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NHS
Sherwood Forest Hospitals
NHS Foundation Trust

CLINICAL AUDIT POLICY

Policy

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Lead Division/ Directorate	*Corporate*		
Lead Specialty/ Service/ Department	*Improvement Faculty*		
Position of Person able to provide Further Guidance/Information	*Audit and Improvement lead officer.* *A summary of the information or guidance that has been used to develop the policy is as follows:* • *Healthcare Quality Improvement Partnership (HQIP) – www.hqip.co.uk*		

	• *New Principles of Best Practice in Clinical Audit – 2011 Robin Burgess* • *Data Protection Act (1998) HMSO* • *Caldicott Report (1997). Department of Health*

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
Improvement and Clinical Audit Group Terms of Reference	*April 2022*
Template control	April 2024

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APPENDICIES

1.0 INTRODUCTION

This policy is issued and maintained by the Director of Culture and Improvement on behalf of the Trust and supersedes and replaces the previous Clinical Audit Policy from 2022.

The policy sets out Clinical Audit work-streams within Sherwood Forest Hospitals NHS Foundation Trust (the Trust) and the way in which they are implemented and monitored. This Clinical Audit Policy gives staff within the Trust comprehensive guidance in relation to all Clinical Audit activity.

This policy describes the practice required for all stages of the Clinical Audit process, with the aim of ensuring that Clinical Audits are undertaken in a robust and systematic manner and provides specific information in relation to the following:

How the Trust sets priorities for audit, including ensuring that both local and national requirements are met

How audits should be conducted in line with the approved Clinical Audit process

Information about how audits are shared

How national confidential enquires are managed

The format for audit reports, including methodology, conclusions and action plans, etc.

How the Trust make improvements as a result of audits

How risks and shortfalls are managed and addressed

How the Trust monitors actions plans and carries out re-audits

How the Trust monitors the documented process and monitors compliance with all of the above

The roles and responsibilities of staff across the Trust including Specialty Clinical Audit Leads.

The specific purpose of this policy is to set out the framework for the conduct of Clinical Audit within the Trust. It provides standards and guidance for all staff participating in Clinical Audit activities; which includes the Trust's procedures and expectations for registering and approving Clinical Audit project proposals and for developing and designing Clinical Audit projects.

When carried out in accordance with best practice standards, Clinical Audit:

- provides assurance of compliance with clinical standards;
- identifies and minimises risk, waste and inefficiencies;
- improves the quality of care and patient outcomes.

The importance which the Department of Health (DH) and healthcare regulators attach to effective Clinical Audit is shown by the extent to which participation in national and local Clinical Audit is now a statutory and contractual requirement for healthcare providers.

In addition to this contractual requirement, the regulatory framework operated by the Care Quality Commission (CQC) requires registered healthcare providers to regularly assess and monitor the quality of the services provided. They must use the findings from clinical and other audits, including those undertaken at a national level, and national service reviews to ensure that action is taken to protect people who use services from risks associated with unsafe care, treatment and support. They must also ensure that healthcare professionals are enabled to participate in Clinical Audit to satisfy the demands of the relevant professional bodies.

The Board is required by NHS England to certify that they have effective arrangements in place for the purpose of monitoring and continually improving the quality of healthcare provided to patients, and must therefore ensure they have in place systems, processes and procedures to monitor, audit and improve quality.

2.0 POLICY STATEMENT

The purpose of this policy is to set out a framework for the conduct of Clinical Audit within the Trust. It provides standards and guidance for all staff participating in Clinical Audit activities. It includes the Trust's procedures and expectations:

- For registering and approving Clinical Audit project proposals
- For developing and designing Clinical Audit projects

It sets out the support that is available from the Improvement and Audit team. All Clinical Audit activity undertaken in the Trust must comply with the requirements of this policy.

The purpose of this Clinical Audit Policy is to maintain and support a culture of best practice in the management and delivery of Clinical Audit within the Trust. The policy clarifies the roles and responsibilities of all staff engaged in Clinical Audit activities.

The Trust will ensure that Clinical Audit is recognised as an effective mechanism for improving the quality of patient care within the context of organisational strategic governance at Board level. The Trust Board has a role in driving quality assurance, compliance and continuous improvement and Clinical Audit seeks to 'close this loop'.

The Trust supports the view that whilst Clinical Audit and participation in National Confidential Enquiries into Patient Outcomes and Death (also known as NCEPOD) is fundamentally a quality improvement process, it also plays an important role in providing assurances about the quality of services and patient care. Clinical Audit has been endorsed by the Department of Health in strategic documents as a significant way in which the quality of clinical care can be measured and improved. This policy also applies when Clinical Audit is undertaken jointly across organisational boundaries. This may involve working with other NHS Trusts or healthcare providers.

Objectives

1. To develop Clinical Audit so that every activity can be linked to improving patient care (and sustaining these improvements).
2. To develop the Clinical Audit support provided to a level where excellent practice is commonplace.
3. To adhere to the principles of Healthcare Quality Improvement Partnership (HQIP) and ensure that the Trust's Clinical Audit processes meet the requirements of "*HQIP's New Principles of Best Practice in Clinical Audit*".
4. To overcome barriers to participation in Clinical Audit by providing appropriate training and support to healthcare professionals at all levels, including the development of Clinical Audit for junior doctors and revalidation.
5. To establish a robust system for reporting the outcomes of Clinical Audit activity, and to escalate to the Patient Safety Committee, when required.
6. To ensure that the Trust meets regulatory and national requirements including participation in national audits and external best practice.

Equality Impact Assessment

The Trust is committed to ensuring that none of its policies, procedures and guidelines discriminate against individuals directly or indirectly on the basis of gender, colour, race, nationality, ethnic or national origins, age, sexual orientation, marital status, disability, religion, beliefs, political affiliation, trade union membership, and social and employment status.

3.0 DEFINITIONS/ ABBREVIATIONS

Clinical Audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review against explicit criteria (typically % compliance or achievement) and the subsequent implementation of change. Clinical Audit is about measuring the quality of care and services against agreed standards and making improvements as a result.

Additionally, the Trust registers Service Evaluation'. This is when the service is measured against 'best practice' criteria but without a % measurement. The organisation may need to

assess where it is in respect of its activity, and to go on to benchmark itself against other providers or make improvements as a result.

Definitions for specific terms used in the policy

The Trust	Means the Sherwood Forest Hospitals NHS Foundation Trust.
Staff	Means all employees of the Trust including those managed by a third party organisation on behalf of the Trust.
CQUIN	Commissioning for Quality and Innovation
Clinical Outcome Review Programmes (previously National Confidential Enquiries)	The main Clinical Outcome Review Programmes: • National Confidential Enquiry into Patient Outcome and Death (NCEPOD) • Child Health Clinical Outcome Review Programme • Maternal, newborn and infant outcome review programme • Medical and surgical outcome review programme • Mental health outcome review programme • National Child Mortality Database (NCMD)
National Clinical Audits and Patient Outcome Programme	The Healthcare Quality Improvement Partnership (HQIP) hosts the contract to manage and develop the National Clinical Audit and Patients Outcomes Programme (NCAPOP). Trust participation in NCAPOP audits is mandatory as it forms part of the NHS Standard Contract.

4.0 ROLES AND RESPONSIBILITIES

Quality Committee

The Quality Committee will receive assurance, via the Patient Safety Committee, that Clinical Audit systems and process are properly governed and monitored.

Patient Safety Committee

The Patient Safety Committee will receive monthly updates and reports from Divisions on audit activities, as part of Divisional updates. The Patient Safety Committee will receive an annual report from the Trust Clinical Audit Lead on Clinical Audit activity. The Patient safety committee will provide assurance on behalf of the Quality Committee.

Improvement and Clinical Audit Group

The Improvement and Clinical Audit Group will provide a forum to share good practice in Improvement and Audit (including regular reports and presentations on the outcomes of Clinical Audit and NCEPOD) and will collectively improve key themes that emerge. This group will also review and ensure the dissemination of policies related to Clinical Audit, and performance on clinical policy compliance.

The group will receive regular reports and presentations of the outcomes of Clinical Audit and NCEPOD.

Divisional and Specialty Governance Meetings

Trust Divisions and Specialties should take responsibility for reviewing the appropriateness of all Clinical Audits and ensures that the Trust is participating in all it mandatory national audits and NCEPOD studies. Each Clinical Audit registration should be assessed by the relevant specialty audit lead for the area where the audit is taking place.

The meetings should keep a log of all Clinical Audit activity and will monitor each stage of the audit; data collection, reporting, action planning and more importantly changes required as a result of the audit to improve patient care. The Divisional / Specialty meetings will also take full responsibility for reviewing their national audit / local audit / NCEPOD compliance and ensuring that audits are undertaken within the outlined timescales and that they can evidence learning as a result of every audit activity undertaken.

Chair of the Improvement and Clinical Audit Group

The Chair of the Improvement & Clinical Audit Group' will:

- Coordinate and monitor the Trust-wide rolling programme for Clinical Audit and ensure that any exceptions are escalated to the Patient Safety Committee.
- Receive appropriate reports, as specified in the ICAG Terms of Reference, and share audit outcomes and associated risks.
- Ensure that there is a Trust-wide process to monitor progress against standards, and to identify Trust-wide opportunities for improvement activities.

Clinical Audit Staffing

The Quality Improvement team provide central support, training and advice to enable clinical staff to undertake relevant and effective Clinical Audits on behalf of the Trust. This includes:

- Taking responsibility for the day-to-day processing of Clinical Audits, advice and guidance on registration, management of the current audit system and providing reports on participation on local Clinical Audits. This also includes approving registrations on AMaT after they have been ratified by a specialty audit lead.
- Escalating issues of risk and participation, supporting clinicians in gap analysis and action planning, and reporting appropriately on issues of compliance.
- Providing an effective Trust-wide knowledge platform to evidence that the Clinical Audit cycle loop is closed and that the Trust can demonstrate how practice has changed and improved patient care as a result of Clinical Audit and improvement.

Specialty Clinical Audit Leads

Each clinical speciality is required to have a person (or persons) responsible for clinical audit, with time agreed for this role within team and individual job planning. The job planning toolkit for clinicians describes responsibility for clinical audit may be agreed as a role within the overarching role of governance lead.

The key tasks of the speciality audit leads are:

- To ensure that their services have comprehensive and effective Clinical Audit plans in place.
- To approve registered audits in AMaT on behalf of their specialty.
- To report progress of all Clinical Audits within their area against agreed timescales/standards.
- To monitor the quality and consistency of final audit submissions and action plans.
- To ensure that Clinical Audits are discussed and results presented at regular meetings for the Division / Specialty. This could be at a dedicated Clinical Audit meeting or part of a wider meeting, such as clinical governance forums.
- To facilitate, along with the Clinical Audit Sponsors, feedback, discussion, implementation of change and service developments/improvements (through business plans and the link to Divisional risk registers) as and when the need is identified via Clinical Audit reports.
- To attend at least 1 ICAG meeting per year or send representation to the meetings if unable to attend

Clinical Audit Lead *the person submitting the registration and undertaking the audit*

- To seek approval for individual Clinical Audits from the Specialty Clinical Audit leads, prior to registering a formal request. If approved, submit details of proposed audits, using the Trusts Clinical Audit registration process.
- Provide a data collection form alongside their audit registration submission.
- Once approval has been given within the registration process, undertake data collection for the audit via the current Audit system where suitable. The Clinical Audit Lead is responsible for ensuring the security and confidentiality of Clinical Audit data.
- Ensure that the audit project is completed to the reporting and action plan stage, including SMART action planning (specific, measurable, achievable, relevant, timebound) using the templates provided by the Clinical Audit team.
- To regularly update the project via AMaT (Audit management and Tracking) system by completing relevant tabs.
- Share Clinical Audit results with relevant peer groups via the appropriate Specialty governance arrangements, or where applicable, higher level Trust wide committees.
- Submit a copy of the final Clinical Audit report/presentation on AMaT.
- The Clinical Audit status will only be formally completed once all these steps have been followed, and ‘proof of completion’ has been provided. This includes having SMART action plans in place and all actions fully completed. If there is no need for action plan the Clinical Audit lead needs to provide justification, why.

Clinical Audit Mentor *the Senior Manager or Consultant authorising the project undertaken by the Clinical Audit Lead on behalf of the clinical area/ speciality*:

- To ensure that the Clinical Audit project has clear objectives and has an achievable time scale.
- To ensure that the Clinical Audit is completed and that the Audit Lead disseminates and presents findings to appropriate staff groups / meetings as well as to the Audit and Improvement team.
- In the event of a Clinical Audit Lead leaving their post before a project is completed, the Sponsor will allocate the project to another member of staff for completion.

- Following the completion of a Clinical Audit, they will ensure that structures are in place to ensure any actions are reviewed and progressed, and that further audit cycles are planned according to the findings.
- For audits where training of junior staff is an important component, the Clinical Audit Sponsor may wish to include the Clinical Audit Lead in the action planning stage. However, the responsibility for developing and implementing action plans lies with both the Clinical Audit Lead and the Audit Sponsor.

5.0 APPROVAL

A formal process for consultation and approval is required for both the initial production and subsequent reviews of this policy. The following individuals and Trust groups / committees have been consulted in the review and update for this policy:

- Divisional Clinical Governance Meetings: November/December 2024
- Improvement and Clinical Audit Group – 29/1/2025
- Patient Safety Committee– 5/2/2025

6.0 DOCUMENT REQUIREMENTS

Agreeing the programme of activity

The Trust Lead for Clinical Audit will take responsibility to ensure that, through the Clinical Audit Team, all areas of Clinical Audit activity is monitored, either via the audit plan or another mechanism.

The Trust operates an audit programme that requires specialties to identify areas of interest or priority for the forthcoming financial year. Such plans should be submitted to the audit team no later than the 1st March each year. This means that whilst the audit plan will contain a list of priorities for the forthcoming year it will still allow specialties to incorporate audits that are registered at any point throughout the year based on urgency and interest.

Prior to the start of every financial year, the Trust will agree the appropriate 'known about' planned programme of Clinical Audit activity. This will include:

- Eligible National Clinical Audits
- NCEPOD studies
- Trust wide Clinical Audits
- Anything that has been rolled over from the previous year (as it is still in progress)

A list of mandatory audits taken from the NHS England Quality account document will be provided to each Division as soon as it is published and it is their responsibility to confirm, by the 31st March, to the Clinical Audit team via ICAG, the National Audits they will participate in for the forthcoming financial year.

Process for agreeing the Clinical Audit Annual Programme.

The Trust will agree an annual Clinical Audit Programme (Forward Plan), focussing on 'must do' activity. However, it will remain adaptable to meet the emerging needs of the trust.
The Trust will take a consultative approach to the development of the Programme. This consultation will seek input from:

- Chairs/Operational Leads of Groups reporting directly/indirectly to CQG (via CQG)
- Divisional Directors/Clinical Chairs
- Chairs of Divisional Governance/Quality & Safety Groups (via divisional reporting)
- Health professionals working within Divisions/specialties.

The Clinical Audit Team will liaise with the above during the final quarter of the preceding financial year, setting a date for comments and proposals to be received by. Activity will be categorised in line with HQIP guidance. Forward plans will be agreed and monitored through Divisional Quality/Safety Groups. Reports on progress against identified activity will be provided by the Clinical Audit & Effectiveness Team. Progress on this activity will also be monitored by CAG and reported to CQG and to the Trust Audit Committee on a regular basis.
The Trust is also committed to supporting clinical audits on other topics of particular interest/concern to individual clinicians. These may include audits prompted by patient safety concerns and patient feedback. In determining the choice of local projects, the Trust expects staff to take the following questions into account:
· Does the proposed audit reflect Divisional priorities (as identified in business plans, etc. This should be determined by the specialty audit lead who has responsibility for approving audits on behalf of the specialty they represent)?
· Can patients and other service users be involved in this project?
· Is the audit a re-audit, thereby enabling confirmation of improvements in practice?

Topics selection and prioritisation

Prioritisation: Clinical Audit projects should contribute to the overall priorities of the organisation, and the wider system, and be clear about how patient care will be improved. However, as resources are finite; both in terms of clinician time and central support function, this places a limit on the number of Clinical Audits that can be carried out over the course of a year and therefore some degree of prioritisation is necessary. The rationale behind prioritisation is about ensuring limited time and resources are allocated to the most important priorities so that improvement to the quality of patient care and outcomes can be targeted to areas of identified need in a systematic way.

The Trust uses the 5-step prioritisation model, as recommended by Healthcare Quality Improvement Partnership (HQIP), in its Clinical Audit plan model:

- Priority 1 External ‘must do’ audits,
- Priority 2 Internal ‘must do’ audits,
- Priority 3 Divisional and Specialty Priorities
- Priority 4 Clinician interest audits.
- Priority 5 Service evaluations, staff questionnaire, patient questionnaire

Priority 1 — External ‘must do’ audits/ topic selection

It is essential to ensure that externally monitored audits that are driven by commissioning and quality improvement are treated as the priority and that appropriate resources are provided to support these. Failure to participate or deliver on these externally driven audits may carry a penalty for the Trust (either financial, reputational or in the form of a failed target or non-compliance — hence ‘must-do’ audits). These are externally monitored and assessed by the

CQC and in some areas by the local CCG commissioner. Priority 1 audits are derived from the following sources:-

- National Clinical Audit Programme
- Audits allowing the Trust to demonstrate compliance with regulation requirements, such as, NICE guidance, National Service Frameworks, National Patient Safety Alerts, National Confidential Enquiries and any other relevant national guidance)
- New national targets and existing commitments
- Other commissioner priorities
- DH statutory requirements, such as infection control monitoring

Priority 2 — Internal 'must do' audits/topic selection

In addition to national Clinical Audit topics, the choice of further topics should be based on the classic criteria of high risk, high cost, or high profile identified by trust management. They may include national initiatives with trust-wide relevance but no penalties exist for non-participation. Many of these projects will emanate from trust governance issues or high profile local initiatives and will include:

- Priorities reflective of organisational objectives
- Clinical risk issues/ patient safety issues
- Serious untoward incidents/adverse incidents/near misses
- Organisational clinical priorities
- Priorities identified via Patient and Public Involvement initiatives / complaints
- CAS Alerts
- Patient Safety First Campaign

Priority 3 — Divisional / Specialty priorities

Divisions / Specialties should also suggest projects that are priority pieces of work and important to them – local priorities. They may include DH initiatives and be Division / Specialty specific, but have no penalties exist for non-participation. Directorate priorities may include:

- Local clinical interest audit agreed by directorate/division/service as a priority
- System priorities
- National audits that do not fall within the Quality Accounts list , e.g. some Royal College projects, NICE audits where there is no mandated requirement to participate
- Locally adopted clinical policies/ guidelines/ benchmarks

Priority 4 — Clinician interest

The priorities set up above should not stifle projects that emerge during the year that contribute to improvements in care. Some of these projects registered later in the year will slot into one of the above categories. However, there will be a number of projects that will not fall into any of the above priorities. It is fully recognised that there is a need to maintain a degree of locally initiated projects. These projects often cannot be determined at the outset of the financial year. They represent innovative ideas from clinicians and can provide valuable educational experience for junior staff. It may be a need for continuing professional development purposes and revalidation. All projects in this category must still meet specialty priorities and be agreed with the specialty audit lead.

Priority 5 – Service Evaluations, staff questionnaire, patient questionnaires

These projects measure against 'best practice' criteria but without a % measurement. The organisation may need to assess where it is in respect of its activity, and to go on to benchmark itself against other providers or make improvements as a result.

Responding to emerging issues/guidance

The Clinical Audit Plan is not intended to be restrictive, hence the need for a hybrid static/rolling programme. Significant national and local clinical guidance will be issued during the year and the Trust will need to be able to respond to this. The Trust needs to create capacity to allow it to respond to this guidance, and similarly to react to other quality and safety issues as they arise.

All audits will normally be approved via the normal registration process, but audits requiring significant resources may need to be taken to the Improvement and Clinical Audit Group for formal approval.

National Clinical Audits and NCEPOD

National bodies require information and evidence to support their understanding of Trust compliance with the assurance of national standards in relation to clinical care being delivered. The collection of this data can both significantly affect both Trust assurance and performance ratings.

Failure to quality assure information centrally may lead to the submission of data and evidence that is not completely accurate and could affect Healthcare Commission ratings. Failure to adhere to submission of data within the required timescales also leaves the Trust at significant risk regarding assurance. The NHS Standard Contract stipulates that the Provider must participate in the national Clinical Audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to its services.

When a National audit report is published a QI officer will register the Audit on AMaT. This will include uploading the report and adding any recommendations detailed within the report. It is the responsibility of the respective national audit lead to perform a gap analysis between the standards of the audit and the recommendations and results set out in the report. Where any gaps in performance are identified, they should take reasonable actions to address these by way of improving patient care.

NCEPOD Local Reporter – this role relates specifically to NCEPOD and provides the Trust link with NCEPOD. The Local Reporter is a member of the Improvement Team and has a co-ordinating role in the Trust. Specifically an NCEPOD Local Reporter will take the lead on:

In advance of NCEPOD publication:

- Receive information from NCEPOD about the requirements of surveys and confirm where the activity is carried out at the hospital.
- Supply details of data and activity to NCEPOD.
- Distribute the confidential enquiry electronic questionnaires to clinicians and monitor that they are returned.
- Receive newsletters from NCEPOD and distribute within the Trust where relevant.

Following NCEPOD publication:

- Receive NCEPOD reports and forward to the Executive Medical Director / Trust Board in accordance with this procedure for noting and action;
- When a report is published a QI officer will register the project on AMaT.
- Engage stakeholders to carry out a gap analysis between the reports recommendations and the current practice at the trust, ensuring that an action plan is formulated to address any gaps.
- Maintain and update the tracker that will detail the NCEPOD reports and other national best practice documents.
- Forward documents and relevant papers for inclusion on the agenda of the Improvement and Clinical Audit Group.

The NCEPOD Local Reporter will also 'horizon scan' for other best practice guidance and notify the Clinical Service Leads of any documents not already identified by the above process.

Divisional / Specialty Responsibilities

It is essential that Divisional Directors, Service Leads, Audit and Governance Leads are cognisant and are prepared to take action to resolve any significant issues around barriers to participation and non-compliance in National Clinical Audits and NCEPODs.

Each Division / Specialty should have in place a framework to ensure that evidence is submitted within the required timescales and is quality assured. It is the Divisions responsibility both in terms of time and resources to ensure that collection of data and data input is fully resourced within the Division to support all mandatory National Audits.

Often where NCEPODs are concerned, the information required can be complex and be required within short timescales. Divisions must ensure that co-operation in these matters is achieved and assist the Clinical Audit Team in the correct allocation of individuals to undertake work such as patient questionnaires and organisational analysis.

The Division / Specialty MUST ensure that they monitor the progress regularly around participation and compliance with National Audits and NCEPODs. Any matters arising should be escalated through Divisional Governance meetings and appropriate actions to rectify this should be taken.

Any non-compliance issues should be reported through to the Patient Safety Committee as soon as the Division becomes aware.

The Divisions should ensure that they provide data to the Clinical Audit team for the purposes of reporting to the Patient Safety Committee. The Clinical Audit team will offer support for Divisions on gap analysis and action planning on National Clinical Audit and NCEPOD published reports.

The process for Clinical Audits

The following section describes the process for ensuring that individual Clinical Audits undertaken at the Trust should follow agreed standards and best practice in Clinical Audit.

All Clinical Audit projects undertaken at the Trust need to be formally registered prior to commencing. In order to register a Clinical Audit, Audit Leads and Sponsors must submit an electronic Clinical Audit registration for approval using the AMaT system. All AMaT users need to create an account.

Once the registration is received by the Clinical Audit Team, this will be reviewed to ensure that the audit is appropriate, that the standards are set, that the sample size is realistic and the audit is viable. The audit officer will then request that the audit is reviewed and approved by the specialty audit lead. Proposed audit projects not conforming to minimum criteria of best practice will be declined and referred to the audit proposer with advice on how best to proceed.

Once the Clinical Audit has been approved the Audit Lead will be notified via email of approval and a unique audit registration number will be allocated.

The current mechanism for undertaking Clinical Audits is via the electronic AMaT system. . It is a Trust expectation that 100% of Clinical Audits will be completed via the current, or any new database system.

An assurance process is required to ensure that Clinical Audit projects are carried out in accordance with best practice and legislation, to facilitate support and advice and to enable the Trust to collect information for external assessments. It is the responsibility of all staff to ensure that this process is followed and that no Clinical Audit activity is undertaken without formal approval. The registration form must be completed in all cases.

The use of Standards & Criteria in Clinical Audit

Clinical Audit involves measuring clinical practice against predetermined standards of best practice. Proposed Clinical Audits must outline the precise evidence-based standards and measurable criteria that the project is intended to achieve. The evidence-based source of all standards and criteria must be clearly cited on the proposal document to allow evaluation under the approval process.

A *standard* describes an overarching statement of care we expect patients to receive. However, standards tend to be quite general about the level of care and the processes they describe. To be able to effectively measure practice, we need to be more specific.

Projects without evidence-based standards are unlikely to be Clinical Audits and, as such, may not be registered as a Clinical Audit. Service improvement and patient surveys are often categorised as audit and these should still be registered via the Clinical Audit registration process.

Additionally, whilst the use of AMaT (or any other audit database that is introduced) is not essential for service evaluation projects, it is still recommended.

<u>Clinical Audit Compliance</u>

Clinical Audit uses a RAG rating to assess the level of compliance within the Trust against the audit standards. The compliance rating or RAG rating is as follows:

Compliance / Adherence

> 90%	86% - 89%	< 85%

These have been locally agreed and are reflected in the trusts Audit system AMaT.

Trust Clinical Audit Database

The Trust uses an electronic system (Audit Management and Tracking (AMaT) to register and monitor Clinical Audit as well as update the individual projects. Staff can register their Clinical Audit online and this populates an overall database and Clinical Audit plan – offering real-time information.

The Clinical Audit team will monitor the Clinical Audit database. The Clinical audit leads are responsible for updating their individual Clinical Audit projects. This database will be used to provide annual and quarterly update reports for the Trust and external bodies. The database will identify where the audit projects are falling behind (subject to the Specialties providing accurate data). It should also identify where projects have stalled, providing notifications to all parties involved.

Case notes

Case notes will only be pulled for approved Clinical Audit projects. By 'approved' this means that the audit should be given an audit registration number by AMaT. All requests for case notes should be submitted on the 'case note request form' and all Audit Leads must commit to ensuring they review requested case notes in a timely fashion. A maximum of 50 sets of case notes will be pulled per audit. For any more than 50, arrangements should be made with a clinicians own Specialty admin / secretaries to obtain these. It is the responsibility of the Audit Lead to ensure the case notes are then returned to case notes store; they will not be collected.

The timescales for the retrieval of case notes for the purposes of Clinical Audit are as follows (subject to resources):

- Priority 1 Audit - up to 7 days*
- Priority 2 Audit - up to 14 days
- Priority 3 Audit - up to 21 days
- Priority 4 Audit - up to 28 days
- Other e.g. Service Evaluation - up to 6 weeks (cannot be guaranteed - only available subject to resources if time permits)

*Specialties are responsible for obtaining case notes for National clinical Audit. However where required the Audit Team may be able to support small requests on an ad-hoc basis. The decision on if support can be provided remains with the Audit and Improvement lead officer.

Dissemination: Presenting findings and reporting completed audits

A Clinical Audit is deemed to be complete at the point where a report has been produced and any actions (if applicable) have been fully completed. It is a good practice for the Audit Lead / Sponsor to use templates which can be found on the Clinical Audit intranet (these are best practice and are optional). This needs to be completed for all Clinical Audit projects, including those that demonstrate full / good compliance. The formal report (in whatever format: report, presentation) must be written within three months of the completion of the data collection/ analysis and forwarded on to the Clinical Audit team, who can also offer support in action planning.

Speciality specific completed audits will then be presented to peers/ relevant Specialty and Divisional governance meetings by the Audit Lead where the findings can be discussed and, where necessary, an action plan agreed and a commitment to re-audit made in a designated time. Some of these audits may have a wider interest and, as such, the Trust would encourage presentations to other relevant groups / meetings, e.g. Grand Round.

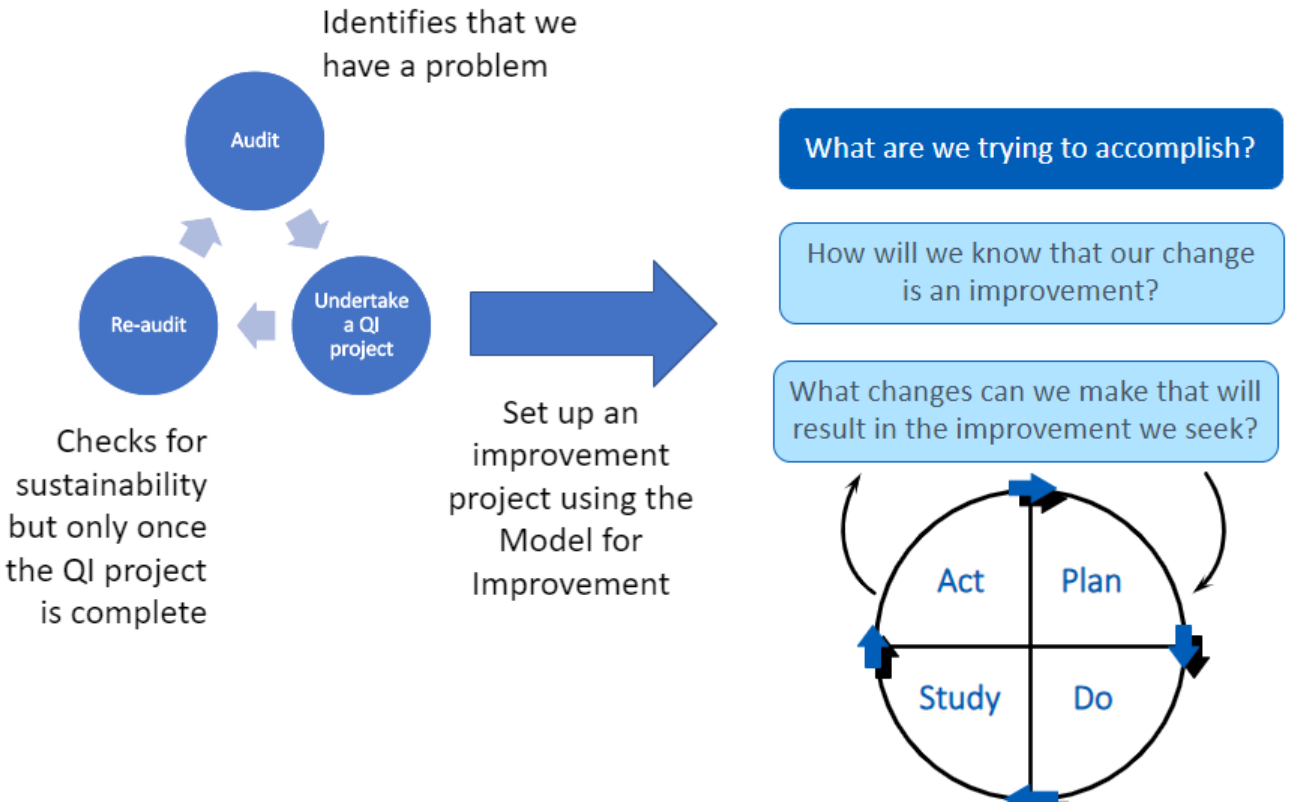
For Clinical Audit projects that have a Trust wide impact the results should be fed back, in the first instance, to the relevant committee before wider Trust dissemination. The 'owning' committee chair will take responsibility for ensuring the action plan is developed and implemented.

It is the responsibility of each Specialty to keep a track of what audits have been completed and any actions which have been identified as needing to be addressed. This should be done in conjunction with Specialty Governance Leads and Divisional Governance Leads and progress against these should be regularly reported thorough either Specialty or Divisional meetings.

The Clinical Audit Action Plan

A 'SMART' action plan must be created and implemented for all Clinical Audit projects if results warrant remedial action (i.e. non-compliance against audit standard demonstrated). The action plan will state the agreed actions, the member(s) of staff responsible for delivering each action, and the target date for completion in each instance. Audit Sponsors will support the Audit Lead and sometimes take the lead on drafting action plans, which will need to be formally approved by the appropriate Head of Service before implementation. This will ensure that action plans are targeted, achievable and are in concordance with the original audit proposal aims and objectives.

We encourage all solutions contained with action plans to be worked through applying QI methodology.

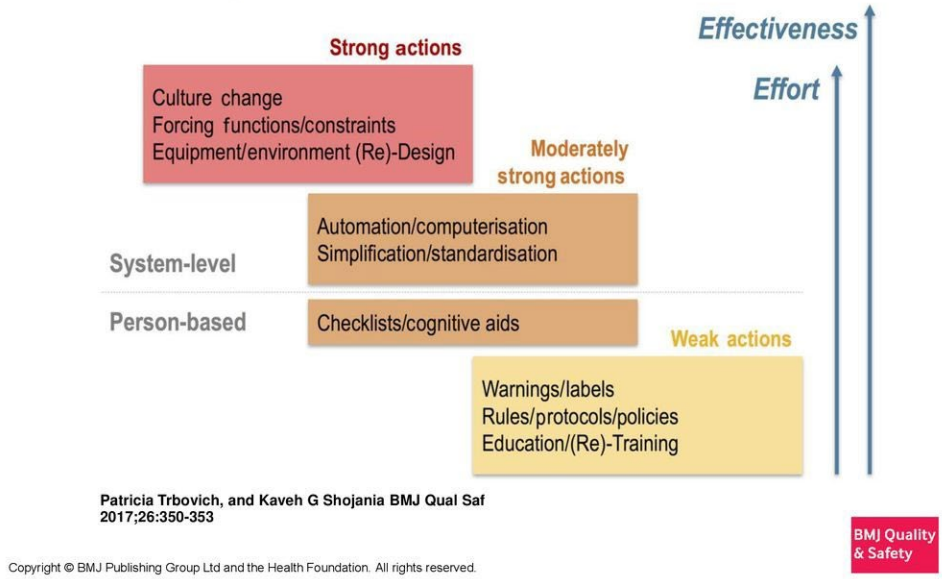


More information relating to QI methodology can be found on the trust intranet site.

We also ask that any action plans formulated are guided by the hierarchy of effectiveness.

The hierarchy of effectiveness depicts the various strategies for modifying behaviour ranked by their effectiveness. This framework for ranking types of corrective actions deems person-based approaches to behaviour change (that rely on individual attention and vigilance) as weaker than ones targeted at the system level. As indicated in the figure, however, stronger corrective actions come at the cost of increased effort. Culture change and forcing functions will have greater and longer-lasting effects than education and new policies, but they also require much greater effort to achieve.

The hierarchy of effectiveness depicts the various strategies for modifying behaviour ranked by their effectiveness.



Patricia Trbovich, and Kaveh G Shojania BMJ Qual Saf 2017;26:350-353

BMJ Quality & Safety

Agreed action plans must be recorded on AMaT. This is to allow the Trust to have a central repository of information regarding the outcome of Clinical Audits.

Not all Clinical Audits will require an action plan, e.g. where an audit shows that standards are being met or guidance followed. For such audits there should be an explicit statement saying 'no further action. If the Audit Lead is of the view that an action plan is not required, this information should be recorded on AMaT. Any decision not to undertake any actions is open to scrutiny by Divisional, Specialty and corporate committees. The possibility of re-audit should be considered as part of this process.

A copy of the final Clinical Audit report/presentation with action plan should be uploaded to AMaT which allows these will be stored centrally for assurance purposes. The responsibility for this lies with the Audit Lead and Sponsor but the Speciality Audit Lead will also play a supporting role in checking that this process has been followed.

Re-audits and targeted re-audit

All Clinical Audits resulting in actions plans must be subject to re-audit within a suitable timeframe to provide evidence of the implementation of action plans and demonstrable improvements in patient care and health outcomes. For the majority of simple actions a re-audit timeframe of 3-6 months post implementation is recommended, but for more complex action plans a more realistic timeframe of 6 months to 12 months post implementation is expected. The re-audit timeframe should be stated as part of the action plan. The trust has a re-audit target of 50% of projects and each Specialty should be aiming to contribute to this.

Data Protection Act, Confidentiality, Caldicott and ethics

Clinical Audit by definition does not involve anything being done to patients other than their normal clinical management; therefore, it does not require formal ethical approval. However, Clinical Audit must be performed within an ethical framework that includes confidentiality of data and results.

Confidentiality and data protection principles

All data relating to living individuals is subject to the conditions of the Data Protection Act, 1998 (DPA) and Caldicott Principles.

Any staff reviewing patients' notes for the purposes of collecting data MUST register their Clinical Audit in line with this policy. Failure to do so means that permission has not been sought and would breach data protection principles. By registering the Clinical Audit, the Trust has assurance that the audit has been reviewed and approved in line with this policy.

Data gathered as part of Clinical Audit may contain information that is confidential; therefore, all data collected for Clinical Audit purposes will be anonymous through the use of randomly assigned key codes at the time of data collection. Where tracking of patients throughout the audit is necessary, this should be through the K, D, NHS or Integrated Sexual Health numbers only.

All data, including the key codes list, whilst in use, should be stored securely, on Trust premises, in locked cabinets. Data in most instances is stored via the approved AMaT system. In exception cases where data collection forms are used, all data collection forms must be destroyed, via the confidential waste process, after the relevant storage period has elapsed.

If data is subsequently transferred to electronic medium for analysis, this data must be completely anonymous and the electronic data must be store in line with relevant Trust policies and procedures.

The Audit Leads and Sponsors are bound by professional and organisational "*Codes of Conduct*" and this includes responsibility for any breaches of confidentiality. It is vital that they ensure that everyone involved in a Clinical Audit project understands their role and responsibilities.

All data collected for Clinical Audit purposes must be relevant to the project aims and objectives and be related to the audit criteria as listed on the registration form. Data extraction outside of this will be contrary to the DPA and the Audit Leads and Sponsors will be liable to disciplinary action. Demographic data is not usually valid or useful (e.g. name, age, ethnicity, post code) unless the guidance being audited states patient must be of a certain age, gender etc.

Personal medical information / data collected for specified Clinical Audits must not be used for any other project as this would contravene the DPA.

Personal medical information / data should not be collected or reviewed by non-Trust staff unless a similar duty of confidentiality is in place, e.g. from the signing of an honorary contract and agreement has been given by the Caldicott Guardian.

Clinical Audit activity must also conform to the requirements of the NHS Confidentiality Code of Practice (2003) which states that "*patients must be made aware that the information they give may be recorded, may be shared in order to provide them with care, and may be used to support local Clinical Audit*" (page 21). If patients have been so informed, Section 60 of the Health and Social Care Act 2001 makes provision for the collection of patient identifiable data for the purposes of Clinical Audit; however best practice would always be the anonymisation of Clinical Audit data unless there was a compelling reason not to do so.

Staff must adhere to nationally defined standards of professional confidentiality in respect of discussions which take place at meetings where Clinical Audit is discussed. The purpose of Clinical Audit is quality improvement and quality assurance, not performance management.

The national data opt-out gives people a clear choice about how their confidential patient information is used for purposes beyond their individual care. The national data opt-out is a service that lets patients choose that their confidential patient information is only used for their own individual care, and not for research and planning. The deadline for health and care organisations to comply with national data opt-out policy is 31 March 2022. This ONLY applies to data being submitted for national studies.

National data opt-outs are held on the NHS Spine against an individual's NHS number and our Medway PAS is currently not spine compliant so we will need to use a service called MESH (messaging exchange for social care and health). This enables users to submit lists of NHS numbers and receive lists back which highlight which patients have opted out.

If the National audit provider confirms the project needs to comply with the National Data Opt-out, the following steps MUST be taken by the Trust's audit lead before data is submitted. All NHS numbers MUST be checked using the Trusts 'National Data Opt-out checker'. This can be found using the link below: -

https://sfhinformationhub.nnotts.nhs.uk/MESH/import_check.

If there is a 'Yes' against an NHS number then that patient MUST NOT be used for the purposes of the audit. This list is updated daily and you should see a time stamp for when the last update occurred.

Ethical framework for Clinical Audit

Clinical Audit projects should not require formal approval from a Research Ethics Committee. However, one of the principles underpinning Clinical Audit is that the process should do good and not do harm. Clinical Audit must always be conducted within the ethical framework described below.

It is unethical for one profession or area to audit other professions / areas without approval and support from that profession / area. If the Clinical Audit covers more than one profession or specialty, then multidisciplinary / cross Speciality sponsor(s) must be agreed when the Clinical

Audit proposal is prepared. Where applicable, Clinical Audit should be conducted by multi-disciplinary teams. This not only adds to the strength of the Clinical Audit methodology but will also ensure that solutions are collectively created and owned. This approach has been proven to ensure the best and most sustainable approach to improvements in patient care and health outcomes.

All healthcare professionals are responsible for their own performance and reasonable steps should be taken to improve performance should Clinical Audit results indicate the need. If Clinical Audits demonstrate failure to achieve evidence-based standards or care on a wider systematic level, then action plans must ensure division or specialty wide solutions. The Clinical Audit Sponsor is responsible for alerting divisional or specialty management to any performance issues that might represent a risk to the Trust.

Ensuring that the Clinical Audit programme is managed efficiently to make best use of resources, and performance management issues associated with poor audit design, poor execution or failure to deliver improvements in patient care are addressed and that any ethical concerns which arise during the design and planning of individual Clinical Audits are addressed.

Ensuring that any instances of serious shortcomings in patient care which come to light through Clinical Audit are communicated with the clinical director of the service involved at the earliest opportunity, and that appropriate steps are taken to address them and that risk management issues identified through Clinical Audit results are addressed in Clinical Audit action plans, and that those plans are implemented effectively.

Publishing of audit results

One of the distinguishing features of Clinical Audit is that the results are only of relevance to the Trust in which the Clinical Audit was undertaken, i.e. the results inform the activities of local clinicians and teams, rather than influencing clinical practice as a whole. Therefore the results of local audit would not ordinarily be considered appropriate for publication, although the methodology used and subsequent change and improvement cycle may be of interest / educational value to others.

The Trust is supportive of clinicians who wish to pursue publishing of relevant materials, however if Clinical Audit Leads and Sponsors wish to consider publishing, in any format, the results of Clinical Audit external to the Trust they must remember that any data or findings resulting from that work belong to the Trust. Requests for permission to publish the results of Clinical Audit must be made, in advance, to the Trust Lead for Clinical Audit. The proposed work to be published will be reviewed for accuracy, concordance with the original Clinical Audit proposal and any other ethical concerns.

This process is in place to provide assurance to the Trust that any works published are of suitable standard and comply with all relevant regulations.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Roles and Responsibilities	Craig Short, Audit and Improvement lead officer	Via audit proposals and completed audit reports	Annually	Both verbal and formal report via the ICAG meeting.
Requirements that audits are conducted in line with the approved process	Craig Short, Audit and Improvement lead officer	Via audit proposals / correspondence and audit reports	Quarterly	Both verbal and formal report via the ICAG meeting
How audit reports are shared and how the organisation makes improvements	Craig Short, Audit and Improvement lead officer	Via action plans within audit reports and speciality clinical governance forum minutes	Quarterly	Both verbal and formal reporting via the ICAG meeting, formal reports to the Patient safety commitee
The national requirements of Clinical Audit and NCEPOD are being met	Craig Short, Audit and Improvement lead officer	Via action plans within audit reports and speciality clinical governance forum minutes	Quarterly	Both verbal and formal reporting via the ICAG meeting, formal reports to the Patient safety commitee
How the organisation monitors action plans /carries out re-audits	Craig Short, Audit and Improvement lead officer	Via speciality / divisional clinical governance forums minutes	Quarterly	Both verbal and formal reporting via the ICAG meeting, formal reports to the Patient safety commitee

8.0 TRAINING AND IMPLEMENTATION

Apart from the Clinical Audit training plan listed in the Clinical Audit Policy there are no other requirements associated with this document. Specific aspects of Clinical Audit require specialist skills to enable successful Clinical Audit, for example using the correct Clinical Audit methodology. This policy sets out how the Trust will ensure that all clinicians and other relevant staff and patients conducting and/or managing Clinical Audits are given appropriate time, knowledge and skills to facilitate the successful completion of the audit cycle.

Improvements in Clinical Audit education and training are key to the delivery of this policy in order to promote Clinical Audit activities that are led by healthcare professionals.

The Trust offers a digital e-learning session which can be accessed on an ad-hoc basis by colleagues at the trust. There will be separate sessions in addition to this which will be for specific groups such as pre-registration pharmacists, junior doctors and nursing / midwifery students. Individual training will also be provided if required. In addition we offer virtual training to individuals on the AMaT system.

Service Improvement training (QI) will be via the Trust 'bronze' and 'silver' level QI training offers.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix 1
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence base:

- Healthcare Quality Improvement Partnership (HQIP) – www.hqip.co.uk
- New Principles of Best Practice in Clinical Audit – 2011 Robin Burgess
- Data Protection Act (1998) HMSO
- Caldicott Report (1997). Department of Health
- GDPR May 2019

Related SFHFT Documents:

- Improvement and Clinical Audit Group Terms of Reference January 2022

11.0 KEYWORDS

12.0 APPENDICES

EQUALITY IMPACT ASSESSMENT FORM (EQIA)
Process Flow Chart

APPENDIX 1 - EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Clinical Audit			
New or existing service/policy/procedure:Existing			
Date of Assessment:5/2/2025			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	None	N/A	None
Gender	None	N/A	None
Age	None	N/A	None
Religion / Belief	None	N/A	None
Disability	None	N/A	None
Sexuality	None	N/A	None
Pregnancy and Maternity	None	N/A	None
Gender Reassignment	None	N/A	None
Marriage and Civil Partnership	None	N/A	None
Socio-Economic Factors	None	N/A	None

(i.e. living in a poorer neighbourhood / social deprivation)			

What consultation with protected characteristic groups including patient groups have you carried out?

- None

What data or information did you use in support of this EqIA?

-

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- No

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

High Level of Impact/Medium Level of Impact/Low Level of Impact *(Delete as appropriate)*

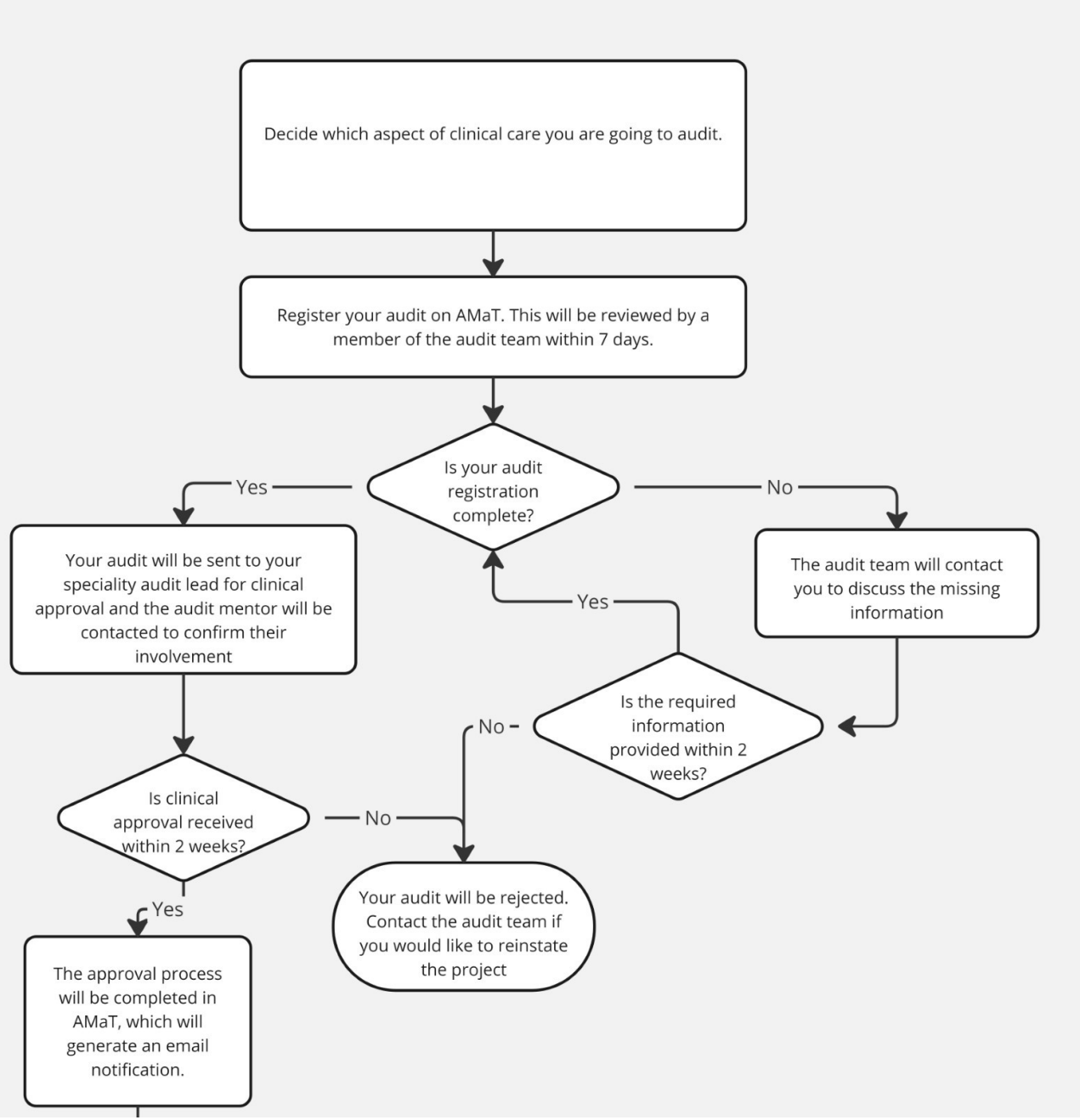
For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

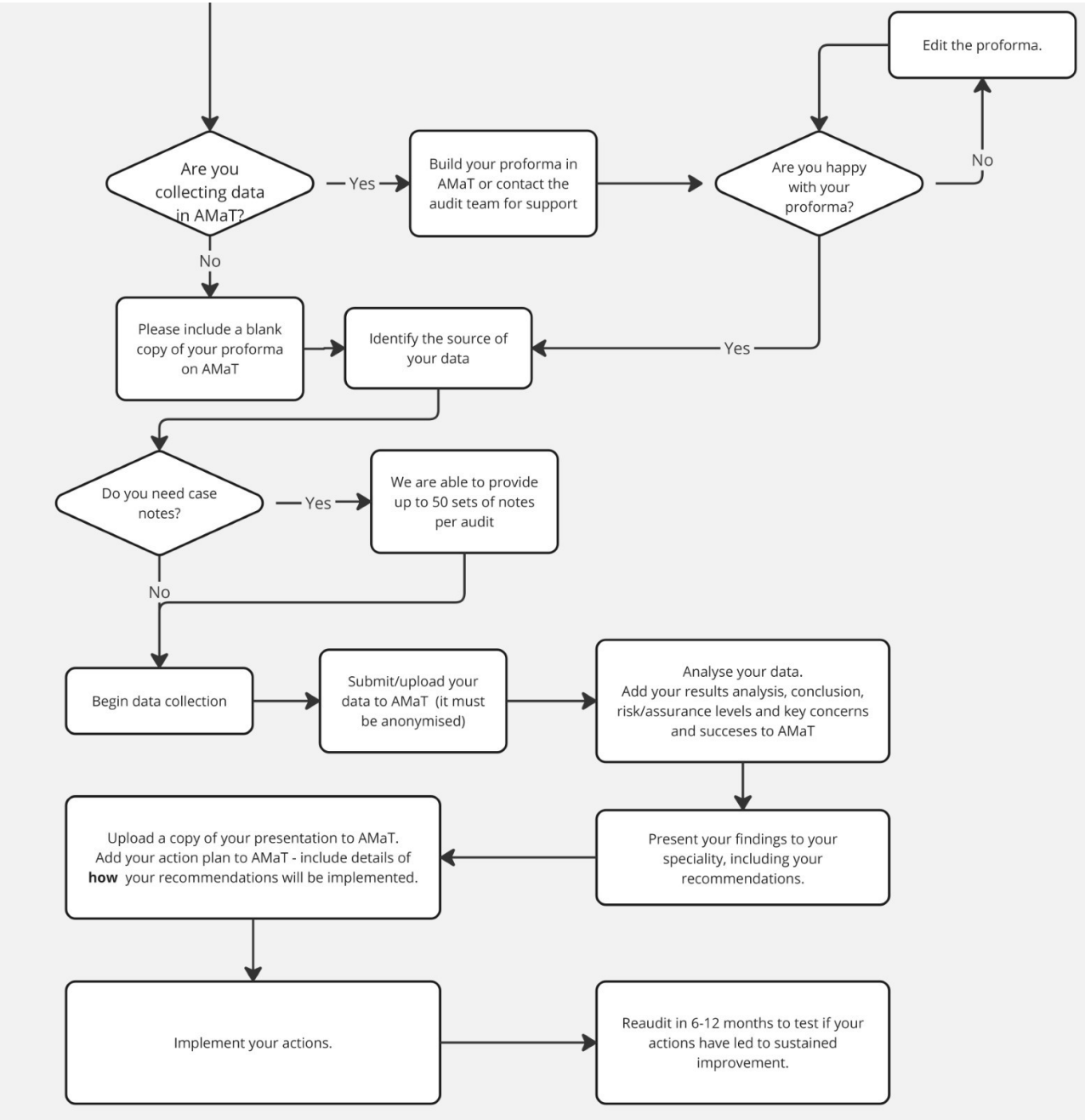
Name of Responsible Person undertaking this assessment:

Signature: 

Date:5/2/2025

APPENDIX 2


Decide which aspect of clinical care you are going to audit.
Register your audit on AMaT. This will be reviewed by a member of the audit team within 7 days.
Is your audit registration complete?
Yes
No
Your audit will be sent to your speciality audit lead for clinical approval and the audit mentor will be contacted to confirm their involvement
The audit team will contact you to discuss the missing information
Yes
Is the required information provided within 2 weeks?
No
Is clinical approval received within 2 weeks?
No
Yes
Your audit will be rejected. Contact the audit team if you would like to reinstate the project
The approval process will be completed in AMaT, which will generate an email notification.


Are you collecting data in AMaT?
Yes
Build your proforma in AMaT or contact the audit team for support
Are you happy with your proforma?
No
Edit the proforma.
No
Please include a blank copy of your proforma on AMaT
Identify the source of your data
Yes
Do you need case notes?
Yes
We are able to provide up to 50 sets of notes per audit
No
Begin data collection
Submit/upload your data to AMaT (it must be anonymised)
Analyse your data.
Add your results analysis, conclusion, risk/assurance levels and key concerns and succeses to AMaT
Present your findings to your speciality, including your recommendations.
Upload a copy of your presentation to AMaT.
Add your action plan to AMaT - include details of **how** your recommendations will be implemented.
Implement your actions.
Reaudit in 6-12 months to test if your actions have led to sustained improvement.