North West Ambulance Service NHS Trust

Clinical Audit Policy

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Change record form

Version	Date of change	Date of release	Changed by	Reason for change
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1.0	April 2008	April 2008		Final document
1.1	October 2010	October 2010		NHSLA Monitoring
0.2	April 2011			Document Review
0.3	May 2011			NHSLA Review Feedback
2.0	July 2011	July 2011	S. Barnard	Trust Board Approval
0.4	April 2012		M Peters	NHSLA Feedback & amendment of performance improvement process
2.1	May 2012	May 2012		Final document
0.5	September 2014		Senior Clinical Quality Manager	Document Review
2.2	December 2014	January 2014		Final Document
0.6	July 2015		Senior Clinical Quality Manager	Document Review
2.3	October 2015	October 2015	Senior Clinical Quality Manager	Final Document
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3.0		August 2017	Senior Clinical Quality Manager	Final Document
0.8	June 2019		Senior Clinical Quality Manager	Document Review
4.0	August 2019	August 2019	Senior Clinical Quality Manager	EMT approved version

Clinical Audit Policy

Contents

1. STATUTORY and MANDATORY REQUIREMENTS

1.1 When carried out in accordance with best practice, clinical audit:

- Improves the quality of care and patient outcomes
- Provides assurance of compliance with clinical standards
- Identifies and minimises risk, waste and inefficiencies.

1.2 Participation in both national and local clinical audit is a statutory and contractual requirement for healthcare providers. The NHS Standard contract forms the agreement between commissioners and providers of NHS funded services who must:

- Participate in national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to their services
- Make national clinical audit data available to support publication of outcome statistics
- Implement and/or respond to all relevant recommendations of any appropriate clinical audit
- Implement an ongoing, proportionate programme of clinical audit of their services in accordance with good practice.
- Provide the co-ordinating commissioner, on request, the findings of any audits carried out.

1.3 The regulatory framework of the Care Quality Commission (CQC) requires registered healthcare providers to monitor the quality of their services. Providers must use the findings from clinical audits and other quality improvement initiatives, including those undertaken at national level such as national confidential enquiries and inquires and national service reviews to ensure action is taken to protect people who use services. Providers must also ensure healthcare professionals are enabled to participate in clinical audit to satisfy the demands of their relevant professional bodies.

1.4 Under the Health Act 2009 the North West Ambulance Service NHS Trust (NWAS) is required to produce an annual Quality Account, which must include information of participation in national and local clinical audits and the actions that have been taken as a consequence to improve the services provided.

2. PURPOSE OF POLICY

2.1 The purpose of this policy is to set out the rationale for clinical audit and provide a framework of key principles for staff undertaking clinical audit projects within NWAS, including standards, guidance and procedures as well as the support available from the Clinical Quality Audit Team:

- For registering and approving clinical audit project proposals
- For developing and designing clinical audit projects.

The key aims and objectives of this policy are to:

- Ensure NWAS has an active on-going audit programme focussing and addressing national priorities and key clinical concerns aligned with the assurance and accountability measurement of the Right Care Strategy.
- Ensure there is clarity over the use of clinical audit as a process to embed clinical quality at all levels within NWAS.
- Promote continual development and sustain a culture that supports quality improvement, best practice and learning.
- Enable health professionals and service users to evaluate and measure practice and standards.
- Assure the Trust Board that systems are in place to develop an audit programme that meets organisational needs for robust information and reports which are received on a regular basis.

2.2 Quality in the NHS was defined in 'High quality care for all: NHS next stage review' led by Lord Darzi and enshrined in legislation through the Health and Social Care Act 2012. This set out three dimensions, which must all be present to provide a high quality service (figure 1); and it is this model that is at the centre of the Right Care Strategy 2018 – 2023.

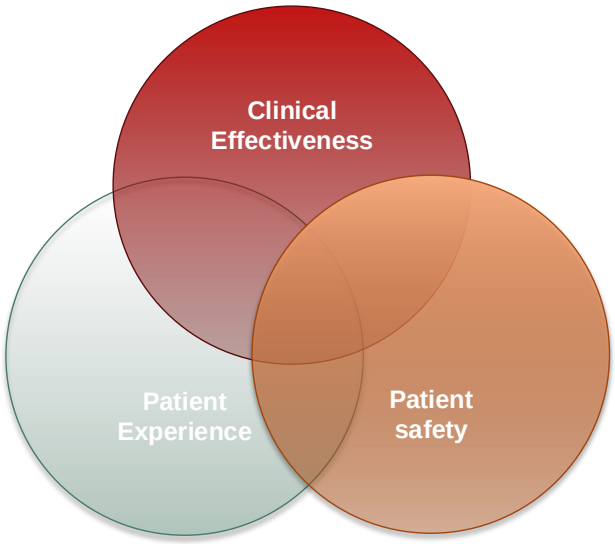

Fig 1: Three Dimensions of a high-quality healthcare service

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

The Trust supports the view that clinical audit is a tool that is used in strategic management as part of the broader quality improvement programme. It plays an important role in providing assurance to the Board about the quality of service and is a vital component of the clinical governance arrangements.

It is important that clinical audit is not seen as an isolated quality improvement activity but as one of a set of tools which teams and the organisation can use to improve the quality of care that is delivered to patients.
It is noted that clinical audit is only one of a range of quality improvement methodologies and should not be used if another is more appropriate see the HQIP Guide to Quality Improvement processes https://www.hqip.org.uk/wp-content/uploads/2018/02/guide-to-quality-improvement-methods.pdf.
Clinical Audit requires the use of a broad range of methods from a number of disciplines e.g. statistics and information management. It can be undertaken by the individual or groups of professionals in single or multi-disciplinary teams and is supported by the Clinical Quality Audit team. In short clinical audit may be undertaken by clinicians and non-clinicians who operate in every clinical setting of the Trust, such as Patient Transport Services, Emergency Control Centres, Urgent Care and Community, Patient Emergency Services and 111.

Applied correctly, clinical audit, as a performance measurement system, will help to provide assurance that clinical protocols and guidance are being adhered to, highlight areas of good or poor practice and identify problems within systems, structures or processes.

Clinical audit can also help measure the effectiveness of clinical protocols by linking actions and processes to outcomes. This will also help create an evidence base to inform the review and development of future protocols or guidance. Taking healthcare to the patient: transforming NHS ambulance services' (DoH 2005) re-enforces this by stating: 'that measures of patient outcomes and experience should be used to promote evidence based practice and to assess how far ambulance services are delivering high quality care'. Clinical audit was cited as the principle activity to support this.

3. DEFINITION

3.1 Clinical Audit may be defined as 'a quality improvement cycle that involves the measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes.' (Healthcare Quality Improvement Partnership 2011)

Simply, clinical audit is all about measuring the quality of care and service against agreed standards and making changes to improve the care and service received by patients. It follows that clinical audit is the component of clinical governance that offers the greatest potential to assess the quality of care routinely provided for NWAS users.

4. DUTIES

4.1 ***Chief Executive*** is responsible for the statutory duty of quality and takes overall responsibility for effective prioritisation to participate in national clinical audit, and for decisions about local clinical audit.

4.2 ***Medical Director*** is the member of the Trust Board who maintains overall responsibility for the clinical audit function of NWAS. The Medical Director is ultimately responsible for managing risks associated with clinical audit in the Trust and ensures that relevant areas of clinical risk are examined through the clinical audit programme.

4.3 ***Clinical Professions Leads:*** (Chief Consultant Paramedic, Chief Nurse and Chief Pharmacist) have responsibility to ensure clinicians participate, and are actively engaged in clinical audit. This will include the provision of educational support to ensure clinicians will have the relevant competencies. When required the Clinical Professions Lead(s) will chair the virtual forum to receive, discuss and approve clinical audit proposals received by the Clinical Quality Officer (CQO). The Clinical Professions leads are responsible for ensuring the completion of action plans ensuring required changes are incorporated into practice.

4.4 ***Senior Clinical Quality Manager*** (SCQM): is responsible for the corporate development, implementation and performance management of an annual clinical audit plan, and the production of any policies or procedures to support clinical audit across the different areas of the Trust. The SCQM will, as required, convene the virtual forum and recruit the appropriate clinicians to participate in receiving, discussing and approving clinical audit proposals received by the CQO. With the CQO the SCQM is responsible for co-ordinating the audit process and the provision of an annual Clinical Audit Report.

4.5 ***Clinical Quality Officer*** (CQO): is responsible for supporting senior clinicians by providing day-to-day support and advice for clinical audit. The CQO is responsible for advising senior clinicians and clinician auditors with best practice methods of data collection, communication and quality improvement aspects of audit. The CQO is responsible for receiving clinical audit proposals and maintaining the Trust Clinical Audit Register. With the SCQM the CQO is responsible for co-ordinating the audit process and collating the annual Clinical Audit Report. The CQO may facilitate clinician audits and provide independent scrutiny to the action plans received by Locality Quality Business Groups or equivalent.

4.6 ***Senior Clinicians*** are responsible for supporting the operational implementation and performance management of the annual clinical audit plan and any related policies and procedures. Senior clinicians are responsible for supporting all clinicians within the Trust to be engaged with clinical audit processes and quality improvement. As required the Senior Clinicians will participate in the virtual forum to receive, discuss and approve clinical audit proposals received by the CQO. Senior clinicians are responsible for action plans and the implementation of change, they are required to keep the CQO and the respective Clinical Professions Leads appraised with progress. This feedback loop is supportive of evidence for the Care Quality Commission.

4.7 ***All Clinicians*** are required to support clinical audit within the Trust and to be actively engaged wherever possible. It is the responsibility of all clinicians to support quality improvements identified from clinical audit and adopt the change, where necessary, to improve the quality of care and patient outcomes.

4.8 ***Quality and Performance Committee*** is responsible for approving the annual clinical audit plan. The committee receives regular reports on the progress of the clinical audit work programme and clinical audit outcomes; and is responsible for receiving assurance that the clinical audit improvements/ findings as recommended by the CEMG are implemented.

4.9 ***Audit Committee*** receives as part of its annual work-plan, regular reports for information of progress against the clinical audit work programme.

4.10 ***Clinical Effectiveness Management Group*** (CEMG) is responsible for setting the annual audit plan and recommending it for approval by the Quality and Performance Committee. As well as monitoring the appropriateness of the programme throughout the year and taking action where necessary the Group reviews the results of clinical audit projects and advises on the development and implementation of clinical audit recommendations to ensure they are specific, measureable, achievable, realistic and timely with the potential to improve patient care.

4.11 ***Locality Quality Business Groups (or equivalent)*** is responsible for identifying any local clinical audits to be undertaken, and progress them through the approval process; to identify learning outcomes and support communication of quality improvement programmes and clinical audit results. The Chair from this group must endure that there is maintained two way feedback with the CQO.

4.12 ***Virtual Forum*** is co-ordinated by the SCQM and its purpose is to provide a mechanism to approve local audit proposals as received by the CQO. As a minimum the forum will include a member of the Clinical Quality Audit Team, and a Senior Clinician and/or Clinical Professions Lead. Any decisions made by the virtual forum will need to be ratified by the CEMG.

5. CONDUCTING CLINICAL AUDIT

5.1 Agreeing an annual programme of activity

Prior to the start of every financial year, the Trust will agree an appropriate planned programme of clinical audit activity. The work programme is developed by the SCQM and the Clinical Professions Leads, Senior Clinicians and the Medical Director who consider patient, clinician, Trust committee, regulatory and commissioner requirements. A key influencer of any clinical audit addition to the Trust work-plan is its ability to contribute to the ambitions described in the Right Care Strategy (2018 – 2023). Similarly audits identified through the introduction of new or amended guidance (Health Notifications, Alerts and Guidance Review Procedure 2019) are also considered for inclusion in the work-plan.

All projects identified as 'National Clinical Audits' through the National Ambulance Clinical Quality Group and National Ambulance Service Medical Directors Group will form the basis of the Trust annual clinical audit work programme and will be assigned the highest priority as described by Healthcare Quality Improvement Partnership (HQIP). See appendix 1 for information about the selection and prioritisation of audits.

5.1.1 Additions to the annual clinical audit programme

It is acknowledged that compiling and prioritising an annual clinical audit plan at the start of the year should not stifle projects that emerge during the year that will contribute to improvements in care. Where an audit is proposed that could not be determined / foreseen at the outset of the financial year a review of the annual programme should be undertaken initially by the Virtual Forum to determine whether and to what extent the audit will attract support from the Clinical Quality audit team. Decisions made by the Virtual Forum will be ratified through the governance structure of CEMG and Quality and Performance Committee.

5.2 Local Clinical Audit Topics

NWAS is committed to encouraging and supporting locally determined clinical audit activity. It is recognised and encouraged that individual clinicians may initiate a clinical audit project on the basis of personal interest, personal development or as part of an educational /training programme. It is important that these initiatives are registered with the CQO so that progress can be monitored and reported through the various governance structures described earlier as this will maximise organisational learning. Once registered the audit will be considered by the Virtual Forum to determine whether and to what extent the audit will be supported by the Clinical Quality audit team. Decisions made by the Virtual Forum will be ratified through the governance structure of CEMG and Quality and Performance Committee.

5.3 Registering and approving Clinical Audits

The Trust will maintain a register of clinical audits undertaken within the organisation. This will support good governance of all audit projects; ensuring that the rationale for the audit is appropriate and also that the principles of the policy and guidance are adhered to. The register will also enable sharing of good practice and avoid any duplication of efforts. The Clinical Quality Officer will manage the register. For each clinical audit project:

- An audit proposal form must be completed by the project lead (appendix 2)
- The proposal must be approved by the virtual forum, in the first instance and ratified by the CEMG.

All audit activity must be registered with the CQO irrespective of the level of facilitation being requested of the clinical quality audit team, and to enable progress review and monitoring for quality assurance purposes.

5.4 Clinical Audit Register Management

The CQO will maintain a central clinical audit registration database which will incorporate details of all clinical audit activity undertaken throughout NWAS. The database (Excel spreadsheet) will be updated regularly by the CQO and will be used to report to the CEMG,

Audit and Quality and Performance Committees on the progress of the annual clinical audit work-programme.

The clinical audit project lead will be required to provide regular progress updates to the CQO.

5.5 Data Protection

All clinical audits will be conducted in accordance with relevant legislation such as the Data Protection Act 2018, the 'Caldicott Priniciples' (Caldicott Committee 1997), Health and Social Care Act 2013, ethical guidelines and the General Data Protection Regulation 2018.

All data collected will be adequate, relevant, not excessive, accurate, processed for limited purposes, treated confidentially and not retained for longer than necessary. Data will be held securely and secured with password protection. Data access will be strictly limited to those directly working with it.

5.6 Use of Standards

By definition, clinical audit involves measuring clinical practice against standards of best practice. It is the NWAS position that all clinical audits will use evidence based standards for measurement, and all clinical audit proposals should include a literature scoping exercise to identify the most recent evidence and guidelines on the topic area. The NWAS Healthcare Notifications, Alerts and Guidance review process may stimulate the need to conduct an audit in response to a change in patient care. The starting point to identify the evidence based standards is usually a review of NICE guidelines, and / or Clinical Practice Guidelines for Use in UK Ambulance Services (JRCALC).

It may be necessary, particularly when auditing a local service or intervention to develop standards specific to that service or intervention. In these cases care must be taken to ensure the standards are valid to maintain confidence in the clinical audit data.

The SCQM, CQO and wider Clinical Quality Audit team will work with the project lead to; design the audit standards in line with the objectives of the audit; assist in identifying the number of cases to be audited; and how they will be selected.

5.7 Reporting and Dissemination

An effective audit carried out in one area of the Trust may be transferable to other parts of the organisation. Once a round of data collection has been completed and the data has been analysed, the findings should be presented at Locality Quality Business Group or equivalent, and potentially the CEMG, for discussion, agreement of action plans and a commitment to complete another audit cycle within a designated time frame.

The CEMG will review all summary clinical audit reports on completion.

It is expected that all clinical audit reports are shared with the SCQM and CQO for review before dissemination. All clinical audit projects will be formally written up using a standard audit report pro-forma located in appendix 3. The content should include:

- Introduction and Background…rationale for audit

- Aims and Objectives
- Criteria and Standards
- Methodology
- Findings (including appropriate graphic representation)
- Recommendations (including re-audit dates and dissemination)
- Conclusion
- Action Plan (as appropriate)

5.8 Action Plans for Improvement

The CEMG will monitor the implementation of actions ensuring any identified required changes are incorporated into practice and into relevant business plans and/ or risk registers as appropriate.

The Right Care Strategy (2018 – 2023) describes the Trust approach to improvement which is the model for improvement as developed by the Institute for Health Improvement. This model asks teams to address three key questions and use Plan, Do, Study Act cycles to instigate small tests of change.

Not all clinical audits will require an action plan e.g. where an audit shows standards are consistently and repeatedly being met, and practice is effective. For such audits there should be an explicit statement in the summary report that no further action is required, along with the rationale for this.

5.9 Repeating Audit Cycles

The clinical audit cycle is not complete until agreed actions are implemented according to the corresponding action plan, and evidence is obtained of the impact of the plan on compliance with standards.

It is the responsibility of the Clinical Professional Lead/ Senior clinician to ensure repeated cycles of clinical audit may be carried out to ensure standards and criteria are consistently and repeatedly being met, and practice is effective.

5.10 Terminating an Audit Project

On occasion it may be necessary to terminate projects that are no longer viable. An audit may be considered for termination (with agreement of the CEMG) if any of the following criteria are met:

- The project exceeds its ‘Best before Date’. A project will be deemed to be ‘out of date’ when a period on 12 months has elapsed since the time at which the last data item was collected.

- There is a lack of data from collaborating parties. When partners fail to provide data in accordance with agreed deadlines: a two month grace period will be allowed after which a further deadline will be negotiated, with escalation to their Medical Director or equivalent. Failure to meet the new deadline will either:
    - Result in the project being terminated, or

- An alternative collaborator found, or
- Methodology revised so that collaboration is not required.

- Any instance where the audit lead fails to comply with NWAS standards of behaviour, their professional code of conduct, ethical guidelines, or contravenes any regulations such as the DPA 2018.

5.11 Clinical Audit Annual Report

The Clinical Audit Annual Report is collated by the CQO and SCQM. The report is received by the Quality and Performance Committee for approval at which point the report is disseminated internally and externally to other ambulance services, hospitals, academic partners and other relevant groups/organisations as appropriate.

The annual report content should include:

- Introduction and background
- National Audit undertaken (summary of results)
- Local audit undertaken (summary of findings)
- Summary of audits registered (including those terminated and rationale for why they were terminated)
- Recommendations for the next 12 months including onward clinical audit programme

6. GOVERNANCE AND ETHICS

6.1 By definition, clinical audit projects should not require formal approval from a Research Ethics Committee. However, clinical audit must always be conducted within an ethical framework, as one of the principles underpinning clinical audit is that the process should 'do good', and should not 'do harm'.

The CEMG is responsible for the ethical oversight of clinical audit across the organisation and any person who has concerns regarding the ethics of clinical audit should refer them to the Chair of the management group.

Each clinical audit project must demonstrate consideration of the following four ethical principles:

- There is a benefit to exiting or future patients that outweigh potential burdens or risks.
- Each patients right to self-determination is respected
- Each patients privacy and confidentiality is preserved
- The activity is fairly distributed across patient groups.

7. EQUALITY IMPACT ASSESSMENT STATEMENT

It was found that the Clinical Audit framework has a positive assessment, as it supports the public health agenda.

8. POLICY REVIEW

The NWAS Clinical Audit Policy will be reviewed every three years; however, should national guidance or legislation change then the policy may be reviewed earlier.

As part of the policy review process, the effectiveness of the policy and its application will be assessed. Information and results from audit systems, adverse incidents, user feedback and external audits/reviews will be used to inform this assessment.

9. BIBLIOGRAPHY AND REFERENCES

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HQIP (2011) *Guide to Ensuring Data Quality in Clinical Audits*

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NWAS 2018 *Right Care (Quality) Strategy 2018 – 2023*

APPENDIX 1: CLINICAL AUDIT PRIORITY IDENTIFICATION

Clinical audit projects will be prioritised in a systematic way, taking into consideration the following issues:

- Is the topic concerned with high cost, high volume or high risk to staff, or to patients/service users?
- Is there evidence of a quality problem, e.g. patient complaints, high complication rates, adverse outcomes or poor symptom control?
- Is there evidence of wide variation in practice?
- Is good evidence available to inform audit standards, e.g. systematic reviews or national clinical guidelines?
- Is the problem measurable against relevant standards?
- Is auditing the problem likely to improve healthcare outcomes as well as process improvements?
- Is auditing the problem likely to have economic and efficiency benefits?
- Is the topic a key professional or clinical interest?
- Are reliable sources of data readily available for data collection purposes?
- Can data be collected within a reasonable time frame?
- Is the problem concerned amenable to change?
- Is the topic pertinent to national or local initiatives or priorities?
- Does the topic lend itself to the process of audit, or is a different process more appropriate e.g. root cause analysis, activity or workload analysis?
- How much scope is there for improvement, and what are the potential benefits of undertaking this audit?
- Other factors include the scope for the direct involvement of patients and carers, and whether the project crosses organisational or disciplinary boundaries.

Priority 1 (P1): External Must Dos: National audit requirements mandated through organisations such as the Department of Health, Care Quality Commission , or other national audit programmes.

Priority 2 (P2): Internal Must Dos: Internal audits mandated through the quality contract with the ambulance service lead commissioners

Priority 3 (P3): External Discretionary: Usually large scale audits commissioned through an external source not mandated through any national programme of audit.

Priority 4 (P4): Internal Discretionary: Usually, but not always, small scale, locally commissioned audit not mandated through any formal programme of audit commission.

APPENDIX 2: CLINICAL AUDIT PROPOSAL FORM

AUDIT TITLE

AUDIT LEAD NAME:	
JOB TITLE:	
DIRECTORATE:	
CONTACT DETAILS:	

IS THIS A RE-AUDIT? Delete as appropriate: YES / NO

If Yes, Have previous audits actions been implemented?

REASONS FOR AUDIT: select all that apply:

Audit against guidelines/standards		**Adverse incident**	
Area of high cost		**Area of high volume**	
Linked to complaint		**Other (please specify)**	
Area of high risk (state rationale for assessment as such)			

MAIN AIM / OBJECTIVE OF THE AUDIT (What are you trying to achieve, your expectations?) Please include how the audit fits with the Right Care Strategy objectives.

SOURCE OF STANDARDS/GUIDELINES: select all that apply

JRCALC		**CQC**	
NICE Guidance		**CQUIN**	
New Procedure/intervention		**NHSLA Guidelines**	
Other		**Other Professional Guidelines**	

Specific standard or Guideline to be audited:

AUDIT DESIGN: HOW DO YOU PROPOSE TO COLLECT THE DATA?

PROPOSED DATA SOURCE: select all that apply:

Patient Report Form		**NWAS Informatics Data**	
Staff Survey		**Interviews**	
Observation		**Patient surveys**	
Focus Groups		**Other (please specify)**	

ANTICPATED SAMPLE SIZE (Please indicate how this was calculated and whether any advice was sought in calculating it?)

WHO IS GOING TO COLLECT/ANALYSE THE DATA? (please indicate the level of support you require from the clinical quality team)

TIMESCALE (to collect the data, to analyse the data?)

DETAILS OF FINANCIAL/RESOURCE IMPLICATIONS (if applicable)

Please confirm that you have attached the following documents: (Delete as appropriate)

Information about patient involvement in the audit (in the audit design)	**Y/N**
Arrangements for obtaining informed consent & identifying participants	**Y/N**
Questionnaires or surveys to be used	**Y/N**
Risk assessment	**Y/N**
Strategy for dissemination	**Y/N**

Please confirm that you are familiar with: (Delete as appropriate)

The Data Protection Act 2018, General Data Protection Regulation 2018 principles of ethics relating to clinical audit	**Y/N**
The Incident Reporting Process	**Y/N**
The Trust Clinical Audit Policy	**Y/N**
The Trust Information Governance Training	**Y/N**

Proposed audit start date	
Proposed audit finish date	
Expected date of final report	

Please send completed proposal to: nwasnt.clinicalaudit@nhs.net
All proposals will be reviewed the Virtual Clinical Audit Forum and any decisions ratified by the Clinical Effectiveness Management Group.

If you have any queries regarding the completion of this form please contact:
Mary Peters
Senior Clinical Quality Manager
Office: 01204 498392
Email: mary.peters@nwas.nhs.uk

OFFICE USE ONLY

Proposal received date		
Audit Register reference number		
Virtual Clinical Audit Forum Date		
Virtual Clinical Audit Forum Decision		
Audit Lead Informed Date(s)	VCAF Outcome	CEMG Outcome
CEMG Received date		
CEMG Decision		

APPENDIX 3: CLINICAL AUDIT REPORT PRO-FORMA

AUDIT TITLE:	
AUDIT LEAD:	

BACKGROUND:

AIM AND OBJECTIVES:

CRITERIA AND STANDARDS :

METHODOLOGY:

FINDINGS:

RECOMMENDATIONS:

CONCLUSION:

ACTION PLAN: