Pennine Care NHS
NHS Foundation Trust

Policy Document Control Page

Title

Title: Clinical Audit Policy

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(please enter tags/words that are associated to this policy)
Clinical Audit Clinical Effectiveness Quality Account
National Clinical Audit and Patients Outcome Programme

Supersedes

Supersedes: Clinical Audit Policy (version 3)
Description of Amendment(s):
- Removal of reference to NHSLA standards to reflect changes in requirements
- Changes to departmental and organisational structures
- Changes to local clinical audit process

Originator

Originated By: Linda Chadburn, on behalf of Andrea Morris

Designation: Head of Integrated Governance

Equality Impact Assessment (EIA) Process

Equality Relevance Assessment Undertaken by: Abdul Khan, Clinical Audit Officer

ERA undertaken on: 19.4.2016

ERA approved by EIA Work group on:

Where policy deemed relevant to equality-

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Approval and Ratification

Referred for approval by: Head of Integrated Governance

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Approved by: Quality Group

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Executive Director Lead: Medical Director

Circulation

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Policy to be uploaded to the Trust's External Website? YES / NO

Review

Review Date: October 2016

Responsibility of: Andrea Morris

Designation: Head of Integrated Governance

This policy is to be disseminated to all relevant staff.

This policy must be posted on the Intranet.

Date Posted: 17th May 2016

Contents

1 Introduction

1.1 Clinical audit is described by NHS England as a way to find out if healthcare is being provided in line with standards and lets care providers and patients know where their service is doing well, and where there could be improvements. The aim is to allow quality improvement to take place where it will be most helpful and will improve outcomes for patients. Clinical audits can look at care nationwide (national clinical audits) and local clinical audits can also be performed locally in Trusts, hospitals or GP practices, anywhere healthcare is provided (NHS England, 2016).

1.2 When conducted in accordance with best practice standards, clinical audit:

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

1.3 Clinical audit is part of an overall framework of quality and participation in both national and local clinical audit is reported in the Trust's Quality Account. The list of clinical audits required to be included in the Quality Account can change on an annual basis and is published by the Healthcare Quality Improvement Partnership (HQIP) on behalf of NHS England early in the year to enable local planning.

1.4 NHS England contract HQIP to support the National Clinical Audit and Patient Outcome Programme (NCAPOP) and this programme includes clinical audits supplied by independent organisations such as professional societies, university institutes and Royal Colleges and participation should be reported in the Quality Account. Other independently funded national clinical audits are not part of the NCAPOP but may be listed for inclusion in the Quality Account accordingly.

1.5 NHS standard contracts for acute hospital, mental health, community and ambulance services came into effect in April 2011. The contract terms apply to new agreements from April 2011 for NHS Foundation Trusts including services provided by Pennine Care NHS Foundation Trust (PCNFT).

1.6 Providers must participate in the national clinical audits which are relevant to the services they provide and must implement all relevant recommendations of any appropriate clinical audit.

1.7 In addition to this contractual requirement, the regulatory framework operated by the Care Quality Commission (CQC) requires registered healthcare providers to regularly assess and monitor the quality of the services provided.

1.8 The Trust is expected to use the findings from clinical audits, including those undertaken at a national level to ensure that action is taken to protect people who use services from risks associated with unsafe care, treatment and support.

1.9 The Trust must also ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of the relevant professional bodies; for example, for medical and clinical revalidation.

1.10 The Trust supports the view that clinical audit is fundamentally a quality improvement process; however clinical audit also plays an important role in providing assurances about the quality of services.

1.11 The Board is required by Monitor, the sector regulator for health services in England, to certify that they have effective arrangements in place for the purpose of monitoring and continually improving the quality of healthcare provided to patients, and must therefore be assured efficient and effective systems, processes and procedures are in place to monitor and improve quality.

1.12 This policy is designed to fulfil these requirements, and all staff are required to ensure that any clinical audits they undertake are conducted in line with this policy.

2 Purpose of the Policy

2.1 This policy provides guidance for all staff participating in clinical audit activities. It includes the Trust's procedures for registering a clinical audit and ensures that clinical audit results are reported and acted upon. The overall aim is to promote high quality clinical audit within the Trust.

3 Definition of Clinical Audit

3.1 Clinical audit is described by NHS England as a way to find out if healthcare is being provided in line with standards and lets care providers and patients know where their service is doing well, and where there could be improvements. The aim is to allow quality improvement to take place where it will be most helpful and will improve outcomes for patients.

3.2 Clinical audits can look at care nationwide (national clinical audits) and local clinical audits can also be performed locally in Trusts, hospitals or GP practices, anywhere healthcare is provided (NHS England, 2016).

4 Scope

4.1 Every employee within the Trust has a responsibility for participating in clinical audit.

4.2 This policy applies equally to all members of staff, either permanent or temporary.

4.3 This policy also applies to staff on honorary contracts, students and trainees, volunteers, patients and carers and members of the public, as well as any staff working for other NHS organisations and involved in collaborative clinical audit activity.

5 Duties and Responsibilities

5.1 Trust Board

5.1.1The Trust Board will seek assurance that clinical audit is used as a strategic tool to align clinical audit activity to broader interests and targets that the Board need to address.

5.1.2 The Board will receive assurance that clinical audit activity listed on the clinical audit programme is focussed on locally identified risks as well as on national issues.

5.1.3 The Board will be assured that the clinical audit programme is delivered efficiently and effectively and that plans to improve practice where necessary are in place to enable evidence base practice to be followed and evidenced.

5.2 Quality Group

5.2.1 The Quality Group will oversee the effective delivery of the clinical audit programme and will be made aware of any issues and concerns regarding the delivery of the programme as well as in relation to the quality of data used for clinical audit.

5.2.2 Any concern regarding the care of a patient highlighted through analysis of data used for clinical audit will be brought to the attention of the Quality Group by the Medical Director.

5.3 Medical Director

5.3.1 The Medical Director is responsible for the statutory duty of quality and takes overall responsibility for clinical audit activity within the Trust and will provide strategic leadership and act as an ambassador for clinical audit.

5.3.2 The Medical Director will bring to the attention of the Quality Group any issue or concern raised by the Head of Integrated Governance in relation to patient care or the effective delivery of the clinical audit programme.

5.4 Head of Integrated Governance

5.4.1 The Head of Integrated Governance will provide operational leadership and oversee delegated responsibilities to the Clinical Effectiveness and Quality Improvement Lead.

5.4.2 The Head of Integrated Governance will escalate any concern or issue raised by the Clinical Effectiveness and Quality Improvement Lead regarding clinical audit activity.

5.5 Clinical Effectiveness and Quality Improvement Lead

5.5.1 The Clinical Effectiveness and Quality Improvement Lead is responsible for maintaining an overview of the Trust's clinical audit policy and related documents, systems and processes.

5.5.2 The Clinical Effectiveness and Quality Improvement Lead is managerially responsible for the Clinical Effectiveness and Quality Improvement Team and for the development and delivery of the Trust's clinical audit programme in conjunction with external organisations, such as HQIP, Royal Colleges and internal professionals, such as Service Directors and service specific leads.

5.5.3 The Clinical Effectiveness and Quality Improvement Lead is responsible for investigating any issue regarding the effective delivery of the clinical audit programme and any issue regarding the quality of data and / or the outcomes of a clinical audit prior to escalating to the Head of Integrated Governance for further discussion and escalation.

5.5.4 The Clinical Effectiveness and Quality Improvement Lead will escalate to the Quality Group non-participation in a national clinical audit following discussion in the first instance with the service involved.

5.5.5 Should a decision be made not to participate in a national clinical audit, the Clinical Effectiveness and Quality Improvement Lead will contact the supplier and request a letter confirming exclusion - excluding the Trust from participation (this will be included in the Quality Account to explain non-participation).

5.6 Quality Improvement Coordinators

5.6.1 Quality Improvement Coordinators are part of the Clinical Effectiveness and Quality Improvement Team and are responsible for the delivery of the clinical audit programme through collaborative working with services, offering support and advice when necessary to ensure all individuals involved in clinical audit activity are equipped to conduct a high quality clinical audit which will achieve improvements in patient care and sustain high quality care.

5.6.2 Quality Improvement Coordinators work collaboratively to ensure the clinical audit programme progresses to schedule, raising any issues for discussion and solution with the Clinical Effectiveness and Quality Improvement Lead.

5.7 Clinical Effectiveness and Quality Improvement Team

5.7.1The Clinical Effectiveness and Quality Improvement Team are responsible for receiving and reviewing clinical audit proposals for inclusion on the clinical audit programme using a robust model to ensure all clinical audits are high quality projects and that there are sufficient resources available to deliver within the agreed timeframes.

5.7.2 The Clinical Effectiveness and Quality Improvement Team will offer support to services involved in priority clinical audit, including:

- Planning a clinical audit
- Supporting the development of audit standards and a data collection tool
- Supporting analysis.

5.7.3 Any other support required from a service or individual involved in priority clinical audit will be made available on an individual basis.

5.8 Service Directors and Service Leads

5.8.1 Service Directors and Service Leads have a responsibility to support clinical audit as part of the overall quality agenda, ensuring their teams embrace all aspects of clinical audit and ensuring it is integrated into local structures.

5.8.2 Service Directors and Service Leads have responsibility to identify any Must Do clinical audits; i.e. national clinical audits, clinical outcome review projects and prescribing observatory for mental health projects relevant for their service to participate; these projects form the annual list devised by NHS England and is shared by the Clinical Effectiveness and Quality Improvement Team in January /February each year.

5.8.3 Service Directors and Service Leads will identify a lead for all Must Do clinical audits the service participates and the details of that lead will be shared with the Clinical Effectiveness and Quality Improvement Team.

5.8.4 Service Directors and Service Leads will provide a rationale to the Clinical Effectiveness and Quality Improvement Team to explain non-participation in any Must Do clinical audit considered either not relevant to their service or when a service considers that they are unable to participate.

5.8.5 Service Directors and Service Leads have the responsibility for identifying key priorities for inclusion in the Should Do section of the clinical audit programme, including the following:

- The Trust's priority work streams as mentioned in the Quality Strategy and Quality Account
- Clinical risks included on local risk registers
- Serious untoward incidents in the service

- Evidence to show that NICE guidance is used appropriately

5.8.6 Service Directors are expected to identify the level of resource required from the Clinical Effectiveness and Quality Improvement Team to support the delivery and achievement of clinical audits to be undertaken within their service; including local key performance indicators (KPI) and Commissioning for Quality and Innovation (CQUIN) targets.

5.9 Clinical Audit Leads

5.9.1 A Clinical Audit Lead should be appointed to oversee the completion of each clinical audit project and should be identified on the clinical audit proposal form.

5.9.2 Clinical Audit Leads are responsible for supporting the development and implementation of action plans to achieve change and improve care.

5.9.3 Clinical Audit Leads are responsible for ensuring an action plan is approved by the relevant service /division.

5.9.4 Clinical Audit Leads are also responsible for data security and ensuring that the clinical audit project complies with information governance requirements.

5.10 Patients, Carers and the General Public

5.10.1 Patients, carers and the general public should be encouraged to engage with clinical audit activity, either indirectly through the use of patient surveys and questionnaires, or directly through participation on project groups or patient forums.

5.11 Other Stakeholder Involvement

5.11.1 The Trust encourages clinical audit activity across internal and external boundaries where improvements to patient outcomes may be identified through shared clinical audit activity.

5.11.2 The identified lead for any clinical audit undertaken with other organisations is responsible to seek advice and support from the Clinical Effectiveness and Quality Improvement Lead to ensure the security of data is maintained and that activity complies with information governance requirements.

5.12 Medical Trainees

5.12.1 Medical trainees are particularly highly active in clinical audit and the Trust is committed to involving and working collaboratively with local academic bodies to ensure medical trainees are able to complete the requirements of the curriculum.

5.12.2 The curriculum for the foundation programme (first two years following qualification) refers extensively to clinical audit. All foundation programme doctors are expected to participate in supervised clinical audit. Doctors who join the accredited training programme are expected to reach the standards set out by the Postgraduate Medical Education and Training Board (PMETB) and must regularly be involved in clinical audit activity, including planning, data collection and analysis.

5.13 Medical Audit Committee

5.13.1 The Medical Audit Committee works in conjunction with the Medical Education Committee and is responsible for the promotion of clinical audit amongst medical trainees.

5.14 Commissioners

5.14.1 The Trust supports the undertaking of relevant audits identified by commissioning bodies; for example CQUIN.

5.14.2 CQUIN projects are agreed through the Performance and Information Department and the Finance Departments. Clinical audit resources are frequently required to support CQUIN projects and the resource required will be determined early in the year to ensure sufficient resources are in place to allow commencement on the 1 April.

5.15 Information Department and the Finance Department

Clinical audit resources required to support any CQUIN should be discussed with the Clinical Effectiveness and Quality Improvement Lead and Service Directors and Service Leads as soon as practicable possible to ensure sufficient resources can be allocated prior to commencement of the clinical audit programme on the 1 April.

6 Clinical Audit Process

6.1 Clinical Audit Programme

6.1.1 The Trust is expected to have a clinical audit programme related to both local and national priorities with the overall aim of improving patient outcomes.

6.1.2 The organisation's strategic objectives and priorities should be considered during the development of the clinical audit programme to ensure that it aligns to the wider quality improvement agenda.

6.1.3 The clinical audit programme should meet the requirements of the Board Assurance Framework and include clinical audits necessary to meet regulatory and commissioner requirements.

6.1.4 A clinical audit programme is developed and agreed each year prior to commencement on the 1 April. The planning stage is from December to March.

6.1.5 The rationale for the development of a robust clinical audit programme is to provide an explicit framework that will enable the Trust Board to receive assurance that clinical practice is supported by best evidenced care and to provide the Trust Board with evidence of compliance against nationally agreed standards.

6.1.6 An effective monitoring schedule of national, organisational and local priorities requires engagement from the Clinical Effectiveness and Quality Improvement Team, the Quality Group and Divisions and Services to ensure it encompasses national and organisational requirements.

6.1.7 The clinical audit programme will include the national clinical audits identified by NHS England for inclusion on the Quality Accounts and will reflect Trust's priority work streams as mentioned in the Quality Strategy and the Quality Account, clinical risks included on divisional risk registers, the corporate risk register and the Board Assurance Framework and relevant, high priority NICE guidance and recommendations.

6.1.8 The clinical audit programme will be communicated to the Quality Group to make it aware of the topics and progress of clinical audits registered through the Clinical Effectiveness and Quality Improvement Team, including all clinical audits led by clinicians and medical trainees.

6.1.9 Information shared with the Quality Group in relation to clinician and medical trainee led clinical audits will be through exception reports, i.e. escalation of any issues and concerns regarding the delivery and management of a clinical audit as well as any issues and concerns regarding the results and outcomes of a clinical audit.

6.1.10 The clinical audit programme will be divided into three sections:

- Must Do clinical audits
- Should Do clinical audits
- Want To clinical audits

6.2 Must Do clinical audits

6.2.1 Must Do clinical audits are those which the Trust is contracted to deliver.

6.2.2 National clinical audits including those that form part of the National Clinical Audit Patient and Outcomes Programme (NCAPOP) and those that require reporting in the Quality Account are disclosed by NHS England around mid-January each year.

6.2.3 All relevant projects which form part of the Clinical Outcome Review Programme (CORP) that require reporting in the Quality Account will be included on the clinical audit programme following discussion with services.

6.2.4 All relevant projects which form part of the Prescribing Observatory for Mental Health UK (POMH - UK) that require reporting in the Quality Account will be included on the clinical audit programme following discussion with services.

6.2.5 The full list of all projects falling within the Must Do section of the clinical audit programme will be shared by the Clinical Effectiveness and Quality Improvement Team with services for discussion and identification of topics relevant for the service to participate in January /February each year.

6.3 Should Do clinical audits

6.3.1 Should Do clinical audits are those which reflect local and organisational priorities.

6.3.2 Clinical audits supporting the Trust's priority work streams as mentioned in the Quality Strategy and the Quality Account should be considered for inclusion on the programme.

6.3.3 Clinical audits which will support the treatments and controls identified against clinical risks included on divisional risk registers, the corporate risk register and the Board Assurance Framework should be considered for inclusion on the programme.

6.3.4 The clinical audit programme should include relevant projects which will provide Board assurance that NICE guidance is used appropriately and the Trust is implementing NICE guidance as recommended.

6.3.5 The clinical audit programme should make clear the resource required from the Clinical Effectiveness and Quality Improvement Team to support the CQUIN programme.

6.4 Want To clinical audits

6.5.1 The Trust is committed to supporting other local clinical audit activity as a significant contributor to the continuous process of service improvement.

6.4.2 It is acknowledged that individual clinicians may plan to undertake a clinical audit project on the basis of personal interest, personal development or as part of an educational or training programme.

6.4.3 Want To clinical audits are those which are considered low priority, including clinician interest.

6.5 Registering a clinical audit

6.5.1 **Must Do and should Do clinical audits** must be registered with the Clinical Effectiveness and Quality Improvement Team during the planning stage of the Clinical Audit Programme (normally January to March each year).

6.5.2 There may be occasions when additional topics need to be included on the Clinical Audit Programme mid-programme and these should be brought to the attention of the Clinical Effectiveness and Quality Improvement Team as soon as is practicably possible.

6.5.3 The process for including a topic on the Clinical Audit Programme is described in two stages:

- Stage One: submission of proposal
- Stage Two: gaining approval.

6.5.4 ***Stage 1: submission of proposal***

- A clinical audit proposal form should be completed for each clinical audit identified by the Division/Service.
- The proposal form should be completed and submitted by the main contact / lead for the clinical audit.
- The completed clinical audit proposal form should be submitted for review to clinicalaudit.penninecare@nhs.net
- All proposals received will be reviewed weekly by the Clinical Effectiveness and Quality Improvement Team.
- Approval in principle, and/or feedback will be provided within 5 working days of the review meeting.
- Where approval in principle is not granted, the clinical audit lead(s) or main contact(s) will be contacted to provide further relevant information.
- Where approval in principle is granted the clinical audit lead(s) or main contact(s) will be invited to further discussions with a member of the Clinical Effectiveness and Quality Improvement Team.

6.5.5 ***Stage 2: gaining approval***

- The clinical audit lead(s) or main contact(s) will be contacted by a member of the Clinical Effectiveness and Quality Improvement Team for further discussions regarding the clinical audit.
- The format of the meeting will include:
    - Completion of a criteria testing tool
    - A review of the standards to be audited against
    - Agreement of timelines for the audit
    - The level of support required from the Clinical Effectiveness and Quality Improvement Team

- The clinical audit lead(s) or main contact(s) will be required to bring relevant documentation to the meeting, e.g. copy of relevant guidance documents, policy documents.
- A clinical audit meeting the required criteria will be granted approval and a clinical audit reference number allocated.
- Formal approval will be confirmed to the clinical audit project lead(s) or main contact(s), together with an outline of discussions and project plan within a project scoping document.
- Details of approved clinical audits will be added to the clinical audit programme.

6.5.6 **Want To clinical audits** must be discussed and agreed with senior management prior to registration with the Clinical Effectiveness and Quality Improvement Team.

6.5.7 It is important not to commence any clinical audit until full approval from senior management and the Clinical Effectiveness and Quality Improvement Team has been granted.

6.5.8 A clinical audit registration form must be submitted and is accessed through contacting the Clinical Effectiveness and Quality Improvement Team.

6.5.9 A unique reference number will be allocated to all clinical audits registered with the Clinical Effectiveness and Quality Improvement Team. It is important to quote this number when contacting the Team to discuss a clinical audit.

6.5.10 It is important to quote the reference number allocated to a clinical audit when registering further cycles of a clinical audit; i.e. a re-audit.

6.6 Use of standards

6.6.1 By definition, clinical audit involves measuring clinical practice against predetermined standards of best practice.

6.6.2 Standards are an agreed statement of best practice, which will improve the quality of care and should be evidence based and ideally taken or adapted from sources including national guidance recommendations e.g. NICE, local guidelines and policies.

6.6.3 Any person planning to undertake a clinical audit will be expected to identify the standards the clinical audit will measure practice against. It is advised that the standards to be measured against are agreed with the identified lead for the clinical audit and the Clinical Effectiveness and Quality Improvement Team.

6.6. A clinical audit will not be approved to commence by the Clinical Effectiveness and Quality Improvement Team until the standards to be measured against are identified.

6.6.5 The Clinical Effectiveness and Quality Improvement Team can be contacted for support regarding the identification of standards should the need arise.

6.7 Sampling and data sourcing

6.7.1 The sample chosen for clinical audits must be sufficient to produce credible results. For small populations a representative sample may be determined by the clinical audit lead and selected randomly. However, care should be taken when auditing areas where there are relatively few cases as individuals are identified more easily.

6.7.2 Samples chosen from large populations need to be representative and it is advised that an electronic sampling technique is used. This approach calculates a sample from a specified population and allows the audit lead to report the audit results with a 5% error margin and with a 95% confidence level.

6.7.3 Advice and support to select a sample which will meet the needs of the audit as well as take into consideration the resources available to undertake the clinical audit can be obtained from the Clinical Effectiveness and Quality Improvement Team.

6.7.4 Data collected for audits should be from a reliable source. The source should be identified during the planning stage of a clinical audit to ensure that all individuals involved in data collection use the source in a consistent manner.

6.8 Data collection and analysis

6.8.1 Data collection tools must include a unique identification number, which refers to the subject audited and the date which data was collected.

6.8.2 It is recommended that the name of the auditor is included on the data collection tool, especially where more than one auditor is collecting the data.

6.8.3 Patient identifiable data (PID) should NOT be collected as part of a clinical audit. All clinical audit data should be anonymised. This means that identifiable information such as name, date of birth, address, postcode and any other combination of details that may identify the individual are removed.

6.8.4 To prevent the collection of PID a patients personal details must not be recorded on the data collection tool. These details must be recorded on a separate sheet with a corresponding unique identification number to that used on the data collection tool.

6.8.5 The document detailing the unique identification number and the corresponding patient details must be stored securely and separately from the data collection tools.

6.8.6 The development of data collection tools is supported by the Clinical Effectiveness and Quality Improvement Team using specialised software. The Clinical Effectiveness and Quality Improvement Team should be contacted for the production of a data collection tool.

6.8.7 The process of data analysis requires the extraction of relevant data from that collected and interpreting that data into useful information. Analysis can be illustrated diagrammatically, using charts or tables. More sophisticated techniques can be used; although these are not normally necessary for clinical audit purposes.

6.8.8 Data analysis is supported by a Data Analyst who is part of the Clinical Effectiveness and Quality Improvement Team.

6.9 Clinical Audit Report

6.9.1 A clinical audit report allows the clinical audit lead to share all aspects of the clinical audit with their audience. A clinical audit report should include the following; and it is recommended that these are used as section headings:

- Introduction
- Aim
- Objectives
- Methodology

- Findings
- Conclusion
- Actions for improvement

6.9.2 ***Introduction:*** A background of the audit, including the relevance of the audit and any current government policy and other key documentation.

6.9.3 ***Aim:*** A definition of the key purpose(s) of the audit.

6.9.4 ***Objectives:*** What the audit is trying to achieve, taken from policy/ requirements; i.e. the audit standards.

6.9.5 ***Methodology:*** An explanation of the criteria for inclusion in the audit, the total population and the sample selected, and the source(s) of information required for data collection.

6.9.6 ***Findings:*** A detailed description of the audit findings numerically and/ or pictorially. An overall comparison of the results should be included, highlighting the level of compliance against each of the standards.

6.9.7 ***Conclusion:*** It is recommended to provide your audience with a brief overview of the clinical audit results.

6.9.8 ***Recommendations for improvement:*** Clinical audits may highlight issues which should be considered for improvement.

6.10 Action Planning

6.10.1 All actions required to support recommendations for improvement should be discussed and agreed by key professionals involved in the audit and any other relevant stakeholders prior to the development and sharing of an action plan.

6.10.2 The relevant service/ division should be aware of all action plans developed from clinical audit and it is the responsibility of the lead allocated to a clinical audit to ensure this happens.

6.10.3 Effective ownership of an action plan will enable effective monitoring and implementation of actions and improvements.

6.10.4 The action plan owner is expected to monitor the progress of action taken until implementation for each clinical audit.

6.10.5 There should be documented evidence of monitoring and implementation of an action plan.

6.10.6 Any issues or concerns regarding the effective implementation of actions should be discussed locally in the first instance and escalated to the Clinical Effectiveness and Quality Improvement Team if necessary.

6.10.7 The Clinical Effectiveness and Quality Improvement Team may decide to highlight any concerns in relation to a clinical audit outside of the normal route and these will normally be discussed with the Head of Integrated Governance prior to further escalation to the Trust's Quality Group if necessary.

6.11 Sharing Results

6.11.1 The results of all clinical audits will be shared within the relevant forum using the appropriate governance reporting framework; e.g. local Quality Governance Forum.

6.11.2 The results of all clinical audits will be shared with the Clinical Effectiveness and Quality Improvement Team.

6.12 Outcomes

6.12.1 Details relating to the Trust's participation in all Must Do clinical audits will be included in the Trust's Quality Account by the Clinical Effectiveness and Quality Improvement Lead.

6.12.2 A description of the action the Trust intends to take in relation to National Clinical Audit reports reviewed over a 12-month period will be included in the Trust's Quality Account by the Clinical Effectiveness and Quality Improvement Lead.

6.12.3 Details of the number of Should Do and Want To clinical audit reports reviewed in a 12-month period will be included in the Trust's Quality Account by the Clinical Effectiveness and Quality Improvement Lead.

6.12.4 A description of the outcomes and actions taken for Should Do and Want To clinical audits will be included in the Trust's annual Quality Account by the Clinical Effectiveness and Quality Improvement Lead.

6.13 Re-Audit

6.13.1 It is good practice to undertake a re-audit to ascertain whether improvements to practice can be seen following the implementation of recommended actions.

6.13.2 All re-audits must be registered with the Clinical Effectiveness and Quality Improvement Team using the process described in this policy; quoting the clinical audit reference number(s) allocated to previous clinical audit cycles completed.

7 Governance Arrangements

7.1 Equality and Diversity

7.1.1 The process for determining the choice of clinical audit projects, and the manner in which sample sizes are drawn up, must not discriminate against any groups in society based on their race, disability, gender, age, sexual orientation, religion and belief.

7.2 Information Governance

7.2.1 All clinical audit activity must take into account the Data Protection Act (1998) and the Caldicott Principles (1997). This means that the data must be:

- adequate, relevant and not excessive
- accurate
- processed for limited purposes
- held securely
- not kept for longer than is necessary

7.3 Storage of data

7.3.1 All clinical audit data must be stored in password protected files on Pennine Care NHS Foundation Trust IT systems and must comply with the Trust's Information Security Policy.

7.3.2 If clinical audit data is to be stored anywhere other than the Trust's IT system, the approval of the Information Governance Manager must be sought prior to the clinical audit commencing.

7.4 Retention of data

7.4.1 Healthcare Quality Improvement Partnership (HQIP) support the Department of Health's recommended minimum retention periods and the Trust will follow that advice accordingly.

7.4.2 Clinical audit data should be stored securely throughout the clinical audit process.

7.4.3 The Department of Health Records Management NHS Code of Practice Part 2 requires that clinical audit records must be kept securely for a minimum period of 5 years after a clinical audit has been completed.

7.4.4 The Code does not define more explicitly the 'records' it refers to and therefore the Trust will always follow the organisation's retention policy regarding the report produced to share the details and outcomes of the clinical audit as well as the dataset used for each individual clinical audit.

7.4.5 The data should be kept for no longer than the agreed period and should be destroyed confidentially after this time.

7.4.6 The Code also states that data input forms (where the data/ information has been input to a computer system) should be retained for a minimum of 2 years. The Trust has made an informed decision that this is only relevant if the data input form is the only source of information; for example, if it is the original record filled in by a patient or a clinician.

7.4.7 Clinical audit proformas (data input forms) are classed as 'summaries' of information which is held elsewhere in the patient record, they are not original source documents in themselves and therefore do not need to be retained as described in the Code.

7.5 Destruction of data

7.5.1 Completed paper clinical audit proformas (data input forms) should be destroyed under confidential conditions 2 months after the clinical audit report has been approved."

7.5.2 At the end of the 5-year retention period it may be decided that it is necessary to retain the records for a longer period due to ongoing administration needs. However, principles of the Data Protection Act should be considered; to ensure that personal data is not kept longer than is necessary and it is advised that the Trust's Information Governance Manager is contacted for clarity.

7.6 Clinical audit database

7.6.1 The Clinical Effectiveness and Quality Improvement Team will maintain a database with details of all clinical audit activity reported to them.

7.6.2 The database includes key information from the registration form submitted, including the name and contact details of the lead, speciality and department, current status of the clinical audit project, planned completion date and whether the clinical audit report has been received and an action plan has been developed and implemented.

7.6.3 The database is only accessible to the Clinical Effectiveness and Quality Improvement Team and used to monitor the progress of the clinical audit programme and escalate any issues and concerns.

7.7 Ethics and consent

7.7.1 By definition, clinical audit projects do not require formal approval from a Research Ethics Committee, but they must be conducted within an ethical framework to ensure that no harm is caused to patients or staff and that the data collection is reliable.

7.7.2 Every clinical audit should conform to the following four principles:

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

7.7.3 In cases where the clinical audit requires asking staff or patients sensitive, intrusive questions, the clinical audit must be discussed with the Clinical Effectiveness and Quality Improvement Lead, who may need to seek advice from other relevant staff within the Trust.

7.7.4 When conducting a clinical audit that involves direct contact with patients or carers, all staff must ensure they are approached in a sensitive and respectful manner. Patients or carers must be given a full written explanation (which requires approval from the Clinical Effectiveness and Quality Improvement Team) as to the purpose of the clinical audit; this should provide assurance regarding confidentiality, including how their data will be used, stored and destroyed. Patients and carers should be given the option not to take part in the clinical audit.

8 Education

8.1 Clinical Audit Education

8.1.1 Prime responsibility for monitoring clinical care lies with the clinicians who provide that care; therefore the Trust is committed to supporting clinicians who carry out clinical audit by providing advice and assistance from appropriately trained and experienced clinical audit staff.

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

8.1.3 Training raises the profile of clinical audit and builds up capacity and capability of all staff involved in clinical audit, thus acting as a driver for quality improvement.

8.1.4 Advice and awareness will be made to those staff identified to manage clinical audit activity within their area.

8.1.5 Training will be offered regarding the process and systems used to propose a clinical audit, register a clinical audit and participate effectively in clinical audit.

8.1.6 Training will be made available, raising awareness of clinical audit methodologies and providing knowledge and skills to facilitate the successful completion of a clinical audit. This will be aimed at all staff and patients and carers involved in clinical audit or planning to be

involved in clinical audit.

9 Monitoring Arrangements

9.1 Monitoring adherence to the policy

9.1.1 Monitoring in relation to this policy is the responsibility of the Author. Should the Author require support from the Trust's Clinical Effectiveness and Quality Improvement Team this should be requested using the process detailed in The Clinical Audit Policy to ensure resources are identified and any audit is included on the Clinical Audit Programme.

9.2 The standards

9.2.1 Monitoring will focus on the following standards:

a) The clinical audit programme includes 100% of relevant national clinical audits required to be included in the Trust's Quality Account.

b) 100% of national clinical audit reports published in a year are shared according to the topic relevance for discussion and action planning if appropriate to do so.

c) An evaluation of the Trust's clinical audit process and system assures the Board that effective arrangements are in place to monitor the quality of healthcare provided to patients.

d) An evaluation of the Trust's clinical audit process and system assures the Board that healthcare professionals feel enabled to participate in clinical audit through:

- Direct support and information provided by the Clinical Effectiveness and Quality Improvement Team.
- Access to training and awareness raising regarding clinical audit methodologies and the skills required to facilitate the successful completion of a clinical audit.

10 Review Arrangements

10.1 The Clinical Audit Policy will be reviewed at a maximum of three-yearly intervals and overseen by the Clinical Effectiveness and Quality Improvement Lead.

10.2 Should national guidance or legislation change, then the policy may be reviewed earlier.

10.3 As part of the policy review process, the results of any monitoring of the effectiveness of the policy and its application will be considered.

10.4 As part of the policy review process, the results of any monitoring of the effectiveness of the systems used for clinical audit activity will be considered.

10.5 As part of the policy review process, the results of any external clinical audits reviews will be considered.

11 References

Data Protection Act (1998)

Caldicott Principles (1997)

Records Management – NHS Code of Practice (2006) Department of Health - NHS Code of Practice (2006)