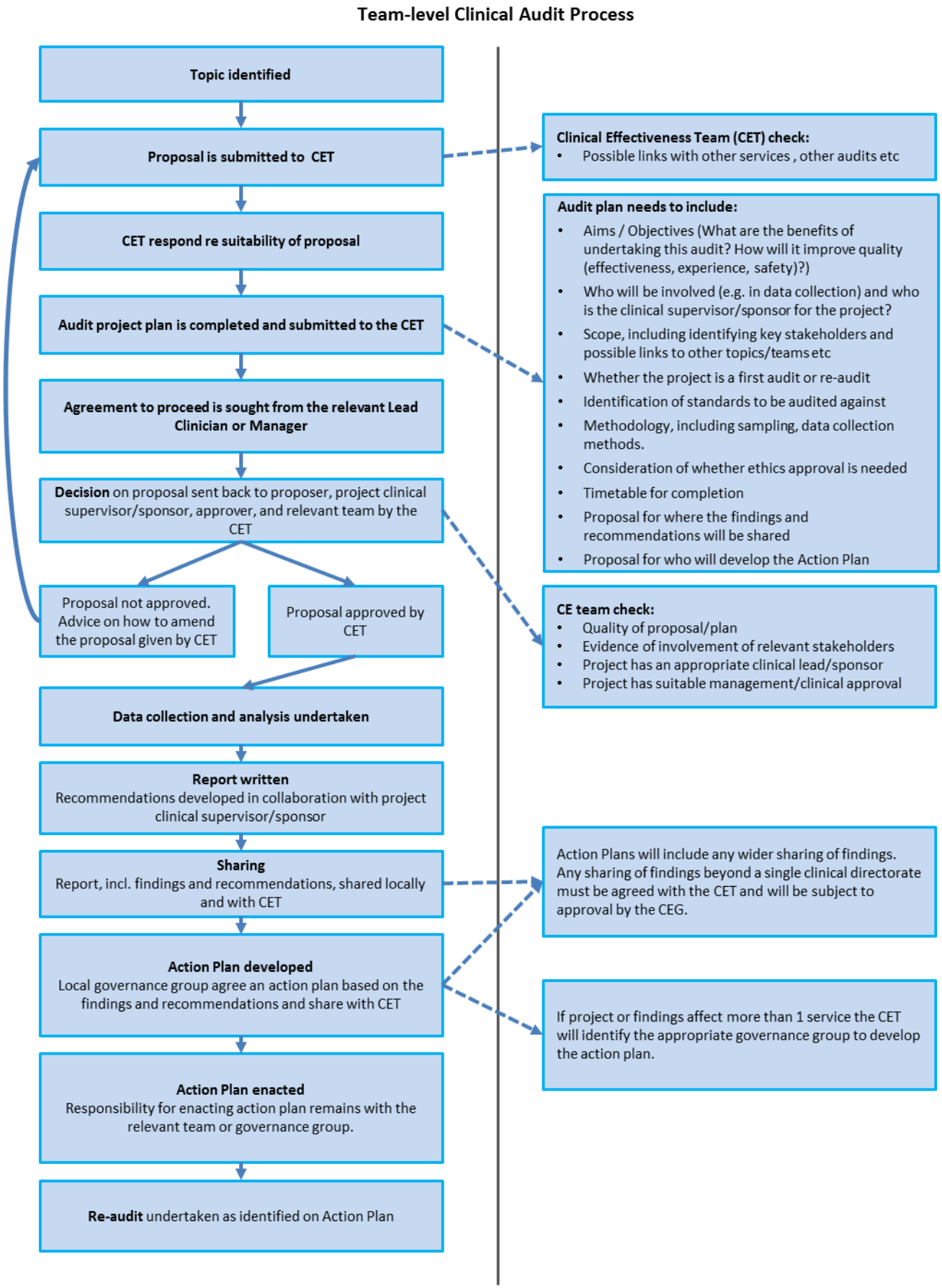
For audits on the Clinical Audit Programme, the Clinical Effectiveness Group will also receive:

- Completed audit reports
- Local data analysis where appropriate (e.g. in the absence of a report for national audits)
- Draft action plans for approval (where determined appropriate)
- Progress updates on action plans (as and when requested by CEG)

The Clinical Audit Programme, or elements thereof, is required to be reported to commissioners on a quarterly basis. CEG will have oversight of such submissions and approve their sharing with commissioners. Compliance with commissioner expectations of reporting, together with any significant comments from commissioners on such submissions, will be included in quarterly reporting to the EDG/QAC.

Each quarter the CEG will provide an assurance report to the QAC that will include progress against the Clinical Audit Programme including any exception reporting CEG wish to escalate. The QAC in turn will offer assurance to the Trust Board of Directors in relation to clinical audit activity. These reports will also be presenting to the EDG as appropriate/required. As appropriate, CEG may wish to provide an exception report to the EDG and/or QAC outside of quarterly reporting timescales.

Local or team-level clinical audits



Determining priorities for local audits
Team-level or 'local' clinical audits 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 is important: clinical audit 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 audit needs to be justifiable in terms of the benefits it will bring about for service users balanced against the amount of time and resources it takes. Clinical audit topics should relate directly to the quality of patient care; i.e. to clinical effectiveness, patient safety or the patient experience. What is important is to design a clinical audit project which will produce meaningful data and recommendations within the time and resources available, and, most importantly, lead to quality improvements.

Clinical audits may be undertaken by individuals but it is recommended that a team/service are involved in determining the appropriate topic to be audited. 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 clinical audit findings show the need for improvement.

The Clinical Effectiveness Team can assist in the choice of clinical audit topics by advising on:

- The suitability of clinical audit for the topic. In some cases there might be a more appropriate way to tackle a quality problem rather than through clinical audit.
- Links to other work – previous, ongoing or planned. This may be clinical audits done on related topics, team-level quality improvement work (such as microsystems), national audits and CQUINs.
- Whether the audit (or a similar audit) has been done previously.

The scope of each audit needs to be considered from the beginning stages of planning an audit project. Scope will be determined by the required data for the audit and the potential impact of expected findings. In most cases local audits will be connected to one team/service. In these instances data will only be from/about that service and its service users and the expected findings are only likely to impact on that single service. If data collection and expected findings are to cross more than one team/service than each of these teams/services need to be involved in planning and agreeing to the project. Where more than one service is involved all decisions regarding agreement to proceed, sharing the findings and action planning must also involve the relevant clinical network management team.

Registering and approval of clinical audit projects
All clinical audit projects must be registered with the Clinical Effectiveness Team (CET). The CET will maintain a database of these audits which will include their registration, project plan and audit report.

The registration of a local audit will be via an electronic form (made available by the CET) and will be viewed as an intention to carry out an audit project. This will initiate a process of determining whether the choice of topic is appropriate and whether the methodology and project plan are acceptable. On receipt of an audit registration form a member of the CET will respond within 1 week outlining the steps required for approval of the audit.

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

Following registration of a clinical audit topic, an audit project plan must be submitted in order for approval to be given and before the audit can begin. This plan must include:

- Topic
- Aims/Objectives
- Scope
- Stakeholders

- Project team
- Clinical supervision (where appropriate)
- Standards to be audited against
- Methodology
- Consideration of whether ethics approval is needed
- Timetable for completion
- Plans for writing up the project
- Initial plans for sharing and presenting the findings and recommendations
- Initial suggestions for who will develop the Action Plan

All local clinical audits must be approved before they can be undertaken. A clinical audit must not commence until written approval is received. Approval will be subject to receipt of a complete audit project plan that is deemed by the CET to be of sufficient quality, as well as written confirmation that a senior member of staff (e.g. team manager, consultant, clinical director, assistant service director) has agreed the audit can proceed. Each clinical audit requires senior agreement that it may proceed. This will be a senior member of staff who has acknowledged that they are aware of the project and are happy for the audit to be undertaken. In most circumstances this should be a senior clinician (such as clinical lead) in the team where the audit will be undertaken. The CET may need to advise on who the most appropriate senior member of staff should be, dependent on the scope of the audit project.

Once a completed audit project plan has been received, along with senior agreement, the CET will inform the member of staff submitting the project plan within 2 weeks whether they may proceed with the audit or not.

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.

Monitoring and supporting local audit activity

The ongoing processes associated with local clinical audits will be monitored by the Clinical Effectiveness Team (CET) and overseen by the Clinical Effectiveness Group (CEG).

The CET will work with project leads and others involved in clinical audits to support their completion to a good standard and within timeframes. However, it is recognised that the CET can only offer limited guidance and support and that the completion and quality of a clinical audit project is the responsibility of those undertaking the project.

The CET will use the audit database (outlined above) to monitor progress of local clinical audits. Each meeting of the CEG will receive and update and exception report based on this information. Exception reporting will identify significant concerns noted by the CET relating to completion or quality of local audits.

The CET may report the detail of particular local audits to the CEG where they feel the CEG's oversight/awareness would be appropriate. This may be due to the scope of the audit project or its findings. It may be due to significant negative findings that the CEG members should be made aware of, or areas of quality improvement that may be rolled-out more widely. In particular the CET will look to report to the CEG any audits they feel should be included on the Clinical Audit Programme at that time or in the future.

Reporting of local clinical audits
All local clinical audits must be written up in a report which must be shared with the CET, who will store them on the clinical audit database.

The Clinical Effectiveness Team provides a report template that should be used whenever possible.

The audit report must include not only the data analysis/findings but also a set of recommendations that can be used to develop an action plan. The final report acts as the official record of the clinical audit. It should include all the information needed to plan a re-audit.

Sharing (including presentation/dissemination)
A final audit report 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 audit may be done via a presentation or via dissemination of the audit report.

Wherever findings are to be shared with a service, agreement from management of that service should be sought beforehand.

Where findings are to be shared with more than 1 service/team the clinical network management team needs to be involved and will direct how this should be done.

Where findings may be of interest to a large number of team/services the Clinical Effectiveness Team should be made aware of this. They may in turn inform the Clinical Effectiveness Group, as appropriate, who may direct how and where the audit findings will be shared and how quality improvement will be achieved from the project.

Action planning
If the findings from a clinical audit are to lead to quality improvement it is likely that an action plan will need to be developed, based on the recommendations from the audit. It is recognised that not all audits will require action plans. This should be made clear in the audit report.

A template action plan will be provided by the Clinical Effectiveness Team (CET) to ensure all relevant fields are included.

The action plan will need to be developed by team/service/professional group who are going to implement it, or the appropriate governance group / leadership.

Where the audit or findings relate to more than one service/team, the clinical network management team needs to be involved in action planning.

Where findings may be of interest to a large number of team/services the Clinical Effectiveness Team should be made aware of this. They may in turn inform the Clinical Effectiveness Group, as appropriate, who may direct action planning and monitoring arrangements.

Monitoring action plans and carrying out re-audits
The action plans developed in response to clinical audits must be monitored and updated by the teams or clinical networks concerned via local governance meetings or groups.

Review and updating of actions plans should consider the impact of the action taken as well as whether the agreed task has been completed. An effective way of doing this is through a repeat audit or re-audit.

Guidance on ensuring good quality in clinical audits is maintained
Guidance on appropriate standards and data quality can be found in the HQIP publication *Guide to Ensuring Data Quality in Clinical Audit*.

By definition, clinical audit involves measuring clinical practice against predetermined standards of best practice. Standards should have validity i.e. they should be capable of giving a true picture of what is being audited. They should have sensitivity i.e. they should pick up problems. They should 'flag' all or almost all cases in the audit for where there is a problem with the quality of care provided and not miss cases where care was poor.

The *Guide to Ensuring Data Quality in Clinical Audit* provides further guidance on how to test for validity, sensitivity and specificity of standards.

The Guide defines data quality in clinical audit as data that is:

- accurate
- available or accessible
- complete
- fit for purpose
- relevant
- reliable
- timely and valid

It provides useful guidance on the selection of the right cases, finding the right data, ensuring the data collection processes produce reliable data, and how to validate data collection and data collation.

Clinical audit practice must take account of equality and diversity issues. For example, the process for determining the choice of clinical audit projects and the choice of service user samples should not inadvertently discriminate against any groups in society based on age, disability, gender reassignment, marital status and civil partnership, pregnancy and maternity, race, religion and belief, sex, sexual orientation. It is recommended that equality data is collected as part of clinical audits, to determine whether any particular groups of service users are experiencing variations in practice.

All clinical audit activity must take account of the Data Protection Act (2018) and the Caldicott Principles (2013.) Data should be:

- adequate, relevant and not excessive
- accurate
- processed for limited purposes
- held securely
- disposed of securely and not held for longer than 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 e.g. by use of Insight or NHS numbers rather than names of patients.

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.