

For use in:	Trust Wide
For use by:	All staff
For use for:	All clinical audit activities
Document owner:	Head of Patient Safety and Effectiveness
Status:	Approved

1. Statutory and mandatory requirements for clinical audit

The NHS Standard Contract, which covers agreements between commissioners and all providers delivering NHS funded services, states that providers must participate in the National Clinical Audit Patients Outcome Programme (NCAPOP) audits that are relevant to the services they provide and must implement all relevant recommendations of any appropriate clinical audit.

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 audit 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 healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of the relevant professional bodies.

The Board is required by Monitor 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 system processes and procedures to monitor, audit and improve quality.

The Trust is required to produce an annual Quality Account, which must include information on participation in national and local clinical audits, and the actions which have been taken as a consequence to improve the services we provide.

2. Purposes and outcomes of this document

2.1 Purposes

The purposes of this document are to:

- Define a framework for carrying out clinical audits to be followed by staff, consistent with current evidence of best practice in clinical audit.
- Facilitate a shared understanding of the purpose of clinical audit and the clinical audit process.
- Clarify responsibilities for carrying out, approving and acting on the clinical audit programme.
- Inform staff carrying out clinical audits about data protection requirements to be followed.

2.2 Outcomes

The intended outcomes of this document are evidence that:

- There is a robust clinical audit programme being implemented.
- The clinical audit process is being carried out consistent with best practice in clinical audit.
- Good practice in comparison with national and professional guidance is being provided or improvements are being made as a result of the findings of clinical audits.
- Roles, responsibilities and accountabilities for the clinical audit programme are clear and are being implemented.

3. Definitions

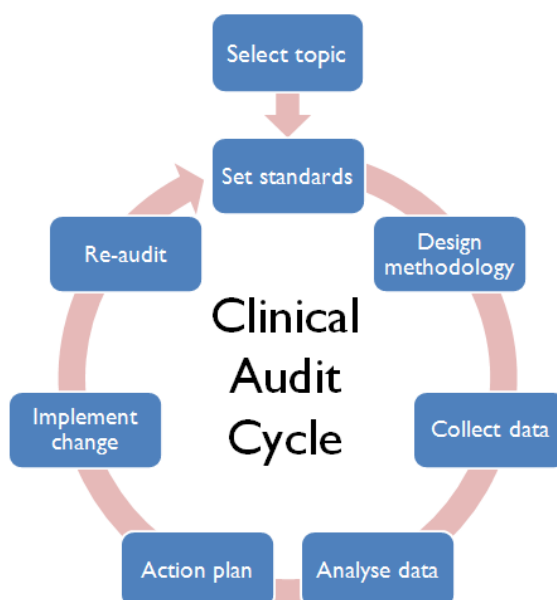
3.1 Clinical audit

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.” (Burgess 2011, p.6).

Clinical audit is a tool which enables staff to assess if best practice standards have been met and therefore can identify which aspects of care need to be improved. It is an approach used to reflect and review practice as part of a continuous cycle to improve the quality of care for patients.

3.2 Clinical audit process

The clinical audit process is best represented as a cycle, whereby each stage needs to be completed before moving onto the next stage.



The clinical audit process involves the following steps:

- Select the clinical audit topic. High priority topics include areas where problems have been identified by staff, service users or carers, areas where there is potential to improve patient care, and compliance with national guidance, local policies and procedures.

- Create a Clinical Audit Project Team with consideration to all relevant stakeholders, including clinicians, clinical audit staff, managers/supervisors, and service users.
- Define aims and objectives of the clinical audit.
- Create a project plan to ensure the Clinical Audit Project Team are aware of expectations.
- Set evidence-based standards to measure clinical practice against. Standards may incorporate agreed national or local measures, or consensus among appropriate colleagues in the absence of agreed standards.
- Design methodology with consideration of target population, sample size, sampling techniques, question design, data collection methods, consent and ethics.
- Collect data based on agreed methodology.
- Analyse data to determine if the standards have been met. If the findings show the standards are being met provide feedback on good practice. If the findings show that standards are not being met analyse the problems identified to find root causes and take action to eliminate or minimise the causes of the problems.
- Re-audit when action is taken to check that implemented actions and changes have led to quality improvement.

A Guide to Clinical Audit, which offers further information about each stage of the clinical audit process is available on the Clinical Audit intranet page.

3.3 Clinical Audit Project Team

The Clinical Audit Project Team is a professional or speciality group that assume responsibility and accountability for the completion of a clinical audit.

3.4 Project Lead

Project Leads are members of staff who are responsible for supervising the progress of the clinical audit. If the clinical audit covers more than one profession or speciality the overall lead must be agreed when the registration form is submitted for approval.

3.5 Clinical Audit Programme

The Clinical Audit Programme is a document that identifies the following:

- The clinical audit topics to be carried out over the financial year.
- The drivers for clinical audits; including national, regional and local priorities.
- The names of members of staff who are responsible for leading the clinical audits.
- The division which the clinical audit project belongs to.
- The committee which will receive the clinical audit report.
- The status of the clinical audit project.
- The planned activity for the clinical audit project, by quarter.

4. Procedure for conducting a clinical audit

4.1 Completion of a Clinical Audit Registration Form

A member of the Clinical Audit Project Team fills in the Clinical Audit Registration Form (available from the Clinical Audit intranet page) and submits it for approval to the Clinical Audit Co-ordinator.

4.2 Review of the Clinical Audit Proposal

The Clinical Audit Co-ordinator will review the Clinical Audit Registration Form and may offer suggestions about how the proposal could be changed to improve the appropriateness and/or effectiveness of the clinical audit.

After the scope of the clinical audit has been agreed the Clinical Audit Co-ordinator will add the project to the Clinical Audit Programme. Support for clinical audit projects will only be given to projects that are on the Clinical Audit Programme and the level of support depends on the priority of the project and the available resources of the Clinical Audit Co-ordinator (see Appendix A for details of the level of support available).

4.3 Completion of the Clinical Audit Report

Once the data has been completed and analysed the Clinical Audit Project Team should complete a draft report on the clinical audit (a clinical audit report template is available from the Clinical Audit intranet page). The draft report should then be submitted to the Project Lead for approval and to discuss recommendations and actions for improvement. Action plans should be specific, measurable, realistic and must have clear implementation timescales with identified leads for each action.

When the final report has been completed with recommendations and actions it should be sent to the Clinical Audit Co-ordinator for reporting and updating the Clinical Audit Programme.

5. Process for developing and monitoring the Clinical Audit Programme

5.1 Development of the Clinical Audit Programme

The Clinical Audit Co-ordinator will prepare a draft Clinical Audit Programme for each Division at the beginning of each financial year that will consist of the following:

- National or regional clinical audits that are relevant for West Suffolk NHS Foundation Trust to participate in for the following financial year.
- Requirements for clinical audit imposed by the West Suffolk Clinical Commissioning Group.
- National guidance for which evidence of implementation is required for the following financial year.

It is the responsibility of the Specialty Clinical Audit Lead, in liaison with relevant clinicians, to add local specialty topics to the draft Clinical Audit Programme.

Discussion, agreement and prioritisation of Clinical Audit Programmes should be discussed annually at Divisional Governance Steering Group meetings to ensure projects are agreed and appropriate support is in place.

5.2 Monitoring of the Clinical Audit Programme

The Clinical Audit Co-ordinator will monitor completion of the Clinical Audit Programme, including checking if clinical audits are being carried out in accordance with the planned timetable and if any interventions are needed to keep the programme on schedule.

5.3 Reporting of the Clinical Audit Programme

The Clinical Audit Co-ordinator will regularly report the status of the Clinical Audit Programme to the Clinical Safety & Effectiveness Committee and the Audit Committee.

6. Protection of Data

All clinical audit projects must adhere to the NHS Information Governance policies and standards. Clinical Audit Project Teams should pay particular attention to the Data Protection Act (1998) and the Caldicott Principles (1997):

1. Justify the purpose(s) of using confidential information
2. Do not use patient-identifiable information unless it is absolutely necessary
3. Use the minimum necessary patient-identifiable information that is required
4. Access to patient-identifiable information should be on a strict need-to-know basis
5. Everyone with access to patient-identifiable information should be aware of their responsibilities
6. Understood and comply with the law

Patient or professional identifiable data should never be reported in any clinical audit project.

7. Ethical Approval

Any clinical audit project that involves any of the following should contact the West Suffolk NHS Foundation Trust Research and Development Team for guidance on applying for ethical approval:

- The clinical audit includes any clinical significant departure from usual clinical care, for example, in implementing a significant change in practice.
- Patient information that is being collection is beyond the information ordinarily collected as part of providing routine patient care.
- Patients or carers are being asked directly for information that would subject them to burden or risk, for example, requesting sensitive information or completion of a long questionnaire or interview.
- The clinical audit collects or discloses any data that could be used to identify a patient or practitioner.

8. Roles and Responsibilities

The roles and responsibilities for clinical audit in West Suffolk NHS Foundation Trust are outlined below and are also available as flowcharts in Appendix B (Clinical Audit Responsibilities Flowchart) and Appendix C (Clinical Audit Trust Reporting Structure).

8.1 Executive Medical Director

The Executive Medical Director has overall responsibility for all aspects of clinical audit management and delivery within West Suffolk NHS Foundation Trust. This includes ensuring:

- The Clinical Audit Strategy is allied to the Board's strategic interests and concerns.
- Clinical audit is used appropriately to support the Board Assurance Framework.
- The Clinical Audit Policy is implemented across all clinical areas.
- Adequate resources are available to support delivery of this policy.
- Any serious concerns regarding the Trust's policy and practice in clinical audit, or regarding the results and outcomes of clinical audits, are brought to the attention of the Board.

8.2 Head of Patient Safety & Effectiveness

The Head of Patient Safety & Effectiveness has overall responsibility for managing the clinical audit process. This includes ensuring:

- The Clinical Audit Policy is fit for purpose.
- Resources are used effectively and efficiently to support the delivery of the Clinical Audit Policy.
- Performance monitoring arrangements are in place at Trust and Divisional level.

8.3 Divisional Governance Managers

Divisional Governance Managers have overall responsibility for ensuring:

- Relevant service and quality issues are included in the Divisional Clinical Audit Programme, including findings from complaints, incidents or claims.
- Reviewing the Divisional Clinical Audit Programme.
- Monitoring the progress of action plans from clinical audit.
- Supporting and directing the delivery of clinical audit within the Divisions.

8.4 Clinical Audit Co-ordinator

The Clinical Audit Co-ordinator has overall responsibility for supporting the clinical audit process, including:

- Developing the Trust and Divisional Clinical Audit Programmes.
- Supporting Divisions in prioritisation, development and implementation of Divisional Clinical Audit Programmes.
- Advising, supporting and training staff in clinical audit methodology, project management and reporting of clinical audit activity.
- Monitoring and reporting activity undertaken against the Trust and Divisional Clinical Audit Programmes to Audit Committee (quarterly), Clinical Safety & Effectiveness Committee (quarterly), and Divisional Governance Quality Boards/ Steering Groups (monthly).
- Co-ordinating participation in national clinical audits to ensure timely and accurate data submission.
- Maintaining the Trust's clinical audit database.

8.5 Clinical Directors

Clinical Directors have responsibility for ensuring:

- The Clinical Audit Policy is implemented throughout their Division.
- The Division participates in all national clinical audits which are relevant to the services it provides.
- Support implementing audit recommendations.
- Specialties review clinical practices through effective clinical audit arrangements.
- Relevant service and quality issues are included in the Divisional Clinical Audit Programme.
- Each speciality has a nominated Clinical Audit Lead.

8.6 Speciality Clinical Audit Lead

Each specialty is required to identify an individual to coordinate clinical audit activities for the area. These individuals are responsible for:

- Agreeing clinical audit priorities for the specialty.
- Ensuring that clinical audit projects are registered on the Divisional Clinical Audit Programme.
- Allocating projects from the Divisional Clinical Audit Programme to members of the team.
- Ensuring that national clinical audit data is reviewed and submitted prior to the deadline.
- Ensuring recommendations from agreed action plans are implemented.

8.7 Clinical Audit Project Lead/Supervisor

Each audit project must have a Project Lead/Supervisor, who retains overall responsibility for the project. For projects being undertaken by medical staff the Project Supervisor must be a consultant, who will retain overall responsibility for the project when junior doctors move on to their next placement or leave the Trust.

The Project Lead/Supervisor has responsibility for:

- Ensuring the project is registered on the Divisional Clinical Audit Programme.
- Ensuring the project meets the criteria for clinical audit.
- Providing a summary of the project's progress to the Clinical Audit Co-ordinator as requested.
- Ensuring the outcome of the project is reported and presented to relevant peer group for discussion of recommendations and actions for improvement.
- Ensuring action plans are implemented.

8.8 Trust Board

The Trust Board has responsibility for receiving and reviewing the annual Quality Accounts report, which includes a summary of clinical audit activity in the Trust.

8.9 Audit Committee

The Audit Committee has responsibility for receiving and reviewing quarterly performance reports which consider:

- Participation in relevant national clinical audits.
- Findings of national clinical audits, including recommendations to address risks.

8.10 Clinical Safety & Effectiveness Committee

The Clinical Safety & Effectiveness Committee has responsibility for:

- Approving the Trust's Clinical Audit Policy & Strategy.
- Approving the Trust's Clinical Audit Programme.
- Receiving a quarterly performance and monitoring report which considers:
 - Progress against the Trust Clinical Audit Programme.
 - Compliance with defined key performance indicators for clinical audit.
 - Findings of national and local clinical audits, including outcomes and recommendations to address risks.
 - Actions to address risks identified through clinical audit, ensuring these are appropriately captured on the Risk Register and implemented.

8.11 Divisional Governance Quality Boards/Steering Groups

The Divisional Governance Quality Boards/Steering Groups have responsibility for:

- Approving Divisional Clinical Audit Programmes.
- Reviewing progress of Divisional Clinical Audit Programmes.
- Ensuring appropriate resources are in place to meet Divisional Clinical Audit Programmes.
- Monitoring Divisional Risk Registers, including actions to address risks identified through clinical audit.
- Escalating significant clinical or operational concerns to Clinical Directors Meeting and Trust Executive Group, respectively.
- Receiving summaries of national clinical audit reports and completed baseline assessments to agree recommendations and actions.
- Receiving completed local clinical audit reports and recommendations.
- Ensuring learning from clinical audit recommendations are disseminated to staff.

8.12 Department/Speciality/Ward Governance Meetings

Department/Speciality/Ward Governance Meetings have responsibility for:

- Identifying clinical audit topics to register on the Clinical Audit Programme.
- Monitoring progress of Department/Speciality/Ward clinical audits.
- Receiving national and local clinical audit results to discuss and agree recommendations and actions.

8.13 NICE & Clinical Audit Committee

The NICE & Clinical Audit Committee has responsibility for:

- Reviewing reports to Audit Committee (quarterly) and Clinical Safety & Effectiveness Committee (quarterly).
- Reviewing the annual Quality Accounts summary of clinical audit activity report.
- Monitoring the Clinical Audit Development Action Plan.
- Supporting development of the annual Clinical Audit Programme.
- Identifying Trust priority clinical audit topics to register on the Clinical Audit Programme.
- Monitoring national clinical audit recommendations and action plans.
- Reviewing progress of Trust and Divisional Clinical Audit Programmes and escalate concerns to Divisional Governance Quality Boards/Steering Groups.

9. Training and development

Staff who require training or support to carry out the clinical audit process should contact the Clinical Audit Co-ordinator, who can provide training as required. A Guide to Clinical Audit, which offers a structured layout of the key aspects of clinical audit is also available on the Clinical Audit intranet page.

10. Monitoring

The Clinical Safety & Effectiveness Committee will monitor implementation, compliance and effectiveness of this policy. This will be achieved through reporting against defined key performance indicators and quarterly review of progress against the Trust Clinical Audit Programme. Key performance indicators for this policy are as follows:

Activity	Key Performance Indicator	Target	Performance
Planning	Divisional Clinical Audit Programmes agreed by Governance Steering Groups by the end of March evidenced through the minutes of the meeting	100%	
Implementation	Arrangements are in place to support clinical audit activities at Divisional/Specialty levels	100%	
	Each specialty identifies a Clinical Audit Lead	100%	
	Agreed priority audits from Trust/Divisional programmes are undertaken with appropriate support	100%	
	Multidisciplinary forums are in place to discuss audit findings	100%	
	Discussion of audit findings at multidisciplinary forums are minuted/recorded	100%	
Learning	Each completed audit to have recommendations	100%	
	Action plans are formulated from recommendations that suggest a change in practice	100%	
	Action plans are implemented, or progress reported to the relevant Divisional Governance Steering Group within 3 months of approval of plan	100%	
	Training in clinical audit methodology available to all staff as needed	100%	

11. Scope

This policy applies to anyone involved in the clinical audit process within the Trust. This includes:

- All staff, both clinical and non-clinical, including staff on short-term, agency, locum, voluntary or honorary contracts.
- Students and trainees.

12. Review

This policy will be reviewed every 2 years. Earlier review may be required in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance.

13. Document Configuration

Author(s):	Head of Governance, Clinical Safety & Effectiveness Manager, Clinical Audit Co-ordinator
Other contributors:	Medical Director, Director of Operations
Approvals and endorsements:	Clinical Safety & Effectiveness Committee
Consultation:	Clinical Directors Meeting
Issue no:	4
File name:	Governance on 'charlie' S:\Audit\Policy PP214\2016 Policy update\PP(16)214 Clinical Audit.doc
Supersedes:	Version 3
Equality Assessed	Yes
Implementation	Dissemination on intranet and Divisional Governance Steering Groups
Monitoring:	See section 9 - Monitoring
Other relevant policies/documents & references:	Risk Management Policy & Procedure PP093 Information Security PP060 Data Protection Policy PP110
Additional Information:	

Appendices

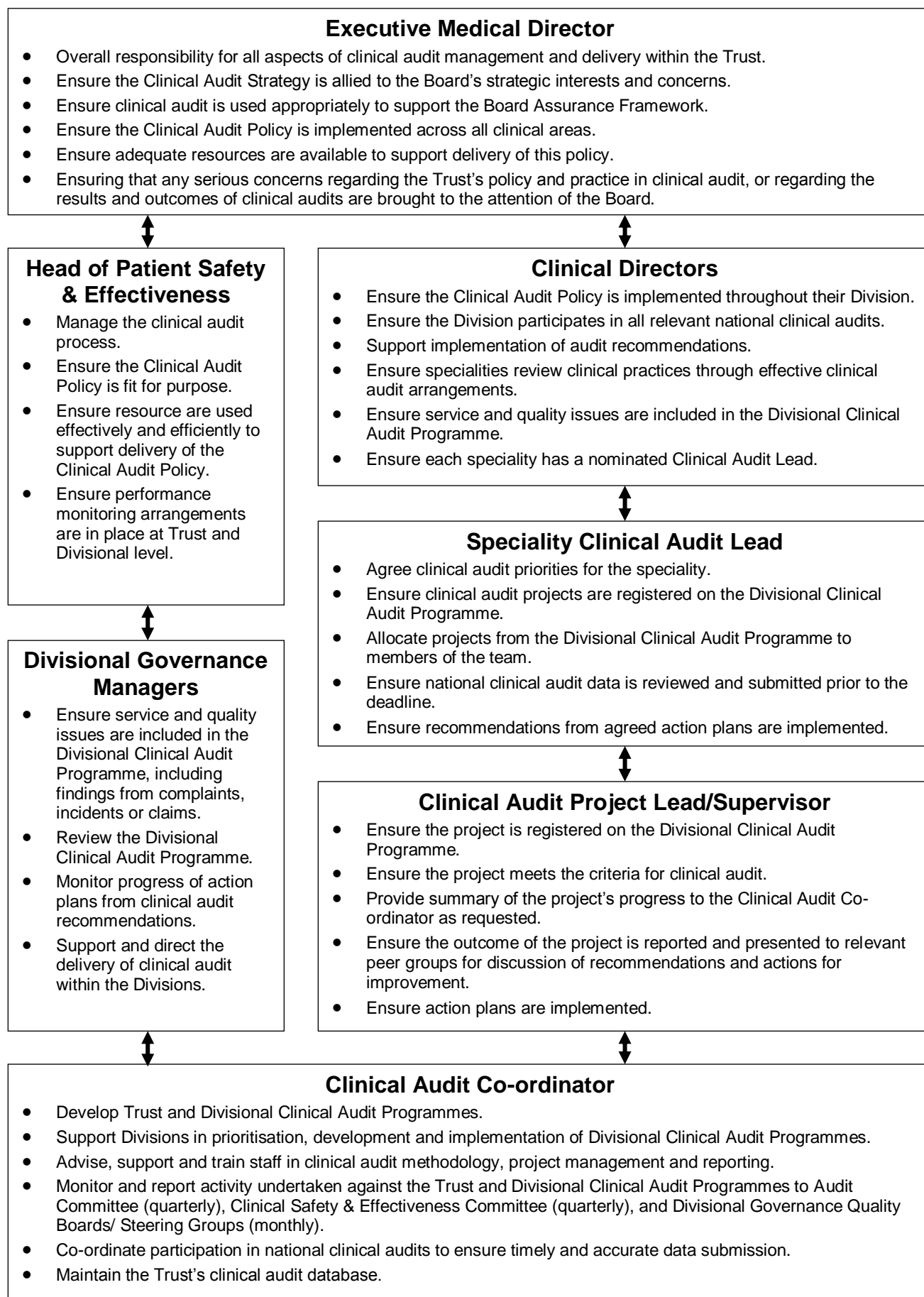
- A: Levels of support for clinical audit projects
- B: Clinical Audit Responsibilities Flowchart
- C: Clinical Audit Trust Reporting Structure

Appendix A: Levels of Support for Clinical Audit Projects

All clinical audit projects must be registered with the Governance Department, even if help with the project is not required.

PRIORITY	TYPE OF PROJECT	LEVEL OF SUPPORT
Priority 1 – Trust “Must Do”	<ul style="list-style-type: none"> • National clinical audit (mandatory) • CQUIN audit • Evidence for accreditation • National audit report recommendations • Outcome of root cause analysis or incident 	<ul style="list-style-type: none"> ➤ Identification of patient sample ➤ Patient list retrieval ➤ Advice on audit methodology ➤ Design of data collection forms ➤ Arrangements for data collection ➤ Analysis of data ➤ Preparation of reports ➤ Formulation of action plan ➤ Support to ensure action plan is implemented ➤ Support for escalation of findings
Priority 2 – Divisional/ Speciality Good Practice	<ul style="list-style-type: none"> • National clinical audit (non-mandatory) • Regional/multi-centre audit • Audit of WSFT Clinical Guideline or Policy • Audit of NICE guidance • Audit of Royal Colleges guidance • Other Divisional priorities including high risk, high volume, high cost or known problems 	<ul style="list-style-type: none"> ➤ Identification of patient sample ➤ Patient list retrieval ➤ Advice on audit methodology ➤ Assistance with analysis of data ➤ Assistance with preparation of reports ➤ Advice on development of action plan ➤ Monitoring completion of action plan
Priority 3 – Clinician Interest	<ul style="list-style-type: none"> • Clinician interest audit • Other Speciality priorities including high risk, high volume, high cost or known problems 	<ul style="list-style-type: none"> ➤ Identification of patient sample ➤ Patient list retrieval ➤ Advice on audit methodology ➤ Advice on development of action plan

Appendix B: Clinical Audit Responsibilities Flowchart



Appendix C: Clinical Audit Trust Reporting Structure

