

## Clinical Audit and Effectiveness Policy

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### Equality Impact

Great Western Hospitals NHS Foundation Trust strives to ensure equality of opportunity for all service users, local people and the workforce. As an employer and a provider of health care, the Trust aims to ensure that none are placed at a disadvantage as a result of its policies and procedures. This document has therefore been equality impact assessed in line with current legislation to ensure fairness and consistency for all those covered by it regardless of their individuality. This means all our services are accessible, appropriate and sensitive to the needs of the individual.

### Special Cases

None.

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# 1 Document Details

## 1.1 Introduction and Purpose of the Document

The purpose of this Policy is to ensure that anyone engaged in the clinical audit processes within the Trust are aware of the principles and procedures involved. Their obligation to participate in clinical audit and to drive quality improvement and provide quality assurance as part of the Great Western Hospitals NHS Foundation Trust (the Trust) accountability to the Care Quality Commission (CQC)/ Monitor/Quality Accounts (QA) and Commissioners.

This includes –

- All employees, both clinical and non-clinical, and those on short-term or honorary contracts
- Students and trainees in any discipline
- This Policy should also apply when clinical audit is undertaken jointly across organisational boundaries.

Statutory and mandatory requirements are imposed on healthcare providers within the NHS in England to use clinical audit to regularly assess and monitor the quality of their services; when undertaken in accordance with evidence based standards, clinical audit can provide assurance of compliance, and helps to identify and minimise risks and/or inefficiencies.

Therefore, the Trust is obliged to:

- Participate in local and/or national multidisciplinary audits of the treatment and outcomes for patients in each clinical division covered by the Trust.
- Have a current Clinical Audit Policy and a prioritised programme that relates to both local and national priorities with the overall main aim of improving patient outcomes.
- Have in place suitable governance systems and arrangements to involve and support all Clinicians to participate in clinical audit.
- Ensure that all Clinicians and other employees responsible for or participating in clinical audits are given appropriate time, knowledge and skills to facilitate the successful completion of the audit cycle (Appendix C).
- Review the results and recommendations of local and national audits undertaken in the Trust, as well as other national findings, to identify required actions and ensure they are reflected in the organisation's aims and objectives as part of the Trust's responsibility to quality improvement.
- Make National clinical audit data available to support publication of consultant-level activity and outcome statistics.
- Implement and/or respond to all relevant recommendations of any appropriate clinical audit
- Provide to the co-ordinating commissioner, on request, the findings of any audits carried out, in particular locally-agreed requirements such as Commissioning for Quality and Innovation (CQUIN) audits.
- Ensure the Trust's management or governance leads receive regular reports on the progress being made in implementing the recommendations of national clinical audits and other national findings, including reviews of the outcomes and any re-audits being conducted where necessary.
- 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 monitored against (Regulations 4 to 20A) of the Health and Social Care Act 2008 (Regulated Activities) (Ref 17) Regulations 2014 and should, where possible, include the experiences of people who use the service. The systems and processes should be continually reviewed to make sure they remain fit for purpose.

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- Ensure Clinical and internal audit processes function well and have a positive impact in relation to quality governance, with clear evidence of action to resolve concerns.
- Ensure there is a continuous rolling programme that measures and improves quality. The Board actively oversees a co-ordinated programme of clinical audit, peer review and internal audit which is aligned with identified risks and/or gaps in other assurance.
- Action plans are completed from audit; and re-audits are undertaken to assess improvement

## 1.2 Glossary/Definitions

The following terms and acronyms are used within the document:

%	Percentage
AMD	Associate Medical Director
CA	Clinical Audit
CA&E	Clinical Audit and Effectiveness
CQC	Care Quality Commission
CQUIN	Commissioning for Quality and Innovation
DDON	Divisional Director of Nursing
DH	Department of Health
GMC	General Medical Council
HQIP	Healthcare Quality Improvement Partnership
IG	Information Governance
MBRRACE	Mothers and Babies: Reducing risks through audit and confidential enquires
NCAPOP	National Clinical Audit and Patient Outcomes Programme
NCEPOD	National Confidential Enquiries into Patient Outcomes and Deaths
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NICE	National Institute of Health and Care Excellence
NPSA	National Patient Safety Agency
PQC	Patient Quality Committee
QA	Quality Accounts
QIA	Quality Impact Analysis
SI	Serious Incident
SMART	Specific, measurable and achievable, realistic and timely
WHO	World Health Organisation

## 1.3 What is 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.

Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.

This definition is endorsed by the National Institute of Health and Care Excellence (NICE) (Ref 3).

## 1.4 What is Clinical Effectiveness?

'The application of best knowledge, derived from research, clinical experience and patient preferences to achieve optimum processes and outcomes of care for patients. The process involves a framework of informing, changing and monitoring practice' ('Promoting Clinical Effectiveness', Department of Health, 1996) (Ref 1).

"It builds on clinical audit and quality improvement and provides a framework for linking research, implementation and evaluation in clinical practice". It is "about doing the right thing in the right way for the right patient at the right time". ('What is Clinical Effectiveness'. Royal College of Nursing. 1996) (Ref 2).

## 2 Main Policy Content Details

### 2.1 Background

The expectation that healthcare professionals should participate in regular Clinical Audit & Effectiveness (CA&E) work was first established in the 1989 Government White Paper, 'Working for Patients' (Ref 1) This has been reinforced and extended by a succession of key national publications, including:

- The New NHS — Modern Dependable (Department of Health, 1997) (Ref 1).
- A First Class Service (Department of Health, 1998) (Ref 1).
- Clinical Governance — Quality in the NHS (Department of Health, 1999) (Ref 1).
- Good Medical Practice (General Medical Council, 2001) (Ref 16).
- Learning from Bristol: the report of the public inquiry into children's heart surgery at Bristol Royal Infirmary 1984–1995 [the 'Kennedy Report'] (Department of Health, 2002) (Ref 1).
- National Standards, Local Action (Department of Health, 2004) (Ref 1).
- Standards for Better Health (Department of Health in 2004) (Ref 1).
- Good Doctors Safer Patients (Department of Health, 2006) (Ref 1).
- Trust Assurance & Safety (Department of Health, 2007) (Ref 1).
- The NHS Next Stage Review Final Report, High Quality Care for All [the 'Darzi Report'], (Department of Health, 2008). (Ref 1).
- The Health and Social Care Act (Parliament, 2012) (Ref 17).
- Essential Standards of Quality and Safety (Care Quality Commission, 2009) (Ref 10).
- Publication of White Paper (July 2010) (Ref 1).
- Health and Social Care Act 2008 (Regulated Activities) Regulations (2014) (Ref 17).
- Clinical Audit – Statutory and mandatory Requirements (HQIP, 2014) (Ref 12).
- Quality Accounts (Health Act 2009) (Ref 17).

All National Health Service (NHS) Trusts have to make an annual declaration regarding their compliance with the specified standards pertaining to Clinical Audits and Effectiveness projects.

### 2.2 Promoting Clinical Quality, Effectiveness and Patient Safety

The Trust is required to meet national standards of best practice in relation to clinical effectiveness as set out by the Department of Health (DH) , CQC, (Acute Trusts & Maternity), Quality Accounts and National Institute of Health and Care Excellence (NICE).

To ensure that quality care is delivered for a positive experience, including being treated according to the patient's wants or needs, and with compassion, dignity, and respect. To ensure quality care is delivered according to the best evidence regarding what is clinically effective in improving patients' health outcome and to ensure quality care is delivered to prevent all avoidable harm and risk to patient's safety. To achieve health benefits that meet their individual needs through healthcare decisions and services based on what assessed research evidence has shown provides effective clinical outcomes, the Trust aims to include:

- The participation, dissemination and response to externally published best practice reports/reviews e.g. National Confidential Enquiries into Patient Outcomes and Deaths



(NCEPOD), Mothers and Babies: Reducing risks through audit and confidential enquires (MBRRACE), NICE.

- Participation in external best practice reviews.
- Participation in National comparative audits.
- Use of clinical quality and performance indicators e.g. Dr Foster performance reports.

The Trust maintains the view that whilst CA & E are fundamentally quality improvement processes, they also have a vital function in providing assurance about the quality of services and promote patient safety

### 2.3 Clinical Audit Cycle – Based on Principles for Best Practice in Clinical Audit

The clinical audit cycle (Appendix C) and stages used are in line with those stated within ‘Principles for Best Practice in Clinical Audit’ published by NICE (2002) (Ref 3). Whilst the nature of clinical audit within the NHS continues to evolve, the core purpose and the component parts remain the same.

- Identify a topic.
- Agree on the standards to be audited.
- Observe practice.
- Compare practice with explicit standards.
- Change practice, if current practice does not meet standards.
- Re-audit to sustain compliance/improvement in care.

The NICE Best Practice Guide has detailed sections on each stage and should be consulted in planning clinical audit.

### 2.4 Annual Clinical Audit Programme

Prior to the start of every financial year, the Trust must agree an appropriate planned programme of CA&E activity.

This CA&E programme will meet the Trust’s corporate requirements for assurance, but must be owned by clinical services. All employees will be provided with the opportunity to submit topics which can then be considered by Divisions using the audit prioritisation tool to incorporate in the Trust Annual Audit Plan.

The organisation Annual Clinical Audit Programme will be approved and ratified by the Patient Quality Committee (PQC) and Commissioners. The process for developing an annual CA&E programme is outlined in (Appendix D).

### 2.5 Choosing and Prioritising National & Local CA&E Topics

The CA&E Department identify mandatory topics (priority 1 and 2 projects) from National Clinical Audit Patient Outcomes Programme (NCAPOP) and from the agreed Quality Schedule with the Commissioners including any re-audits of these projects.

The Divisions will identify Divisional Priorities (priority 3 projects) from the following sources:

- Complaints.
- Risk management tool.
- Dr Foster performance indicators
- Local Safeguarding Children Board.
- Safeguarding adults.
- Incident reporting trends.
- Serious Incidents.

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Any audits proposed as additions to the Divisional Audit Programme **must** have the agreement of the Divisional Director/ Associate Medical Director (AMD).

The Trust is committed to supporting locally determined clinical audit activity to significantly contribute to the process of continuous service quality improvement. It is acknowledged that individual clinicians may initiate a clinical audit project on the basis of personal interest, personal development, or as part of an educational or training programme. It is important that these are registered and approved within the division and reported through their existing clinical governance structures to maximise organisational learning. Each specialty is responsible for monitoring and reporting their local audit activity, ensuring this follows the existing clinical governance processes. Overall, the Divisional Audit Programme will be monitored by the Divisional Quality Governance Facilitators; monthly reports of CA & E activity will be provided at the Division level, where any issues arising will be discussed and where required escalated to the PQC.

## 2.6 Clinical Audit Exception Form

There may be exceptional circumstances whereby participation in a mandatory Clinical Audit can be difficult – for example, a severe delay starting data collection, insufficient patient sample to meet the minimum requirement set by the audit criteria, or, where the methodology is not practicable/achievable i.e, where specific data cannot be identified/obtained.

In these circumstances, the Audit/Service lead(s) **MUST** notify their relevant Divisional Leads and the Clinical Audit Department immediately. This ensures the exception is raised at the earliest opportunity and adequate assessment of risks/impact for the Service and the Trust can be undertaken.

The Audit/Service/Divisional lead(s) will be required to complete the Clinical Audit Exception Form (Appendix R) within four weeks of initial notification (as above). This should follow the local Governance arrangements to ensure the completed form has Divisional assessment and approval prior to submitting to the Clinical Audit Manager to formally report to the Medical Director, the Patient Quality Committee and/or the Clinical Commissioning Group(s) for final oversight.

## 2.7 Registration of Clinical Audit

The CA Registration Form (Appendix E) must be completed for priority 1, 2 and 3 projects prior to commencement, regardless of the level of support required from the CA&E Department. This ensures all agreed audits are registered on the CA&E programme, prioritised correctly and any associated administrative or technical support is scheduled accordingly.

The CA Registration Form is available on the Trust Intranet Site and can also be obtained via CA&E Department and Divisional Quality Governance Facilitators. The Trusts process for audits is outlined in Appendix D.

## 2.8 Approval of Clinical Audit

The Project Lead will ensure the projects have been approved by the Division. If the Proposal involves other specialities, appropriate approval will need to be obtained from that Division prior to submission of the CA Registration Form.

Audits have a greater chance of success if all employee likely to be affected by the audit process or the changes identified, are involved at the outset. Employees must not audit other people's work without their consent.



## 2.9 Approved Process for Conduction Clinical Audits

Please follow process as laid out in Appendix D.

The criteria and standard for an audit must be clearly stated in the CA Registration Form (Appendix E) and logged on Clinical Audit Programme Database.

CRITERIA in REGISTRATION FORM to meet following –

- Clinical audits are approved and registered
- Clinical audits are based on standards and conducted in line with this policy

Criteria are those aspects of care that the auditor wishes to examine. Explicit rather than implicit criteria should be preferred. Systematic methods should be used to derive criteria from evidence. These include methods for deriving criteria from good-quality guidelines or from reviews of the evidence. Criteria should relate to important aspects of care and be measurable. Adjustment for case mix is generally required for comparing the outcomes. If the criteria incorporate, or are based on, the views of professionals or other groups, formal consensus methods are preferable. If there is insufficient evidence to determine target levels of performance in audit, reference to levels achieved in audits undertaken by other professionals will be useful.

Standards are the pre-stated or implicit levels of success that the auditor wishes to achieve. An exception must be stated and is any clinically acceptable reason why the standard of care will not be met. Measurement of outcome can be used to identify problems in care, provided outcomes are clear, influenced by process and occur within a short period. In some audits, benchmarking techniques could help participants in audit to avoid setting unnecessarily low or unrealistically high target levels of performance.

## 2.10 Sample Size

Sample sizes will vary according to the criteria of the project, and should be agreed at the outset. A sample size calculator is available on the Clinical Audit Intranet page.

## 2.11 Data Collection

The Audit Lead will need to ensure that the person(s) collecting the data are identified and informed prior to undertaking the audit.

Data collection will need to be accurate and complete. The Audit Lead will also need to indicate the source(s) of the data to be used for the audit; as a working principle, the clinicians should embark on data compilation.

The CA&E Department are able to support Audit Leads in developing data collection proforma's and database to assist with analysing. It is advisable to pilot the data collection proforma in the first instance.

## 2.12 Data Validation Prior to Data Submission

Local quality checks and validation of data for audits confirm the accuracy and completeness of information used for clinical audits. Transparency raises the credibility of data compared at national level for National Audits. It also highlights local data quality issues. Data for clinical audits can be obtained from multiple sources within and outside the hospital.

Data sources include:

- Electronic Patient System
- Trust informatics system
- Medical notes
- Other in-hospital databases
- External organisations i.e. Ambulance Services/Primary Care
- Patient survey
- Observing clinical practice

### 2.13 Agreeing on Compliance (stating compliance)

Clinical audit can include assessment of the process and/or outcome of care. To enable meaningful comparison, multiple recommendations need to be followed:

- Identification and assessment of audit criterion and standards.
- Development of instruments for measurement of the quality of guidelines i.e. Access database/Excel spreadsheet for accurate data analysis.
- Evaluation of criterion against standards.
- Working out the compliance with the pre-stated standards for the audit.

The overall compliance should be stated as percentage ('%') based on the clinical audit findings.

### 2.14 Format for Audit Reports

The Trusts CA&E Report Template should be used for documentation of audit results and action plans. The re-audit can only be undertaken if the action plans from the first audit have been implemented and evidence has been submitted accordingly. The Local and National Report Templates are available from the CA&E Department and the Divisional Quality Governance Facilitators.

### 2.15 Process for Dissemination of the Audit Report and Action Plan

- Results are being reported and disseminated
- Action plans are being agreed and implemented

Then it should state:

- Who will perform the monitoring
- When and how the monitoring will be performed
- What will happen if any shortfalls are identified – Risk Assessment (tool)
- Where the results of the monitoring will be reported
- How the resulting action plan will be progressed and monitored

Results and findings will be discussed and action plans agreed at the appropriate department meetings/forums, as agreed on the Clinical Audit Registration Form (Appendix E). Arrangements for presentation of results at the agreed forum should be made prior to compiling reports to avoid any delays in implementing action plans.

The final report and action plan should be disseminated to all relevant employees; the circulation list should be included within the audit report.

Not all clinical audits will require an action plan, e.g. where an audit shows that standards are consistently and repeatedly being met, and practice is effective. For such audits there should be an

explicit statement within the report template that no further action is required, along with the reason(s) for this.

Action plans should be specific, measurable and achievable, realistic and timely (SMART). Actions should have clear implementation timescales with identified leads for each action. Action plans should also have been approved by the relevant Clinical Lead or Department.

The outcomes of all audits will be made available at appropriate committees; at Divisional level the respective Governance Facilitator will report divisional led audits (priority 3 and priority 2 projects), and at PQC by the Clinical Audit & Effectiveness Manager will report organisation led audits (priority 1).

## 2.16 Process for Implementing Improvement

It is the responsibility of the Audit Lead to present the action plan to the Departmental/Division to inform them of any resource implications or change in Clinical practice. This will need to be taken into account when developing business plans.

It is also the responsibility of the Audit Lead to implement actions from the Clinical audit and to submit evidence to the clinical audit department / Divisional Quality Governance Facilitators to demonstrate these actions are complete.

Once actions have been taken to improve quality, assurance must be available to show whether these actions have been effective, or if additional steps might be required.

## 2.17 Re- Auditing to Sustain Compliance/Show Improvement in Care

Although improving performance is the primary goal of audit, sustaining that improvement is also essential. Re-audit is important to determine whether agreed actions have been implemented according to the action plan. CA&E projects will lead to follow up audits unless no action plan is required.

At the same time as when the annual Trust CA&E Programme is being developed, all 'Completed' audits from the start of the previous financial year can be identified for consideration as re-audits (unless they were completed with no actions being required, as compliance with all standards was achieved).

Clinical lead/teams are also responsible for monitoring the implementation of their respective action plans. Audit Leads will only be able to re-audit, once the actions plans from the first audit has been successfully implemented and embedded in clinical practice.

The CA Registration Form (Appendix E) for re-audit must be submitted, along with the completed action plan from the first audit, to the Divisional Governance Facilitator.

## 2.18 External Dissemination

If any audit findings are considered for dissemination outside the Trust e.g. at a regional meeting, conference or for official publication, details must be submitted on the CA Registration Form.

## 2.19 Clinical Audit Certificate

The Audit Lead can receive an official Trust CA&E Certificate. Only registered audits prior to commencing the audit will enable the Audit Lead or group to receive a certificate.

The certificate will be completed by the Clinical Audit & Effectiveness Department or Divisional Governance Facilitator.

## 2.20 Respecting Equality and Diversity when choosing a Clinical Audit Project

When selecting audits or samples, no patient should be deliberately excluded on the grounds of ethnic origin or nationality, disability, gender, gender reassignment, marital status, age, sexual orientation, race, trade union activity, religion or political or religious beliefs. Please refer to the Quality Impact Assessment (Appendix B).

For patient surveys/questionnaires, every effort will be made to ensure the inclusion of valid responses from those who have been included in the initial sample but may have difficulty understanding or responding to the requested feedback.

## 2.21 Medical Notes Retrieval for Clinical Audit

Notes for clinical audits will only be made available once the project has been registered and approved by the Clinical Lead. The CA&E Department are able to support audits by retrieving medical case notes for registered audits

The auditor must specify:

- If notes are required for the audit;
- The location for case notes to be left. This should be in a safe but accessible place in the event they are required for an emergency admission, clinic appointment.
- Timescales for case notes review. The auditor should adhere to timescales specified on the CA Registration Form (Appendix E), in order for CA&E Department to support medical case note retrieval. It will not be the responsibility of CA&E Department to organise the case notes if they are persistently being taken and retrieved.

Depending on the sample size in the audit, notes will be pulled in batches of either 10 or 20 sets at a time. It will be the responsibility of the case note reviewer to contact the CA&E Department when further batches of medical notes are required.

For projects that are not required to be registered, notes can be obtained directly from Health Records.

## 2.22 Information Governance: Collection, Storage and Retention of Data and Confidentiality

All CA&E activity must take account of:

- Data Protection Act (1998) (Ref 5).
- The Caldicott Principles (1997) (Ref 6).
- NHS Confidentiality Code of Practice (2003) (Ref 7).
- Records Management: NHS Code of Practice for Health & Social Care (2006), (Ref 8).
- IG Toolkit number 13-201 (confidentiality and data protection assurance) (Ref 9).

Data will be:

- Adequate, relevant and not excessive.
- Accurate.
- Processed for limited purposes.
- Confidential.
- Anonymised **wherever** possible.
- Not kept for longer than is necessary.
- Held securely.
- Transferred securely.
- Destroyed securely.

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Anyone involved in the collection, storage and retention of data collected for CA&E purposes in the Trust (or in addressing the findings) should ensure that the data is kept securely and is only accessible to those involved in the CA&E activity. This applies to paper records and electronic storage devices i.e. personal computers, laptops, memory sticks etc.

The Department of Health publication *Records Management: NHS Code of Practice for Health & Social Care* (2006) (Ref 8) requires “audit records” to be retained for a period of **five years** and then destroyed under confidential conditions.

CA&E activity must also conform to the requirements of the *NHS Confidentiality Code of Practice* (2003) (Ref 3) 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”. If patients have been so informed, Section 60 of the Health and Social Care Act 2001(Ref 17) makes provision for the collection of patient identifiable data for the purposes of clinical audit; however best practice would always direct an organisation to anonymise clinical audit data unless there was a compelling reason not to do so.

In whatever format or forum audit results are shared or discussed, employees must treat this as confidential information not to be disclosed. Any data presented outside the Trust requires the approval of the Clinical Leads.

Final audit reports must be anonymised, so no patient or employee member may be identified (unless with their consent), even if the relative ‘performance’ of different Clinicians might otherwise be revealed - the purpose of CA&E being quality assurance and improvement, not performance management.

Trust compliance with all local and national data and information requirements is the responsibility of the Records Management and Information Governance. This is responsible for assuring the Information Governance Steering Group that all matters of records management adhere to those indicated in the National Information Toolkit.

## 2.23 Confidentiality Agreements

There may be occasions when an organisation engages individuals in its clinical audit activities who are not directly employed by that organisation, e.g. those that are on honorary contracts, volunteers, patients and the public. It is important that they understand the regulations that apply to the practice of clinical audit, so training is an important consideration. It is also recommended that individuals in this situation sign a Confidentiality Agreement with Information Governance.

Anyone not directly employed by this Trust who will be involved in any CA&E activity must be given a copy of this Policy and also sign a relevant Confidentiality Agreement with Information Governance.

## 2.24 Involvements in Clinical Audit

### 2.24.1 Involving Patients and the Public

The Trust is committed to the principle of involving patients/carers in the CA&E process, either indirectly through the use of patient surveys and questionnaires, or directly through participation of patients, carers and members of the public through the use of patient feedback; Clinicians can measure patient perception of service delivery, outcomes of treatment and patient satisfaction.

National strategies and guidelines include patient feedback in their recommended quality measures. National audits on patient feedback also provide assurance of best practice and drive improvements locally.

### 2.24.2 Multi-disciplinary, Multi-professional Audit and Working with other Organisations

The Trust is committed to participation in multi-disciplinary/interface audits within the organisation and in partnership with other organisations to ensure a smooth integrated care pathway.

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

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

A Pathway/joint audit must meet one or more of the following criteria:

- Complete audit cycles conducted by professionals across multiple divisions or from both primary and secondary care working together as a team to improve patient care.
- They may audit care given to patients who attend either or both settings and prepare a report and subsequent feedback (compliance to discharge letters, compliance to outpatient letters)
- Undertaken by a member of an organisation and audit other organisation's practice after seeking approval.
- Examine the quality of communications between hospital, primary care and other organisations i.e. Tertiary Centres.
- Members of different organisations share responsibility for the audit.
- Regional or Network driven audits i.e. South West Cancer Collaborative/Avon Gloucester Weston Somerset Network.
- National audits that mandates interface/joint working for audit completion.

### 2.24.3 Involving Clinical Managers

Clinical Managers are essential as drivers of change. It is particularly important to involve managers if the anticipated outcome of a clinical audit/effectiveness audit raises resource/financial implications.

### 2.24.4 Involving Clinicians

Clinicians responsible for or participating in CA&E activity should have appropriate time, knowledge and skills to undertake this.

The Trust expects all Foundation year 2 and higher grades to undertake at least one clinical audit during their placement in the Trust. Foundation year 1 Doctors are encouraged to participate/undertake clinical audit where possible. The Trust also expects all the nursing professionals/other healthcare professionals to engage in clinical audits.

## 2.25 Clinical Audit and Effectiveness Department Database

Approved Clinical Audit projects registered centrally onto the Clinical Audit Programme will be maintained by the Clinical Audit department; progress with audit activity is regularly monitored. Reports are generated to provide assurance to internal committees, external regulators and assessors. The Clinical Audit Programme is also available via the Trustwide Dashboard which is accessible for divisions and local specialists to monitor and manage their audit activity and generate reports.

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## 2.26 Ethics and Consent to Participate in Audit

CA&E activity should always be conducted within an ethical framework that encompasses the following four principles:

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

If ethical concerns arise during the planning stages, you may wish to re-evaluate if your project is research as opposed to clinical audit.

## 3 Protected Characteristics Provisions

No special measures or provisions are required

## 4 Duties and Responsibilities of Individuals and Groups

### 4.1 Chief Executive

The Chief Executive is ultimately responsible for the statutory duty of quality and for the effective prioritisation to participate in national clinical audits and for decisions about local clinical audits and the implementation of this document.

### 4.2 Trust Board

The Trust Board is responsible for ensuring that the organisation consistently follows the principles of good governance applicable to the Great Western Hospitals. This includes the development of systems and processes for governance and risk management which support this policy.

The Trust Board will want to be assured that clinical audits are:

- Material – i.e. that they are prioritised to focus on key issues and that the value outweighs the cost
- Professionally undertaken and completed – i.e. clinical audits are undertaken and completed to a professional standard, including the quality of data being analysed
- Producing results- outcomes that are shared and acted upon
- Followed by improvements-that are made and sustained

### 4.3 Ward Managers, Matrons and Managers for Non Clinical Services

All Ward Managers, Matrons and Managers for Non Clinical Services must ensure that employees within their area are aware of this document; able to implement the document and that any superseded documents are destroyed.

#### 4.4 Document Author and Document Implementation Lead

The document Author and the document Implementation Lead are responsible for identifying the need for a change in this document as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and resubmitting the document for approval and republication if changes are required.

#### 4.5 Target Audience – As indicated on the Cover Page of this Document

The target audience has the responsibility to ensure their compliance with this document by:

- Ensuring any training required is attended and kept up to date.
- Ensuring any competencies required are maintained.
- Co-operating with the development and implementation of policies as part of their normal duties and responsibilities.

All health professionals are expected to carry out regular clinical audit as part of their work programme. The Trust must ensure that appropriate support and direction is provided to professional groups.

#### 4.6 The Patient Quality Committee (PQC)

This Committee is responsible for overseeing all Clinical Audit activity in the Trust, including the implementation of the CA&E programme.

The PQC includes key representatives from each Clinical Division, Allied Health Professionals, Medical, Nursing, Management, Clinical Audit, Infection Prevention & Control, Health & Safety, and Clinical Risk Management.

Responsibilities include:

- Provides assurance to the Trust Board about the Trust CA&E activity.
- Review and approve the Trust's Annual Audit Programme and Annual Report.
- Actively support the implementation of the Trust wide Audit Plan to ensure quality of patient care is in line with the best available evidence of clinical and cost effectiveness.
- They also make the decisions about participation in any CA&E audits, based on their quality and relevance to the organisation

(For Foundation Trusts) the Board is required by Monitor to declare via an Annual Governance Statement the effectiveness of the system of internal control, the role and conclusions of clinical audit, and a plan to address weaknesses and ensure continuous improvements of the system-covering an outline of the actions taken, or proposed, to deal with any significant gaps in control.

#### 4.7 Senior Managers/Associate Medical Directors / Divisional Directors of Nursing/Heads of Services/Matrons

Clinical Managers are responsible for ensuring that service development and delivery is underpinned by an effective programme of clinical audit, which forms part of the Continuing Professional Development regime for their team. Clinical Managers are essential as drivers of change. It is particularly important to involve managers if the anticipated outcome of a clinical audit/effectiveness project raises resource/financial implications.

Responsibilities include:

- To ensure that this policy is implemented throughout their division
- Producing prospective Divisional Audit Plan with their Divisional Governance Facilitator.
- To ensure that all clinical audit activity within their directorate is registered on the Trust database and complies with nationally accepted best practice standards
- To ensure that their directorate participates in all national clinical audits, national confidential enquiries and inquiries, and national service review that are relevant to the services provided
- To work with clinicians, service managers, directorate and divisional governance and quality managers, and clinical audit employees, to ensure that the clinical audit programme meets all clinical, statutory, regulatory, commissioning, and Trust requirements.
- Identifying appropriate clinical leads for the planned audits.
- Monitoring, supervising, supporting the Trust wide Audit Plan and address any issues identified.
- Discuss the results at Divisional Clinical Governance meetings and any actions progressed at a Divisional level.
- Provide feedback to all their employees on the results of audits leading to action and implementation.
- Support the clinical leads/teams in ensuring that the action plans from the audit are implemented and embedded in clinical practice and standards re-audited.
- All line managers, ensure that all employees reportable to them have adequate education and knowledge to undertake clinical audits.

#### 4.8 Medical Director and Deputy Director of Quality Governance

Responsibilities include:

- To ensure that the Trust clinical audit strategy and annual programme of work are aligned to the Board's strategic interests and concerns
- To ensure that clinical audit is used appropriately to support the Board Assurance Framework
- To ensure this policy is implemented across all clinical areas
- To ensure that any serious concerns regarding the Trust's policy and practice in clinical audit, or regarding the results and outcomes of national and local clinical audits, are brought to the attention of the Board
- Maintain an overview of all clinical audits and ensure a robust monitoring and reporting and dissemination system is in place for all clinical audits.
- Oversee and ensure completed projects are presented at the PQC meetings.

#### 4.9 CA&E Manager

Responsibilities include:

- Arrange for the Annual Clinical Audit Programme to be reviewed and approved at the Patient Quality Committee, prior to the start of the financial year.
- Overseeing and co-ordinating the Trust's Annual CA&E Programme, supported by the Medical Director, the Trust Board, and relevant Board Sub Committees. To ensure that the programme meets a range of requirements, including National Audits, audits of NICE guidance, audits in support of NHSLA Standards, audits of National Patient Safety Agency (NPSA) guidance, Essence of Care, plus audits which respond to locally identified concerns.
- Monitor the Trust's participation in National Clinical Audits and NCEPOD.
- Identifying and co-ordinating Trust wide clinical audits.
- Providing leadership and practical guidance regarding the implementation of evidence-based practice.
- Overseeing and providing clinical audit training within the Trust as applicable.

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- Investigating any alerts relevant to the Trust identified by the Imperial College Dr Foster database and reporting the investigation findings to PQC.
- Horizon scanning.
- Providing regular reports to the PQC.
- Meet quarterly with the Medical Director and to prepare updates for the Trust's Governance Committee.
- Monitor the effectiveness of CA&E Policy and raise any non- conformance with the Divisional governance and if required, channelled up to PQC; using internal audit methodology for monitoring compliance against the use and completeness of Trust approved documents.
- Monitor Trust wide clinical audit activities and provide reports for external regulators and assessors when required.
- Provide the Annual Clinical Audit Report for review and approval at the PQC Committee; encompassing progress with clinical audit activity across the organisation, including participation of National and Mandatory audits, achievements and exceptions, Clinical Audit Department, ensure that all employee members of CA&E Department have adequate resource, education and knowledge to fulfil their roles and responsibilities effectively.

#### 4.10 Divisional Quality Governance Facilitators

Responsibilities include:

- Working with and advising respective Divisions and Heads of Services to ensure Divisional audit programme meets the National Agenda, Trust objectives and Divisional priorities.
- Consulting and providing advice to clinical employee on the selection of topics to audit.
- To provide the Clinical Audit & Effectiveness Department with the CA Registration Form (Appendix E) from their respective Divisions scored using the Priority Scoring Tool (Appendix Q)
- Support the facilitation and implementation of the National and Local Clinical Audit Process (Appendix D).
- Maintain joint working with the Clinical Audit Team to organise and facilitate support for audit projects.
- Monitor the progress of their respective Divisional audit programme; identifying and escalating gaps in progress to the Divisional Governance Board.
- Contribute to the Divisional Quality Report with details of current clinical audit activity.
- Assisting audit leads with the preparation of practical recommendations for change on the basis of completed audits.
- Supporting audit leads in the monitoring of action planning for change.
- Establishing, with other audit team members, appropriate schemes for disseminating audit information.

#### 4.11 Clinical Governance Lead/Educational Lead

Responsibilities include:

- Supporting and providing specialist advice to Clinical Leads on the proposed audits.
- Supervising Audit Leads during clinical audit process.
- Working with CA&E Divisional Member in monitoring audit process and address any issues identified.
- Identify and support training & education on clinical audit.
- Endorse Clinical Audit Certificate to the Clinical Leads on successful completion of the audit.

#### 4.12 Clinical Leads/Matrons/Individual Healthcare Professionals

Clinicians responsible for participating in CA&E activity should have appropriate time, knowledge and skills to undertake this, as required by CQC. The Trust expects all F2 and higher grades to undertake at least one clinical audit during their placement in the Trust. F1's Doctors are encouraged to participate/ undertake clinical audit where possible. It is an essential element of General Medical Council (GMC) medical re-validation. The Trust also expects all the nursing professionals/other healthcare professionals to engage in clinical audits.

Responsibility for undertaking clinical audit rests with Divisions/specialities. It is mandatory to complete the CA&E registration form prior to commencing priority 1, 2 and 3 audits.

Responsibilities include:

- Identifying the topic to be audited. They should be aware of opportunities for focused audit activity which may arise from day to day work, guidance from NICE, NCEPOD, new Interventional Procedures and feedback from complaints, incident report trends, Serious Incidents (SI), NPSA notices, Dr Foster performance indicators, on-going monitoring of other key elements of patient safety activity. Topics outlined in the Divisional Audit Plan will take precedence.
- If the audit is identified as a divisional priority (priority three), clinicians are responsible for filling in the CA&E Audit Registration Form (Appendix E) and getting it approved by the Clinical Governance Lead/ Head of Services and Educational Lead (if appropriate). If the audit involves another Division, it must be discussed and approved by appropriate Clinical Governance Lead/ Head of Services of the other Division involved.
- Ensuring that the criterion to be audited have clearly defined standards and exceptions clearly stated as established by national/local guidance.
- Ensuring all key elements of the audit process are addressed, including time scales for the audit. In the event of inability to meet deadlines (e.g. employee relocation) ensure it is handed over to another member in the team to maintain continuity and accomplish the audit.
- Ensuring that the ethical framework is adhered to and incorporated in the audit.
- Ensuring that the findings of audits are shared with all relevant colleagues and any changes required as a result of an audit are implemented where necessary/possible and an action plan is devised after conducting gap analysis to ensure this happens.
- Approach the CA&E Department in a timely fashion to identify audit and effectiveness work that requires their support/advice. The Divisional Quality Governance Facilitators provide a link between the CA&E Department and the Specialties/Divisions.
- Ensuring that the action plans from the audit is implemented and embedded in clinical practice and standards re-audited.

The Audit lead has overall responsibility for ensuring the actions on this plan are undertaken and acted on before a re-audit takes place. The action plan and evidence must be submitted to the CA&E Department along with the CA Registration Form for re-audit to take place.

#### 4.13 The Clinical Audit & Effectiveness Department (CA&E)

Responsibilities include:

- Working collaborately with the Divisional Quality Governance Facilitators
- Provide administrative support relating to the Trust Clinical Audit Plan
- Support the monitoring of the Clinical Audit programme and provide updates where required
- Support and facilitate both the National and Local Audit Processes (Appendices F- P)
- Assisting clinical divisions in putting together directorate audit plans
- Providing advice for choice of topic and appropriate methodology
- Assisting with design of data collection forms and surveys

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- Identifying appropriate patient sample for audit
- Designing databases for collation of audit data
- Assisting with data analysis
- Assisting with preparation of draft reports
- Producing reports for the Patient Safety Committee, Swindon and Wiltshire Commissioners, Quality Accounts and CQC Evidence
- Providing training and education in Clinical Audit and Effectiveness at introductory, intermediate and advanced levels
- Tailoring such training to meet the regular and ad hoc needs of medical, nursing and other employees and contributing to the educational programmes of the Academy

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

## 5 Monitoring Compliance and Effectiveness of Implementation

The arrangements for monitoring compliance are outlined in the table below: -

Measurable policy objectives	Monitoring / audit method	Monitoring responsibility (individual / group /committee)	Frequency of monitoring	Reporting arrangements (committee / group to which monitoring results are presented)	What action will be taken if gaps are identified?
All registered audit projects use the standardised process and mandatory templates.	Validation Dashboard logs progress of the Clinical Audit process (includes: Registration form, data collection form, report template and action plan template)	CA&E Dept. / Divisional Quality Governance Facilitators	Continuous	Exceptions are reported to Divisional Governance Facilitators.  Exceptions relating to Mandatory audits are reported to PQC.	Any gaps/exceptions identified will be initially reported to the divisions via monthly report and, if necessary, will be escalated, reported and followed up at PQC



Measurable policy objectives	Monitoring / audit method	Monitoring responsibility (individual / group /committee)	Frequency of monitoring	Reporting arrangements (committee / group to which monitoring results are presented)	What action will be taken if gaps are identified?
Improvements are made and documented following the completion of action plan	Evidence of implemented actions is required to be submitted by the audit lead to show improvements or a change in practice.	Audit Lead	Continuous	A summary of key learning from completed audits to be included in monthly divisional quality reports, and included as a sub-section of the reports produced for PQC, Governance Committee and the Quality Report for the Executive committee.	Any gaps/exceptions identified will be initially reported to the divisions via monthly report and, if necessary, will be escalated, reported and followed up at PQC

### 5.1 Process for Monitoring Compliance and Effectiveness

The Monitoring of effectiveness with this Policy will be the responsibility of the CA&E Manager. The Manager will ensure that regular audit of the process is undertaken. The results of the audit will be fed back to CA&E Department and Divisions; an action plan will be implemented where any shortfalls are identified. The actions will be monitored through the CA&E Department.

The progress of the organisation's CA&E Programme and its outcomes will be monitored throughout the year by the PQC and quarterly Divisional Performance meetings.

There are several key aspects of CA&E activity that will be monitored by the CA&E Department:

- Number of audits registered on the Trust Wide Audit Plan
- Status report on all audits.
- Audits that have completed.
- Completed audits showing compliance.
- Completed audits showing gaps in performance (Led to change in practice)
- Proportion of audits that have been identified as multi-organisational/joint audits.
- Participation in mandatory national audits
- Audits that have been withdrawn.
- Audits that have been delayed or stalled.
- A lack of response to a request for information about the progress of an audit or action plan.
- Adherence to approved Trust documents:
  - The completeness of CA Registration form.
  - Data collection form was submitted.
  - CA report template was used.
  - Actions plans are formulated using CA template.

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- If re-audit, action plan updated from the first audit and re-submitted along with CA registration form.

The CA&E Manager will raise any matters arising from any of these elements with the Divisional governance and if required channelled up to PQC.

## 6 Review Date, Arrangements and Other Document Details

### 6.1 Review Date

This document will be fully reviewed every three years in accordance with the Trust's agreed process for reviewing Trust-wide documents. Changes in practice, to statutory requirements, revised professional or clinical standards and/or local/national directives are to be made as and when the change is identified.

### 6.2 Regulatory Position

CQC (Care Quality Commission) regulate the Trusts activity and its right to provide services.

### 6.3 References, Further Reading and Links to Other Policies

The following is a list of other policies, procedural documents or guidance documents (internal or external) which employees should refer to for further details:

Ref. No.	Document Title	Document Location
1	Promoting Clinical Effectiveness. Department of Health. (1996)	<a href="http://webarchive.nationalarchives.gov.uk">http://webarchive.nationalarchives.gov.uk</a>
2	What is Clinical Effectiveness. Royal College of Nursing. (1996)	<a href="http://www.rcn.org.uk">http://www.rcn.org.uk</a>
3	Principles for Best Practice in Clinical Audit published by NICE (2002)	<a href="http://www.nice.org.uk">http://www.nice.org.uk</a>
4	Criteria and Indicators of Best Practice in Clinical Audit (2009)	<a href="http://www.hqip.org.uk/">http://www.hqip.org.uk/</a>
5	Data Protection Act (1998),	<a href="https://www.gov.uk">https://www.gov.uk</a>
6	Caldicott Principles (1997), (revised 2013)	<a href="http://systems.hscic.gov.uk">http://systems.hscic.gov.uk</a>
7	NHS Confidentiality Code of Practice (2003)	<a href="http://systems.hscic.gov.uk/infogov/codes/confcode.pdf">http://systems.hscic.gov.uk/infogov/codes/confcode.pdf</a>
8	Records Management: NHS Code of Practice for Health & Social Care (2006)	<a href="https://www.gov.uk">https://www.gov.uk</a>
9	Information Governance (IG) Toolkit number 13-201	<a href="https://www.igt.hscic.gov.uk">https://www.igt.hscic.gov.uk</a>
10	CQC Regulation 17: Good Governance Essential Standards of Quality and Safety (Care Quality Commission, 2009)	<a href="http://www.cqc.org.uk">http://www.cqc.org.uk</a>
11	Clinical Audit Support Centre	<a href="http://www.clinicalauditsupport.com">http://www.clinicalauditsupport.com</a>

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Ref. No.	Document Title	Document Location
12	The National Clinical Audit and Patients Outcomes Programme Clinical Audit – Statutory and mandatory Requirements (HQIP, 2014)	<a href="http://www.hqip.org.uk">http://www.hqip.org.uk</a>
13	KINN S (1997) The relationship between clinical audit and ethics. [online] Journal of Medical Ethics. 23 (4). 250-253. Available from British Medical Journals last accessed 16th July 2015	<a href="http://jme.bmj.com">http://jme.bmj.com</a>
14	NHSLA Safety and Learning Service	<a href="http://www.nhsla.com">http://www.nhsla.com</a>
15	Clinical Audit Programme Guidance Tools	<a href="http://www.hqip.org.uk">http://www.hqip.org.uk</a>
16	Good Medical Practice (General Medical Council, 2001)	<a href="http://www.gmc-uk.org/guidance/">http://www.gmc-uk.org/guidance/</a>
17	The Health and Social Care Act (Parliament, 2012) Health and Social Care Act 2008 (Regulated Activities) Regulations (2014) Health Care Act 2009	<a href="http://www.legislation.gov.uk/">http://www.legislation.gov.uk/</a>
18	CA&E Report Template	Clinical Audit Department
19	CA&E Registration Form	Clinical Audit Department

#### 6.4 Consultation Process

The following is a list of consultees in formulating this document and the date that they approved the document:

Job Title / Department	Date Consultee Agreed Document Contents
Divisional Quality Governance Facilitators	28/02/2017
Health Records Manager	01/03/2017
Clinical Midwifery Manager	20/07/2017
Theatre Quality Lead	23/07/2017
Head of Midwifery	20/07/2017

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## Appendix A – Equality Impact Assessment

# Equality Impact Assessment

### Are we Treating Everyone Equally?

Define the document. What is the document about? What outcomes are expected?

Consider if your document/proposal affects any persons (Patients, Employees, Carers, Visitors, Volunteers and Members) with protected characteristics? Back up your considerations by local or national data, service information, audits, complaints and compliments, Friends & Family Test results, Staff Survey, etc.

If an adverse impact is identified what can be done to change this? Are there any barriers? Focus on outcomes and improvements. Plan and create actions that will mitigate against any identified inequalities.

If the document upon assessment is identified as having a positive impact, how can this be shared to maximise the benefits universally?

### Our Vision

Working together with our partners in health and social care, we will deliver accessible, personalised and integrated services for local people whether at home, in the community or in hospital empowering people to lead independent and healthier lives.



### Trust Equality and Diversity Objectives

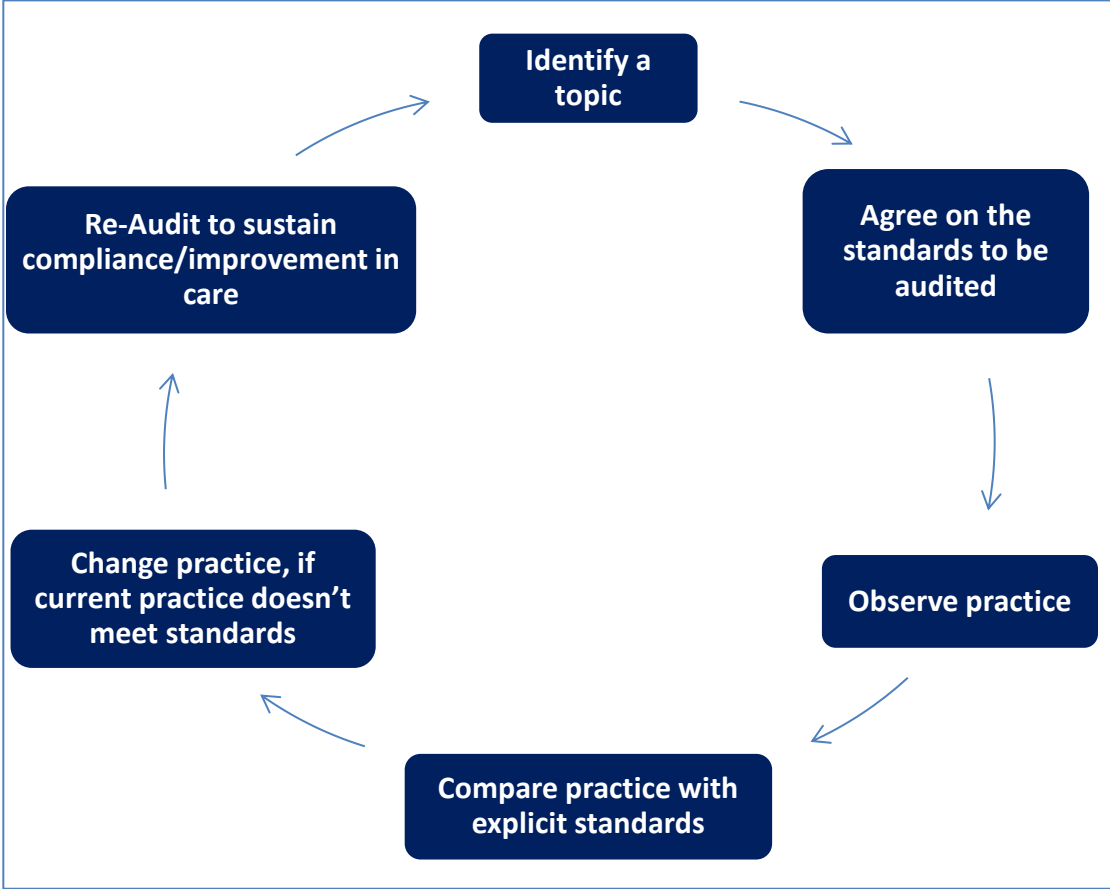
Better health outcomes for all	Improved patient access & experience	Empowered engaged & included staff	Inclusive leadership at all levels
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## Appendix B – Quality Impact Assessment Tool

<p><b>Purpose</b> - To assess the impact of individual policies and procedural documents on the quality of care provided to patients by the Trust both in acute settings and in the community.</p>		
<p><b>Process</b> -The impact assessment is to be completed by the document author. In the case of clinical policies and documents, this should be in consultation with Clinical Leads and other relevant clinician representatives.</p> <p>Risks identified from the quality impact assessment must be specified on this form and the reasons for acceptance of those risks or mitigation measures explained.</p>		
<p><b>Monitoring the Level of Risk</b> - The mitigating actions and level of risk should be monitored by the author of the policy or procedural document or such other specified person.</p> <p>High Risks must be reported to the relevant Executive Lead.</p>		
<p><b>Impact Assessment</b></p> <p>Please explain or describe as applicable.</p>		
1.	Consider the impact that your document will have on our ability to deliver high quality care.	The purpose of this document is to provide detailed guidance for healthcare professionals in the process of Clinical Audit. This in turn will encourage the drive for change and improvements, promote the monitoring and delivery of high quality care.
2.	The impact might be positive (an improvement) or negative (a risk to our ability to deliver high quality care).	Positive Impact. Quality Improvement is expected by the nature of the clinical audit process.
3.	Consider the overall service - for example: compromise in one area may be mitigated by higher standard of care overall.	No service impact is expected
4.	Where you identify a risk, you must include identify the mitigating actions you will put in place. Specify who the lead for this risk is.	NA
<p><b>Impact on Clinical Effectiveness &amp; Patient Safety</b></p>		
5.	Describe the impact of the document on clinical effectiveness. Consider issues such as our ability to deliver safe care; our ability to deliver effective care; and our ability to prevent avoidable harm.	Positive impact. Implementing this document will support health care professionals to monitor clinical practice and identify areas for improvements. Improving patient outcomes, safety and services delivered.
<p><b>Impact on Patient &amp; Carer Experience</b></p>		
6.	Describe the impact of the policy or procedural document on patient / carer experience. Consider issues such as our ability to treat patients with dignity and respect; our ability to deliver an efficient service; our ability to deliver personalised care; and our ability to care for patients in an appropriate physical environment.	As above.
<p><b>Impact on Inequalities</b></p>		
7.	Describe the impact of the document on inequalities in our community. Consider whether the document will have a differential impact on certain groups of patients (such as those with a hearing impairment or those where English is not their first language).	None.

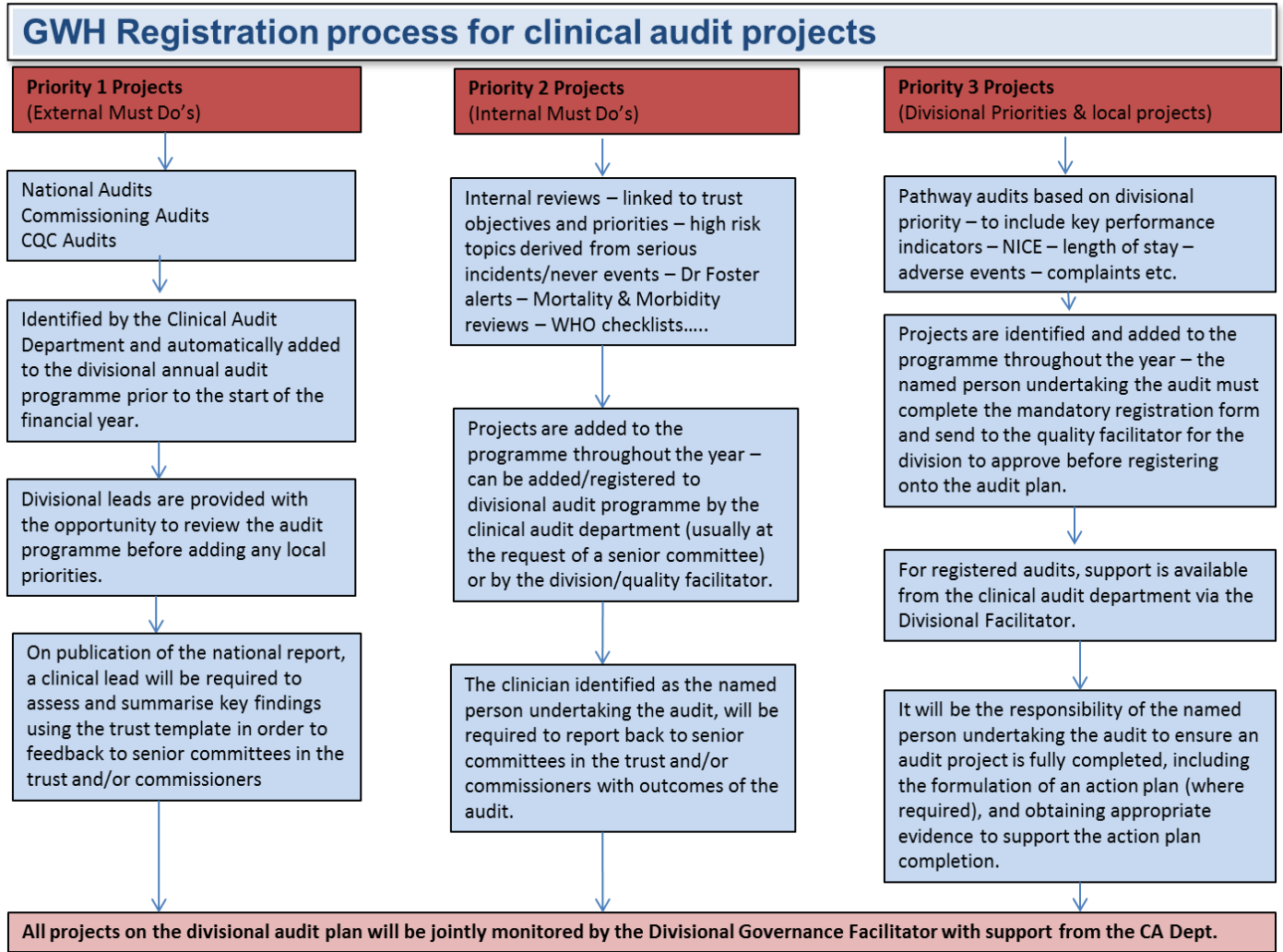
### Appendix C – Clinical Audit Cycle



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## Appendix D – Process for Undertaking CA&E Project



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## Appendix E - Clinical Audit & Effectiveness Registration Form

*This form is a Mandatory requirement for all projects that are registered onto the Audit Programme*

<b>Audit Ref No:</b>	<i>Clinical Audit Use Only</i>	<b>Audit/Project Title:</b>			
<b>Date of Submission:</b>	<i>Clinical Audit Use Only</i>	<b>Audit Lead Name:</b>		<b>Job Title:</b>	
<b>Department:</b>		<b>Email:</b>			
<b>Division</b>	<i>Choose an item.</i>	<b>Tel/Ext/Bleep:</b>			

1. Which of the following elements does your project relate to?
<input type="checkbox"/> Mandatory NCAPOP Audit (National Clinical Audit Programme)
<input type="checkbox"/> Commissioning Contract Audit
<input type="checkbox"/> National Confidential Enquiry - MBRRACE-UK
<input type="checkbox"/> National Confidential Enquiry - NCEPOD
<input type="checkbox"/> Dr Foster Investigation
<input type="checkbox"/> Mortality Review
<input type="checkbox"/> CQC Alert <input type="checkbox"/> CQC Action Plan
<input type="checkbox"/> CQUIN <input type="checkbox"/> Quality Accounts
<input type="checkbox"/> Aims to improve efficiency
<input type="checkbox"/> Area of local concern
<input type="checkbox"/> Clinical Governance Plan objective
<input type="checkbox"/> Demonstrate Compliance with regulation
<input type="checkbox"/> Demonstrate Compliance with local policy
<input type="checkbox"/> Demonstrate Compliance with external accreditation
<input type="checkbox"/> Link to NICE – Ref No:
<input type="checkbox"/> Non-Mandatory National Audit
<input type="checkbox"/> Regional – With whom:
<input type="checkbox"/> Risk Management tool <input type="checkbox"/> Serious Incident
<input type="checkbox"/> Complaint
<input type="checkbox"/> Re-Audit ( <i>Evidence of the previous actions must be submitted</i> )
<input type="checkbox"/> Other

2. Quality Impact Analysis	No Relevance (0)	Some Relevance (1)	Almost meet (2)	Fully Meets (3)	<i>Clinical Audit Use Only</i>
High Frequency/Volume	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
High Cost	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	*
High Risk	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	*
Potential for change	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	*
Evidence based standards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	*
Direct Involvement with patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Wide variation in practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Multidisciplinary project	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Interface Project	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	*
3. What are the aims and Objectives of your project?					
<b>Aims:</b>					
1.					
<b>Objectives:</b> 2.					
3.					
4. Criteria and Standards. (please continue on a separate sheet if necessary)					
Criterion	Standard	Exceptions			
<i>e.g. All patients should have a smoking status recorded on admission</i>	<i>e.g. 100%</i>	<i>e.g. Infants/babies</i>			
1.					
2.					
3.					
4.					
5.					

5. Sampling	
What sampling method are you going to include?	<input type="checkbox"/> Random <input type="checkbox"/> Consecutive
What will be the sampling period?	<input type="checkbox"/> Retrospective <input type="checkbox"/> Concurrent
What will be your sample size? <i>No. of Patients</i>	Sample period? <i>dd/mm/yy – dd/mm/yy</i>

6. Data Collection	
Who will be collecting the data?	
Where is the data going to be obtained from?	
Start data collection: <i>dd/mm/yy</i>	Finish data collection: <i>dd/mm/yy</i>

7. Analysis, Reporting, Presenting – Completion Date/Deadline			
Deadline to Input data:	<i>dd/mm/yy</i>	Deadline to Submit Local Report:	<i>dd/mm/yy</i>
Deadline to Analyse data:	<i>dd/mm/yy</i>	Expected date to Present Results:	<i>dd/mm/yy</i>

8. What support is required with your project?			
<input type="checkbox"/> No help required	<input type="checkbox"/> Identify patients	<input type="checkbox"/> Development of data collection tool	<input type="checkbox"/> Basic Data analysis
<input type="checkbox"/> General advice on audit methods	<input type="checkbox"/> Case note retrieval (where available)	<input type="checkbox"/> Data input	<input type="checkbox"/> Preparation of draft report

## Approval

APPROVAL – (Local audits must be channelled through the approval process within the Division prior to registering onto the audit programme).	
<i>If your audit involves another specialty/division, please confirm this has been discussed and approved by the appropriate clinical lead.</i>	<input type="checkbox"/> Yes - Specialty / Division:  <i>Date:</i>
<i>I confirm that this audit/project has been approved.</i>	<i>Signed - Head of Service:</i> _____ <i>Date:</i> _____  <i>Signed - Divisional Lead:</i> _____ <i>Date:</i> _____

**Approving Signatories** – please note, to avoid projects becoming overdue/withdrawn at a later date, you should assess this for relevance against the Service/Division’s current priorities; by approving this project you also agree to ensure it is completed by the required deadline using the correct divisional governance processes. Projects relating to clinician interest only do not require to be registered.

## Checklist

- Ensure all the fields on this form are completed
- Determine relevant deadline dates are realistic and achievable – for national audits, a local report is required within 3 months post publication of the national report.
- Identify/inform/liaise with key individuals who are going to be involved in the project

## Next steps

In order to ensure the audit/project progresses on schedule, Audit/Project leads should –

- Submit completed registration form to Divisional Governance Facilitator to review Quality Impact Analysis and channel through the divisional approval process
- Ensure the audit is captured on the department governance/team agenda for local monitoring
- Finalise the report – Summarising key assurances, areas for development, recommendations and associated actions
- Identify risks where there are gaps in service/poor performance and escalating accordingly
- Present the findings at department governance/performance meeting and to agree/finalise actions and report
- Channel local report through Divisional governance for approval and sign off
- Submit final/approved copy of the report to clinical audit department
- Ensure the action plan is monitored via your department for implementation and collation of evidence
- Ensure the action plan evidence is submitted to the clinical audit department in order to close of the audit on the programme
- Inform the approving signatories and the clinical audit department if your audit becomes delayed

**For further information please contact the Clinical Audit Department or your Divisional Governance Facilitator.**

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## Appendix F – Audit Due To Start Email Template (1)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** Audit Due to Start: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

### Audit Due to Start – Response Required

Dear XXXXXXX

This is to inform you that the XXXXXX AUDIT TITLE XXXXXXXX commences on DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please confirm by DAY, DATE, MONTH, and YEAR that arrangements are in place in order to proceed with this accordingly.

Please ensure that -

- Key team members to be involved have been identified and informed
- Arrangements are in place for Data collection
- This project is added to your **Department Governance** agenda to locally monitor progress
- You are aware of the data submission deadline - DAY, DATE, MONTH, and YEAR

**Please Note:** Failure to respond to this email will result in a reminder being sent to you in 1 week, and will include the Clinical Lead and Head of Service for escalation/further management.

#### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.
- If additional support is required, please get in touch with us immediately to avoid any delays.

#### Next Steps:

- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process
- You will be contacted again 1 month before the data collection/submission deadline is due to enquire the progress of this project

If you have any questions, please contact the Clinical Audit Department.

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## Appendix G – Audit Due To Start Reminder Email Template (1a)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** **REMINDER!** - Audit Due to Start: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email –

### REMINDER - Audit Due to Start – Response Required

Dear XXXXXX

I recently informed you that the XXXXXX AUDIT TITLE XXXXXXXX is due to commence on DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please confirm immediately that arrangements are in place in order to proceed with this accordingly.

Please ensure that -

- Key team members to be involved have been identified and informed
- Arrangements are in place for Data collection
- This project is added to your **Department Governance agenda** to monitor progress – please see attached process/flow chart for guidance
- You are aware of the data submission deadline - DAY, DATE, MONTH, and YEAR

**Clinical Leads/Heads of Service:** Please confirm with the Audit Lead that this project is organised to start; alternatively, if you identify reasons why this is unlikely to commence as scheduled, this should be escalated through the correct divisional governance process for further discussion and management.

### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.
- If additional support is required, please get in touch with us immediately to avoid any delays.

### Next Steps:

- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process
- You will be contacted again at 1 month before the data collection/submission deadline is due to enquire the progress of this project

If you have any questions, please contact the Clinical Audit Department.

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## Appendix H – Audit Data Collection Deadline Email Template (2)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** Audit Data Collection Deadline: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# Audit Data Collection Deadline – Response Required

Dear XXXXX

This is to inform you that the XXXXXX AUDIT TITLE XXXXXXXX data collection deadline is DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please confirm by DAY, DATE, MONTH, and YEAR that this is on schedule to have all the data collected/entered by this date.

**Please Note:** Failure to respond to this email will result in a reminder being sent to you in 1 week, and will include the Clinical Lead and Head of Service for escalation/further management.

### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.
- If additional support is required, please get in touch with us immediately to avoid any delays.

### Next Steps:

- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process
- You will be contacted again by the above deadline requesting confirmation that all data has been submitted

If you have any questions, please contact the Clinical Audit Department.

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## Appendix I – Audit Data Collection Deadline Reminder Email Template (2a)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** Audit Data Collection Deadline: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# Audit Data Collection Deadline – Response Required

Dear XXXXX

This is to inform you that the XXXXXX AUDIT TITLE XXXXXXXX data collection deadline is DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please confirm by DAY, DATE, MONTH, and YEAR that this is on schedule to have all the data collected/entered by this date.

**Please Note:** Failure to respond to this email will result in a reminder being sent to you in 1 week, and will include the Clinical Lead and Head of Service for escalation/further management.

### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.
- If additional support is required, please get in touch with us immediately to avoid any delays.

### Next Steps:

- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process
- You will be contacted again by the above deadline requesting confirmation that all data has been submitted

If you have any questions, please contact the Clinical Audit Department.

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## Appendix J – Confirmation of Data Collection Email Template (3)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** Confirmation of Data Collection: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# Confirmation of Data Collection – Response Required

Dear XXXXX

You will be aware that the XXXXXX AUDIT TITLE XXXXXXXX data collection deadline was DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please can you confirm by DAY, DATE, MONTH, and YEAR that the data collected was submitted by the required deadline. This information is required for reporting purposes.

**Please Note:** Failure to respond to this email will result in a reminder being sent to you in 1 week, and will include the Clinical Lead and Head of Service for escalation/further management.

### Next Steps:

- The National Report for this audit is expected to be published on or around DATE, MONTH, and YEAR
- We will contact you at this time requesting you to review the results and benchmark local performance
- A local report template will be provided for you to complete
- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process

If you have any questions, please contact the Clinical Audit Department.

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## Appendix K - Confirmation of Data Collection Reminder Email Template (3a)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** REMINDER! - Confirmation of Data Collection: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# REMINDER - Confirmation of Data Collection – Response Required

Dear XXXXX

You will be aware that the XXXXXX AUDIT TITLE XXXXXXXX data collection deadline was DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please can you confirm immediately that the data collected was submitted by the required deadline. This information is required for reporting purposes.

**Clinical Leads/Heads of Service:** Please confirm with the Audit Lead that this project is progressing as planned; alternatively, if you identify reasons why this did not meet the required deadline, this should be escalated immediately through the correct divisional governance process for further discussion and managed as an exception.

### Next Steps:

- The National Report for this audit is expected to be published on or around DATE, MONTH, and YEAR
- We will contact you at this time requesting you to review the results and benchmark local performance
- A local report template will be provided for you to complete
- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process

If you have any questions, please contact the Clinical Audit Department.

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## Appendix L - National Audit Report Published Email Template (4)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** National Audit Report Published: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

### National Audit Report Published – Action Required

Dear XXXXXXXX

This is to inform you that the National Audit Report for the XXXXXX AUDIT TITLE XXXXXXXX has now been published.

As the identified lead for this project, you are required to review the national results and recommendations, and benchmark local service/ practice/ performance.

A template has been attached for you to complete -

- You are only required to provide concise information including key assurances and areas for development
- Ensure that local recommendations are adequately reflected in the action plan
- Identify and arrange to share key learning amongst the department/division/ or across the organisation i.e. team meetings, newsletters etc
- You should consider what level of assurance the local results demonstrate and complete this section in the report template accordingly
- If you have identified areas for development, you should consider the risks and assess them accordingly using the risk matrix in the report template

#### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.
- If additional support is required, please get in touch with us immediately to avoid any delays.

#### Next Steps:

- All completed reports should be reviewed at your local Department Governance meeting for assessment and approval
- All approved reports should then be channelled through to Divisional Governance for final oversight and sign off
- Once your report has been approved and signed off, a copy should be submitted to the Clinical Audit Department
- **ALL** completed National Audit Reports are expected to be reported to the Patient Quality Committee within 3 months of national report publication; the deadline to submit your completed report to the Clinical Audit Department is DAY, DATE, MONTH, and YEAR
- You will be contacted again 1 month before the above deadline to enquire the progress of your report

If you have any questions, please contact the Clinical Audit Department.

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## Appendix M - Local Report Deadline Reminder (4a)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** REMINDER! – Local Report Deadline: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# REMINDER – Local Report Deadline – Action Required

Dear XXXXXXXX

This is to remind you that the local report for the XXXXXX AUDIT TITLE XXXXXXXX is due to be submitted to the Clinical Audit Department by DAY, DATE, MONTH, and YEAR, in order to report to the Patient Quality Committee.

As the identified lead for this project, you are required to review the national results and recommendations, and benchmark local service/ practice/ performance.

Key points -

- You are only required to provide concise information including key assurances and areas for development
- Ensure that local recommendations are adequately reflected in the action plan
- Identify and arrange to share key learning amongst the department/division/ or across the organisation i.e. team meetings, newsletters etc
- You should consider what level of assurance the local results demonstrate and complete this section in the report template accordingly
- If you have identified areas for development, you should consider the risks and assess them accordingly using the risk matrix in the report template

### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.
- If additional support is required, please get in touch with us immediately to avoid any delays.

### Please note:

- All completed reports should be reviewed at your local Department Governance meeting for assessment and approval
- All approved reports should then be channelled through to Divisional Governance for final oversight and sign off
- Once your report has been approved and signed off, a copy should be submitted to the Clinical Audit Department
- **ALL** completed National Audit Reports are expected to be reported to the Patient Quality Committee within 3 months of national report publication

If you have any questions, please contact the Clinical Audit Department.

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## Appendix N – Overdue Local Report Reminder Email Template (4b)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** REMINDER! – Overdue Local Report XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# OVERDUE Local Report – Action Required

Dear XXXXXXX

This is to remind you that the local report for the XXXXXX AUDIT TITLE XXXXXXXX was due to be submitted to the Clinical Audit Department by DAY, DATE, MONTH, and YEAR, in order to report to the Patient Quality Committee.

As the identified lead for this project, you are required to review the national results and recommendations, and benchmark local service/ practice/ performance.

**Clinical Leads/Heads of Service:** Please confirm with the Audit Lead that this project is progressing as planned; alternatively, if you identify reasons why this did not meet the required deadline, this should be escalated immediately through the correct divisional governance process for further discussion and managed as an exception.

### Please note:

- All completed reports should be reviewed at your local Department Governance meeting for assessment and approval
- All approved reports should then be channelled through to Divisional Governance for final oversight and sign off
- Once your report has been approved and signed off, a copy should be submitted to the Clinical Audit Department
- **ALL** completed National Audit Reports are expected to be reported to the Patient Quality Committee within 3 months of national report publication

If you have any questions, please contact the Clinical Audit Department.

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## Appendix O – Audit Action Plan Evidence Email Template (5)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** Audit Action Plan Evidence: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# Audit Action Plan Evidence – Response Required

Dear XXXXXXX

This is to remind you that evidence for the XXXXXX AUDIT TITLE XXXXXXXX action plan is due by DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please can you provide supporting documents which demonstrates that the recommendations have been implemented. A copy of the action plan has been attached for your reference.

**Please Note:** Failure to respond to this email will result in a reminder being sent to you in 1 week, and will include the Clinical Lead and Head of Service for escalation/further management.

### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.

### Next Steps:

- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process

If you have any questions, please contact the Clinical Audit Department.

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## Appendix P - Overdue Audit Action Plan Evidence Email Template (5a)

**Send to:** Audit Lead

**Cc:** Clinical Audit Facilitator, Clinical Lead, Head of Service, Deputy Divisional Director, Associate Medical Director

**Email Subject:** **OVERDUE!** Audit Action Plan Evidence: XXXX/XX – Title of Audit here

**Copy/Paste** the following text into the main body of the email -

# OVERDUE - Audit Action Plan Evidence – Response Required

Dear XXXXXXX

This is to remind you that evidence for the XXXXXX AUDIT TITLE XXXXXXXX action plan was due by DAY, DATE, MONTH, and YEAR

As the identified lead for this project, please can you provide supporting documents which demonstrates that the recommendations have been implemented. A copy of the action plan has been attached for your reference.

**Clinical Leads/Heads of Service:** Please confirm with the Audit Lead that this project is progressing as planned; alternatively, if you identify reasons why this did not meet the required deadline, this should be escalated immediately through the correct divisional governance process for further discussion and managed as an exception.

### Important!

- If you foresee any delays, in the first instance, please inform your Department Governance/Clinical Lead/Head of Service.

### Next Steps:

- Please ensure this update is reported at your local **Department Governance** meeting as part of your local monitoring process

If you have any questions, please contact the Clinical Audit Department.

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## Appendix Q – Priority Scoring Tool

Priority 1) External ‘must do’ audits –	
<p><i>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 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 commissioners.</i></p>	
<p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• NCAPOP</li> <li>• Quality Accounts</li> <li>• Audits demonstrating compliance with regulation requirements e.g. audits with the aim of providing evidence of implementation of NICE technology appraisals, clinical guidelines and public health guidance and other national guidance such as that coming from NPSA alerts or NICE Evidence Summaries</li> </ul>	<ul style="list-style-type: none"> <li>• Regional Commissioning for Quality and Innovation CQUINS and other commissioner priorities</li> <li>• DH statutory requirements, such as infection control monitoring</li> <li>• External accreditation schemes, e.g., NHS Litigation Authority, cancer peer review audit</li> <li>• The Productive Series from the NHS Institute for Innovation and Improvement</li> <li>• Re-audits of any of the above.</li> </ul>
Priority 2) Internal ‘must do’ audits –	
<p><i>In addition to national clinical audit topics, the choice of further topics should be based on the classic criteria of high risk or high profile identified by Trust management or Trust clinical audit strategy documents. 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.</i></p>	
<p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• Priorities reflective of organisational objectives for clinical audit as outlined in local clinical audit strategy</li> <li>• Clinical risk issues</li> <li>• Serious untoward incidents/adverse incidents</li> </ul>	<ul style="list-style-type: none"> <li>• Organisational clinical priorities</li> <li>• Priorities identified via Patient and Public Involvement initiatives</li> <li>• Complaints</li> <li>• Access</li> <li>• Patient Safety First Campaign</li> <li>• Re-audits of any of the above.</li> </ul>
Priority 3) Directorate priorities –	
<p><i>divisions/services are asked to suggest projects that are priority pieces of work and important to them – local priorities. They may include DH initiatives and be directorate/ division/service specific but no penalties exist for non participation.</i></p>	
<p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• National audits not part of NCAPOP, e.g. some Royal College initiated projects lie outside of NCAPOP and Quality Accounts.</li> </ul>	<ul style="list-style-type: none"> <li>• Local clinical interest audit agreed by directorate/division/service as a priority</li> <li>• Locally adopted clinical standards benchmarking e.g., Essence of Care</li> <li>• Re-audits of any of the above.</li> </ul>
Priority 4) Clinician interest – (DO NOT REQUIRE REGISTERING ON THE TRUSTS AUDIT PROGRAMME)	
<p><i>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 employees. REQUIRES DIVISION APPROVAL</i></p>	

<p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• <b>High frequency/volume of service</b> — most frequent reasons for referral, admission or treatment or most frequent procedures performed</li> <li>• <b>High risk</b> — services or aspects of services with higher than average risk potential to employees or patients, due either to the nature of the treatment or procedure or the potential risk if the service is delivered inappropriately</li> <li>• <b>High cost</b> — aspects of a service that involve higher than average costs or which could involve high costs if not provided properly</li> <li>• <b>Potential for change</b> — the anticipated potential for change arising from the project with the support of those individuals who can effect change</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Existence of evidence-based guidelines/standards</b> – the level by which the project is comparing current practice against evidence based practice/guidelines</li> <li>• <b>Direct impact on patients</b> — a judgement based on the anticipated outcomes of the project, taking into account direct patient benefit</li> <li>• <b>Direct involvement with patients/families</b> — does the project directly include patients or families?</li> <li>• <b>Multidisciplinary project</b> — the level of involvement between different disciplines</li> <li>• <b>Interface project</b> — the level of involvement at the interface between two or more NHS establishments or organisations, particularly the primary care/secondary care interface.</li> </ul>
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**Quality Impact Analysis**

There will be a number of projects that will not fall into priorities 1 to 3 of the model outlined above. 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 employees. All this leads to the need to develop a transparent system for decision making about whether or not (and to what extent) a locally conceived project should attract clinical audit resources

One way to prioritise “clinician interest” projects in order of importance is to use Quality Impact Analysis (QIA). It has been stated in *Principles for Best Practice* that topics for clinical audit need to be prioritised in a systematic way. It should be the responsibility of a delegated individual such as a clinical audit lead (or local clinical governance team) within the clinical area to assess potential projects on the above criteria, so that a decision is made as to whether or not a project should be carried out. This can ensure that good quality projects are being undertaken. /division/service audit projects could be identified from this process

The below list provides criteria (weighted for importance) in scoring projects for priority. This allows for the use of questions to help determine priorities among topics for audit.

- Key:**
- If the criterion has no relevant, score = 0
  - If the criterion has some relevant, score = 1
  - If the criterion is met in parts, score = 2
  - If the criterion is fully met, score = 3

The scores can range between 0 and 42, with higher scores demonstrating higher priority

	No relevance (0)	Some relevance (1)	Almost meets (2)	Fully meets (3)
High frequency/Volume				
High cost				
High risk				
Potential for change				
Evidence based standards				
Direct involvement with patients				
Wide variation in Practice				
Multidisciplinary project				
Interface project				

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## Appendix R - Clinical Audit Exception Form

This form is to be used by Audit/Service/Divisional lead(s) to notify of exceptional circumstances whereby participation in a mandatory Clinical Audit may be difficult. This form **MUST** have Divisional assessment and approval prior to submitting to the Clinical Audit Manager for presenting to the Patient Quality Committee and/or Clinical Commissioning Group(s) for final oversight.

<b>Date of Application:</b>	<i>Click here to enter a date.</i>	<b>Audit Lead:</b>	<b>Job Title:</b>	
<b>Department:</b>		<b>Head of Service:</b>	<b>Division</b>	<i>Choose an item.</i>

<b>Audit Ref No:</b>		<b>Audit/Project Title:</b>	<b>Audit Frequency:</b>	<i>Choose an item.</i>
<b>Audit Priority:</b>	<i>Choose an item.</i>	<b>Relates to:</b>	<i>Choose an item.</i>	

Sample		Data Collection	
Sampling period	Retrospective <input type="checkbox"/> Concurrent <input type="checkbox"/>	Data obtained from:	
Sample size	<i>No. of patients</i>	Start data collection:	<i>dd/mm/yy</i>
Sample period	<i>dd/mm/yy – dd/mm/yy</i>	Finish data collection:	<i>dd/mm/yy</i>

Analysis, Reporting, Presenting – Completion Date/Deadline			
Deadline to Input data:	<i>dd/mm/yy</i>	Deadline to Submit Local Report:	<i>dd/mm/yy</i>
Deadline to Analyse data:	<i>dd/mm/yy</i>	Expected date to Present Results:	<i>dd/mm/yy</i>

Reason for Exception

Mitigating details <i>(please include relevant details – i.e. previous audit results/compliance against NICE guidelines/current action plan/service developments/details of business case etc)</i>

Associated Risks for non/delayed participation <i>(please include relevant details – i.e. financial penalties/ outlier status/strategic risks/provision of assurances/external contracts etc)</i>

Department & Divisional Sign-Off			
<i>Name of Department Meeting</i>	<i>Click here to enter a date.</i>	<i>Name of Divisional Meeting</i>	<i>Click here to enter a date.</i>

**Note:** This document is electronically controlled. The master copy of the latest approved version is maintained by the owner department. If this document is downloaded from a website or printed, it becomes uncontrolled.

Comments:

**Signed – Divisional Lead:**

*Date:*

**Please ensure all the fields on this form are fully completed prior to submitting to the Clinical Audit & Effectiveness Manager for final sign-off by the Patient Quality Committee.**

**Patient Quality Committee Sign-Off**

Comments:

**Discussed at Patient Quality Committee. Date:**

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