Pennine Care
NHS Foundation Trust

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This policy applies to all staff employed by Pennine Care NHS Foundation Trust	
Purpose:	
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.	
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Other Trust documentation to which this policy relates (and when appropriate should be read in conjunction with):	
Policy Associated Documents:	
IG003	Information Governance Policy
CO11	Information Security Policy
Other external documentation/resources to which this policy relates:	
	HQIP – www.hqip.org.uk
	CQC – www.cqc.org.uk
	NICE – www.nice.org.uk

CQC Regulations This policy supports the following CQC regulations:	
17	Good Governance

Contents Page

1. INTRODUCTION

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, 2018).

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.

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.

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.

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).

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.

The Care Quality Commission (CQC) is the independent regulator of health and social care services in England, and the regulatory framework operated by CQC requires registered healthcare providers to regularly assess and monitor the quality of the services provided.

The Board or delegated group or Committee should seek assurance that there are 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.

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.

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.

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.

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

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. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES

Trust Board

The 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.

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.

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.

Quality Committee

The Quality Committee 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.

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 Committee by the Medical Director.

Medical Director
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.

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

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

Clinical Effectiveness and Quality Improvement Lead
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.

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 Associate Director of Quality Governance for further discussion and escalation.

The Clinical Effectiveness and Quality Improvement Lead will escalate to relevant Forums, non-participation in a national clinical audit following discussion in the first instance with the service involved.
The Clinical Effectiveness and Quality Improvement Lead will work closely with other members of the Quality Governance Team to identify and design clinical audits required in response to service need; e.g. following serious incidents.

Clinical Effectiveness Programme Manager
The Clinical Effectiveness Programme Manager is responsible 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 Associate Directors and service specific leads.

The Clinical Effectiveness Programme Manager will oversee and monitor delivery of the clinical audit programme; using resources within the Clinical Effectiveness and Quality Improvement Team efficiently and effectively, raising any issues regarding delivery of the programme or clinical audit projects to the Clinical Effectiveness and Quality Improvement Lead.

Should a decision be made not to participate in a national clinical audit, the Clinical Effectiveness Programme Manager 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).

Clinical Audit Project Managers
Clinical Audit Project Managers are part of the Clinical Effectiveness and Quality Improvement Team and are responsible for managing projects on the clinical audit programme using project management methodologies and 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.

Clinical Effectiveness Project Managers work collaboratively to ensure the projects within the clinical audit programme progress to schedule, raising any issues for discussion and solution with the Clinical Effectiveness Programme Manager.

Clinical Effectiveness and Quality Improvement Team
The 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.

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.

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

Managing Directors and Associate Directors
Managing Directors and Associate Directors 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.

Managing Directors and Associate Directors 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 early each year.

Managing Directors and Associate Directors 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.

Managing Directors and Associate Directors 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.

Managing Directors and Associate Directors 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

Associate 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.

Clinical Audit Clinical Leads

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

The Clinical Effectiveness and Quality Improvement Team will support Clinical Audit Clinical Leads in the development and implementation of action plans to achieve change and improve care, following publication of National and local reports.

Clinical Audit Clinical Leads are supported by the Clinical Audit Project Managers to be responsible for data security and ensuring that the clinical audit project complies with information governance requirements.

Medical Trainees

Medical trainees are particularly highly active in clinical audit and quality improvement 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.

The Information Department

The Information Department are required to work closely with the Clinical Effectiveness Programme Manager and Clinical Audit Programme Managers to ensure data requests meet the project needs.

4. CLINICAL AUDIT PROCESS

4.1 Clinical Audit Programme

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.

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.

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

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

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

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.

The clinical audit programme will be communicated to the Quality Committee 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.
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.

Information shared with the Quality Committee 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.

The clinical audit programme will be divided into three sections:

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

4.2 Must Do clinical audits

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

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.

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.

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.

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 early each year.

4.3 Should Do Clinical Audits

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

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.

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.

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.

4.4 Outcomes of Must Do and Should Do Clinical Audits

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 Programme Manager.

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 Programme Manager.

4.5 Want To Clinical Audits: Clinician Led

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

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.

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

Stage 1: submission of interest

- Any person interested in, or intending to undertake a clinical audit should contact the Clinical Effectiveness & Quality Improvement team at the following email address: clinicalaudit.penninecare@nhs.net
- You will receive advice to complete a registration form, identify measures and develop a data collection tool
- Where there are queries, or clarification is required, the applicant and their senior manager or audit and quality lead will be contacted by a member of the Clinical Effectiveness and Quality Improvement Team for further discussions regarding the clinical audit.
- Once all relevant documentation is agreed, formal approval will be confirmed to the clinical audit project lead(s) or main contact(s), together with a clinical audit reference number. If not approved this will be confirmed to the clinical audit project lead(s) or main contact(s), with a rationale.
- Details of approved clinical audits will be added to the clinician led clinical audit database.

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.

It is important to quote the clinical audit reference number when contacting the Team to discuss a clinical audit, or when planning further cycles of a clinical audit; i.e. a re-audit. Once the clinical audit is completed, a copy of the clinical audit should be shared with the

relevant clinical lead or senior manager prior to being submitted to the Clinical Effectiveness and Quality Improvement Department. Once reports have been received and reviewed by the relevant Senior Lead, a Clinical Audit Certificate will be issued. Clinical audit reports and/or results should not be shared outside of the organisation in any format without firstly seeking advice from the Clinical Effectiveness and Quality Improvement Team.

5. GOVERNANCE ARRANGEMENTS

5.1 Equality and Diversity

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.

5.2 Information Governance

All clinical audit activity must take into account the General Data Protection Regulation (GDPR), Data Protection Act (2018) and the Caldicott Principles. 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
- The duty to share information can be as important as the duty to protect patient confidentiality

5.3 Storage of data

All clinical audit data must be stored in password protected files on Pennine Care NHS Foundation Trust IT systems, not computer hard drives or laptops, and must comply with the Trust's Information Security Policy. 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.

5.4 Retention of data

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

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

The Department of Health Records Management NHS Code of Practice for Health and Social Care 2016, published by the Information Governance Alliance (IGA) requires that clinical audit records must be kept securely for a minimum period of 5 years after a clinical audit has been completed.

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.

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

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.

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.

5.5 Destruction of data

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

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 General Data Protection Regulation and 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.

5.6 Ethics and consent

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.

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

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

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.

6 EQUALITY IMPACT ANALYSIS

As part of its development, this document was analysed to consider / challenge and address any detrimental impact the policy may have on individuals and or groups protected by the Equality Act 2010. This analysis has been undertaken and recorded using the Trust's analysis tool, and appropriate measures will be taken to remove barriers and advance equality of opportunity in the delivery of this policy / procedure

7. FREEDOM OF INFORMATION EXEMPTION ASSESSMENT

Under the Freedom of Information Act (2000) we are obliged to publish our policies on the Trust's website, unless an exemption from disclosure applies. As part of its development, this policy was assessed to establish if it was suitable for publication under this legislation. The assessment aims to establish if disclosure of the policy could cause prejudice or harm to the Trust, or its staff, patients, or partners. This assessment has been undertaken using the Trust's Freedom of Information Exemption Guide, and will be reviewed upon each policy review.

8. INFORMATION GOVERNANCE ASSESSMENT

This Policy has been analysed to ensure it is compliant with relevant information law and standards as in place at the time of approval, and are consistent with the Trust's interpretation and implementation of information governance components such as data protection, confidentiality, consent, information risk, and records management.

Compliance will be reviewed against any changes to legislation / standards or at the next review of this document.

9. SAFEGUARDING

All staff have a responsibility to promote the welfare of any child, young person or vulnerable adult they come into contact with and in cases where there are safeguarding concerns, to act upon them and protect the individual from harm.

All staff should refer any safeguarding issues to their manager and escalate accordingly in line with the Trust Safeguarding Families Policy and Local Safeguarding Children/Adult Board processes.

10. MONITORING

The effective application of this policy, including adherence to any standards identified within will be subject to monitoring using an appropriate methodology and design, such as clinical audit.

Monitoring will take place on a biannual basis and will be reportable to the Quality Group via the Clinical Effectiveness and Quality Improvement Team.

11. REVIEW

This policy will be reviewed three-yearly unless there is a need to do so prior to this; e.g. change in national guidance.

12. REFERENCES