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<td>Designation: Head of Research and Clinical Effectiveness</td>
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### Integrated Governance Group

Referred for approval by: Paul Duthie  
Date of Referral: 9<sup>th</sup> September 2011  
Approved by: NICE and Clinical Effectiveness Panel  
Approval Date: 20<sup>th</sup> May 2011  
Date Ratified at IGG: 20<sup>th</sup> September 2011  
Executive Director Lead: Medical Director

### Circulation

Issue Date: 30<sup>th</sup> September 2011  
Circulated by: Corporate Governance  
Issued to: (see over)  
Policy to be uploaded to the Trust’s External Website?  YES

### Review

Review Date: 1<sup>st</sup> October 2012  
Responsibility of: Reagan Blyth  
Designation: Head of Research and Clinical Effectiveness

An e-copy of this policy is sent to all wards and departments (Trust Policy Pack Holders) who are responsible for updating their policy packs as required.  
This policy is to be disseminated to all relevant staff.  
This policy must be posted on the Intranet.  
Date Posted: 30<sup>th</sup> September 2011
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1  NATIONAL CONTEXT

1.1  Key policy drivers

The expectation for healthcare professionals to participate in regular clinical audit was first established in the 1989 Government White Paper, ‘Working for Patients’. This has been reinforced and extended by a succession of key national publications, including:

- The New NHS — Modern Dependable. (Department of Health, 1997)
- A First Class Service. (Department of Health, 1998)
- Clinical Governance — Quality in the NHS. (Department of Health, 1999)
- Good Medical Practice. (General Medical Council, 2001)
- Good Doctors Safer Patients. (Department of Health, 2006)
- Trust Assurance & Safety (Department of Health, 2007)

Since the creation of Standards for Better Health by the Department of Health in 2004, all NHS Trusts have had to make an annual Declaration including their compliance with Standard C5d, which states that “Healthcare organisations [must] ensure that clinicians participate in regular clinical audit and reviews of clinical services.”

In 2008, the Care Quality Commission (then known as the Healthcare Commission) introduced an ‘Engagement in Clinical Audits’ indicator which places the following expectations on NHS Trusts:

- to participate in local and/or national clinical audits of the treatment and outcomes for service users in each clinical directorate covered by the Trust
- to have a clinical audit strategy and programme related to both local and national priorities with the overall main aim of improving service user outcomes
- to make available suitable training, awareness or support programmes to all clinicians regarding the Trust's systems and arrangements for participating in clinical audit
to ensure that all clinicians and other relevant staff conducting and/or managing clinical audits are given appropriate time, knowledge and skills to facilitate the successful completion of the clinical audit cycle

• to undertake a formal review of the local and national clinical audit programme undertaken in the Trust to ensure that it meets the organisation's aims and objectives as part of the wider quality improvement agenda

• to provide the Trust's management and governance leads with regular reports on the progress being made in implementing the outcomes of national clinical audits, and review the outcomes, with additional audits or re-audits being conducted where necessary.

Furthermore, the NHS Litigation Authority has introduced a pilot standard for Clinical Audit (Standard 5.1) stating that the organisation has “an approved documented process for ensuring that all clinical audits are undertaken, completed and reported on in a systematic manner that is implemented and monitored”.

More recently, recommendation 5 of the Frances Report (2010) states that “the Board should institute a programme of improving the arrangements for audit in all clinical departments and make participation in audit processes in accordance with contemporary standards of practice a requirement for all relevant staff.”

2 PURPOSE OF THIS POLICY

2.1 Statement of purpose

This policy provides guidance for all staff participating in clinical audit activities. It includes the Trust’s procedures and expectations for registering and approving clinical audit project proposals 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 Locally accepted definition

“Clinical Audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and implementation of change” (NICE, 2002)

Clinical audit is an ongoing process that follows a set series of activities. Figure1 (page 4) shows the clinical audit process for this Trust.

3.2 Improvement and assurance
The Trust supports the view that whilst Clinical Audit is fundamentally a quality improvement process, it also plays an important role in providing assurances about the quality of services.

Figure 1. The Clinical Audit Process
4 SCOPE

4.1 The target audience

This policy applies to anyone engaged in clinical audit activities within Pennine Care NHS Foundation Trust, including all staff, students, volunteers, service users and carers. It also applies to staff who wish to work for other NHS organisations and wish to collect data for collaborative or network clinical audit projects.

5 DUTIES AND RESPONSIBILITIES

Chief Executive is responsible for the statutory duty of quality and takes overall responsibility for this policy.

NICE and Clinical Effectiveness Panel (NCEP) is a corporate panel and one of their responsibilities is to oversee NICE clinical audit activities within the Trust. This is a multi-disciplinary group chaired by the Medical Director. The NCEP reports to the Integrated Governance Group and will escalate findings there. The Head of Research and Clinical Effectiveness and the Clinical Audit Manager attend these meetings.

Risk and Clinical Governance Committee (RCGC) is a corporate group with responsibility for overseeing non NICE clinical audit activities within the Trust. There is multi-disciplinary membership from key departments and the group is chaired by Deputy Director of Nursing and Integrated Governance. The RCGC reports to the Integrated Governance Group and will escalate findings there. Quarterly updates will be provided by the Clinical Audit Department.

Head of Research and Clinical Effectiveness (Head RCE) is managerially responsible for the clinical audit team and for developing and prioritising the clinical audit programme in conjunction with the NCEP and RCGC and Service Directors. The Head RCE is also responsible for approving clinical audit projects.

Service Directors have the responsibility for developing and prioritising the clinical audit calendar in conjunction with the Head RCE in consultation with the Divisional and Borough Integrated Governance Groups.

Clinical Audit Manager (CAM) is responsible for approving clinical audit projects, monitoring and reporting progress with the clinical audit programme. Promotes best practice in clinical audit throughout the Trust. Reports to the Head of Research and Clinical Effectiveness.

Clinical Audit Co-ordinators are responsible for the development of audit projects in conjunction with services; ensuring effective working through the provision of clinical audit support and advice.
Clinical Audit Leads are responsible for ensuring completion of the clinical audit project to Trust standards and the implementation of change, even when other staff involved leave the organisation. Each clinical audit project should have a clinical lead that is a senior and permanent member of Trust staff. They are also responsible for data security and ensuring that the clinical audit project complies with information governance.

Managers are responsible for ensuring that service development and delivery is underpinned by clinical audit and that it forms part of their own and staff continuing professional development.

Clinical / Professional Staff are individually accountable for ensuring they audit their own practice as defined by their profession’s codes of conduct.

Reporting mechanism for clinical audit. The reporting mechanism for clinical audit reports is shown in Figure 2 (page 6).
Figure 2: Reporting Mechanism

Service Development Group → Trust Board

Service Development Group → Integrated Governance Group

Integrated Governance Group → Risk and Clinical Governance Committee

Risk and Clinical Governance Committee → Divisional Integrated Governance Groups

Divisional Integrated Governance Groups → Borough Integrated Governance Groups

Borough Integrated Governance Groups → Dissemination

Risk and Clinical Governance Committee → NICE and Clinical Effectiveness Panel

NICE and Clinical Effectiveness Panel → Head of Research and Clinical Effectiveness

Head of Research and Clinical Effectiveness → Clinical Audit Department

Clinical Audit Department → Clinical Audit Leads submit clinical audit report and action plan

Clinical Audit Leads submit clinical audit report and action plan → Services / Clinical Areas

6 COMMITMENT TO STAKEHOLDER ENGAGEMENT, COLLABORATION AND PARTNERSHIP

6.1 Involving service users and the public

Service users and carers often assess quality of care in different ways to healthcare professionals: they can provide a unique perspective based on their personal experience and can help design services around service user needs.

The Trust promotes a commitment to the principle of involving service users/carers in the clinical audit process either indirectly through the use of service user surveys/questionnaires or directly through participation of identified individuals on project steering groups or service user forums.

6.2 Multi-disciplinary and multi-professional clinical audit, and partnership working with other organisations

Multi-disciplinary and cross-organisational working are hallmarks of good clinical audit practice. The Trust encourages clinical audits undertaken jointly
across professions and across organisational boundaries. Partnership working with other local and regional organisations will be encouraged where improvements to the service user journey may be identified through shared clinical audit activity.

It is expected that all projects which involve the use or monitoring of medicines, have a pharmacist listed in the project team, to ensure pharmacy is aware of the activity. Representatives of all those affected by the clinical audit should also be included in the project team.

6.3 **Involving clinical and non-clinical managers**

Clinical audit project teams should also include partnership with clinical and non-clinical managers. It is particularly important to involve managers if the anticipated outcome of a clinical audit project raises resource implications so that this can be escalated to the relevant groups.

6.4 **Involving medical, dental and healthcare students and doctors in training**

Medical staff are required to participate in clinical audit as part of their ongoing education and re-validation. The Trust encourages the participation of all medical, dental and healthcare students and doctors in clinical audit.

Prior to any clinical audit project starting, Educational Supervisors are responsible for ensuring that all clinical audit projects are registered and approved by the Clinical Audit Department.

The Clinical Audit Department will only provide certificates or letters of confirmation of participation in clinical audit for projects that have been registered and approved by the Clinical Audit Department AND have a clinical audit report and action plan submitted to the Clinical Audit Department.

Educational Supervisors will not sign off the clinical audit section in the medic’s training log without a certificate or letter of confirmation from the Clinical Audit Department.

If a student / trainee doctor leaves the Trust, it is the Audit Lead’s responsibility to ensure that the project is completed by another member of staff.

Any data collected during a doctor’s time with the Trust, remains the property of the Trust at all times.

6.5 **Working with commissioners**

The Trust welcomes and encourages commissioning bodies wishing to perform clinical audit within the organisation. Any such body should identify topics and refer them to the Clinical Audit Department in January / February
for review and inclusion on the annual audit programme that runs from 1 April to 31st March. Any requests for audits outside this period will only be accepted as resources allow.

7 CHOOSING TOPICS AND PLANNING PROJECTS

7.1 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. This programme should meet the Trust’s corporate requirements for assurance, but must be owned by clinical services. The proposed programme will be prepared by the Clinical Audit Department following consultation with the Service Directors, Divisional and Borough Integrated Governance Groups, Planning Performance and Information, IGG, NCEP, and RCGC. The annual programme is ratified by the IGG.

The programme will be prepared by the Clinical Audit Team from all known internal and external ‘must do’ audits. It will include those required for the NHS Litigation Authority, national clinical audits that are considered relevant to the Trust and clinical audits of relevant national guidelines including NICE. In addition, clinical audit topics that align with Trust priorities or have been identified as clinical governance priorities will be included. When developing the programme, all services will be consulted and have an opportunity to identify key priority topics they wish to carry out in their area.

The Trust is committed to supporting other locally determined clinical audit activity as a significant contributor to the continuous process of service improvement. It is acknowledged that individual clinicians may initiate a clinical audit project on the basis of personal interest, personal development or as part of an educational or training programme. It is essential that these are registered with the Clinical Audit Department and reported through existing clinical governance structures to maximise organisational learning.

7.2 Choosing and prioritising local clinical audit topics

There are many reasons why clinical audits are undertaken, although in essence there are two main drivers: quality improvement and quality assurance. Within the Trust, clinical audit resources are finite, and as such clinical audit resources will be restricted to projects with measurable standards and criteria that are expected to deliver improvement and assurance according to agreed Trust priorities.

Where there are no standards for a project and none can be agreed, it will be classified as a service evaluation project. These may include service/practice developments or evaluations, baseline audits, activity analysis and benchmarking. These projects should be registered with and reported to the
Clinical Audit Department, but support will be limited and dependent on other priorities.

8  GOVERNANCE OF CLINICAL AUDIT

8.1 Systems for registering and approving clinical audits

For every clinical audit project that is undertaken, a Clinical Audit Application Form (Appendix B) must be completed by the Audit Lead and have the approval of the Audit Lead’s supervisor / line manager. The application form must be sponsored by the Audit Lead’s supervisor / line manager.

The Clinical Audit Application Form must be sent to the Clinical Audit Department where it will be reviewed by the Clinical Audit Manager to ensure the project complies with good clinical audit practice as outlined in this policy. Approval from the Clinical Audit Department must be obtained BEFORE the clinical audit can commence.

All clinical audit activity must be registered with the Clinical Audit Department irrespective of the level of facilitation being requested of the Department.

All those with a major involvement in the clinical audit project (stakeholders) must be identified and contacted for their approval, before the clinical audit commences. The clinical audit method must be described in the Clinical Audit Application Form. This should include consideration of sample size and type, details of the data to be collected (a copy of the data collection tool should be submitted with the application form) and the method of data collection.

Where possible, routinely collected data from existing sources (e.g. case notes, I.T. systems) should be used. However, in cases where the data is not currently collected or is incomplete, collection of new data may be necessary. In such cases, only data relevant to the clinical audit are to be collected.

All clinical audit data collection tools should be validated by performing a Pilot Clinical Audit to ensure:

- the sample size and type are appropriate
- data collected can be compared to standards and criteria
- data collected answers the clinical audit objectives.

Any necessary amendments to the clinical audit method or tool must be agreed by all concerned and approved by the Clinical Audit Department before the clinical audit commences.
8.2 **The use of standards and criteria in clinical audit**

By definition, clinical audit involves measuring clinical practice against predetermined standards of best practice. Standards are an agreed statement of best practice which will improve the quality of care, they will usually be broken down into measurable criteria with an expected level of compliance (e.g. 100% of records will contain the service user’s date of birth).

Standards should be evidenced based and ideally taken or adapted from sources including national guidance recommendations e.g. NICE, clinical audit criteria, network or local guidelines and policies.

Clinical audit project applications which do not include standards as described on the Clinical Audit Application Form will not be registered as clinical audit.

8.3 **Equality and diversity**

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

All relevant local policies will have an equality impact assessment which should provide guidance to those developing clinical audits to ensure that discrimination is avoided.

8.4 **Information governance: collection, storage and retention of data and confidentiality**

All clinical audit activity must take account of the Data Protection Act (1998) and the Caldicott Principles (1997). This means, for example, that data should be:

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

Clinical audit activity must also conform to the requirements of the NHS Confidentiality Code of Practice (2003) which states that “Patients must be made aware that the information they give may be recorded, may be shared in order to provide them with care, and may be used to support local clinical audit”. This is achieved via the user leaflet “How we use your information”.

Service user identifiable information should NOT be collected as part of a clinical audit. All clinical audit data should be anonymised for patients, service users and staff. This means that identifiable data such as name, address, postcode, date of birth, and any other combination of details that may identify the individual are removed. Special care will need to be taken when auditing areas where there are relatively few clinical cases, and individuals could be identified more easily.

To prevent the collection of identifiable information, a Clinical Audit ID Sheet (available from the Clinical Audit Department) should be used. Service user details are recorded next to a relevant clinical audit code which is cross referenced on the clinical audit proforma. The Clinical Audit ID Sheet should be kept as a paper copy only and stored in a secure location as with other confidential information. The Clinical Audit ID Sheet should be destroyed once the clinical audit report has been approved.

Where the clinical audit involves the service user being contacted to complete a clinical audit questionnaire, the department concerned must write out to service users, explaining what the clinical audit is, the reason for the clinical audit and to whom the information may be disclosed e.g. the clinical audit department. The content of this letter must be approved by the Clinical Audit Department and Information Governance. Completion and return of the clinical audit questionnaire by the service user can be taken as implied consent (Pennine Care Trust Confidentiality Policy).

Completed paper clinical audit proformas should be destroyed six months after the clinical audit report has been approved. Paper clinical audit records, e.g. application forms, proforma templates, reports and presentations will be retained by the Clinical Audit Department for five years to comply with guidance provided in the Department of Health publication Records Management: NHS Code of Practice (2006). Electronic clinical audit records will be retained by the Clinical Audit Department for a period of 10 years minimum.

All clinical audit data must be stored securely in password protected files on Pennine Care NHS Foundation Trust IT systems and 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.

8.5 Clinical audit database

The Clinical Audit Department will maintain a database with details of all clinical audit activity reported to them.

The database will include key information from the Clinical Audit Application Form, including the name and contact details of the project lead, specialty and
department, current status of the project, planned completion date and whether a clinical audit report and action have been received.

The database will only be accessed by the Clinical Audit Department and will support the monitoring of clinical audit project. Progress and data held will be used as part of governance reporting arrangements and this is why it is vital that all clinical audit activity is logged with the Department.

8.6 Ethics and consent

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

Every clinical audit should conform to the following four principles:

- there is a benefit to existing or future service users or others that outweighs potential burdens or risks
- each service user’s right to self-determination is respected
- each service user’s privacy and confidentiality is preserved
- the activity is fairly distributed across service user groups.

In cases where the clinical audit is investigating a sensitive area or asks staff/service users sensitive, intrusive questions, the clinical audit must be discussed with the Head of Research and Clinical Effectiveness who may seek advice from other relevant staff within the Trust.

When conducting a clinical audit that involves direct contact with service users / carers, all staff must ensure they are approached in a sensitive and respectful manner, they should be given a full written explanation (which needs approval from the Clinical Audit Department and Information Governance) as to the purpose of the clinical audit, should be assured about confidentiality and the length of time their data will be held and be given the option not to take part in the clinical audit.

No clinical audit will examine the work of another professional or specialty without their knowledge. Suitable stakeholder selection of key members of staff within professions or specialty will ensure dissemination of clinical audit information to relevant staff.

9 TRAINING AND DEVELOPMENT

9.1 Overall organisational approach

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. 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.

9.2 Provision of clinical audit training

The Trust will make available suitable training, awareness or support programmes to all clinicians regarding the Trust's systems and arrangements for participating in clinical audit.

The Clinical Audit Department will provide clinical audit training that can be accessed by all healthcare professionals who are responsible for auditing the quality of care they deliver. This will include:

- clinical audit workshops
- prioritised programme of clinical audit training
- toolkit for Clinical Audit
- templates, leaflets, information and resources available on the Clinical Audit intranet site.

9.3 Employment and development of clinical audit staff

The Trust will employ a team of suitably skilled clinical audit staff to support its programme of clinical audit activity. The Trust will also ensure that these staff have access to further relevant training in order to maintain and develop their knowledge and skills.

10 REPORTING AND DISSEMINATION OF RESULTS

10.1 Reporting

A Clinical Audit Template Report, including guidance on what should be included in the report, is available on the intranet (see Appendix C). Completed reports should be sent to the Clinical Audit Department and should include an action plan produced from clinical audit recommendations. These will be used when reporting governance information about clinical audit activity within the Trust.

10.2 Dissemination

Regular summary reports, together with recommendations, should be communicated to all relevant areas of the organisation and Trust committees. A successful clinical audit in one area may be transferable to other parts of the organisation.

Publication of finalised clinical audit results where learning can be shared outside the Trust, for example at appropriate conferences and in relevant
journals are encouraged. Authority must be obtained by the clinical audit lead and all the clinical audit stakeholders and the Clinical Audit Department made aware.

10.3 Clinical audit annual report

An Annual Clinical Audit Report will be produced by the Clinical Audit Department. It will include outcomes and conclusions from clinical audit projects, together with an update on the implementation of action plans. This report will be approved by the IGG for dissemination to staff and will be available on the intranet.

11 ACTION PLANS AND IMPROVEMENT

11.1 Action plans

The main purpose of clinical audit is to deliver improvements in clinical practice. Where the results of a clinical audit indicate sub-optimal practice, an action plan must be produced. An example action plan can be found in The Clinical Audit Report Template in Appendix C.

Action plans should be specific, measurable and achievable/realistic. They should have clear implementation timescales with identified leads for each action. Action plans should also have been approved by the relevant head of service or department.

Where an audit shows that **ALL** standards are being met, there will be no need for an action plan, however, such clinical audits must have an explicit statement saying 'no further action required' in the clinical audit summary report and a reason given for no re-audit.

Clinical Audit Leads and specialty staff are responsible for ensuring the identified changes are incorporated into practice and relevant business plans. Services are responsible for the implementation and monitoring of action plans. The Clinical Audit Department will randomly audit action plans to determine the level of implementation.

11.2 Re-audit

Re-audit is important to determine whether agreed actions have been implemented according to the action plan. The Clinical Audit Department will support forward planning of re-audits when timescales have been given. Projects due for re-audit will be considered during planning of the annual programme. Where appropriate, re-audit may focus on specific aspects that require improvement.
12 MONITORING EFFECTIVENESS

12.1 Monitoring the effectiveness of clinical audit activity

The Clinical Audit Manager will ensure that all projects approved by the Department comply with this policy. Projects that do not comply will not be approved.

All approved clinical audit projects are required to submit clinical audit reports and action plans to the Clinical Audit Department. The Clinical Audit Department will monitor the progress on the implementation of actions plans via the Risk and Clinical Governance Group (RCGG), Borough/Divisional Integrated Governance Groups (DIGG/BIGGs) and will co-ordinate with Clinical Audit Leads to ensure that re-audits are performed to show improvements in practice.

Where action plans are not being implemented or where there are resource or governance considerations they will be sent to the DIGG, BIGG, RCGG or NCEP for consideration and resolution or further escalation.

On a quarterly basis, the Clinical Audit Department reports progress on clinical audits and action plans to the IGG for discussion and dissemination via the DIGG/BIGGs. Any queries raised are dealt with by the Clinical Audit Department and reported back to the IGG.

The following is a list of standards / indicators that will be monitored by the Clinical Audit Department and reported in the Clinical Audit Annual Report and for the Trust’s annual Quality Account reporting:

**Indicators:**
- Number of clinical audits registered with the department within the year
- Number of clinical audits approved / rejected
- Number of clinical audits registered by division / service
- Number of national, regional and local clinical audits registered.

**Standards:**
- 100% of clinical audits undertaken will have approval from the Clinical Audit Department
- 100% of approved clinical audits will have a report submitted
- 100% of approved clinical audits will have an action plan submitted OR have best practice confirmed
- 25% of approved clinical audit projects will be re-audits
• 100% of approved clinical audit projects will meet national AND organisational priorities
• 100% participation in relevant National Clinical Audit and Patient Outcomes Programme
• 20% of approved clinical audit projects will be multidisciplinary
• 100% of abandoned clinical audits have a documented reason for abandonment.

The IGG will review and approve the annual Clinical Audit Report which will include details of clinical audit activity throughout the Trust, details of changes to clinical practice and impact of the clinical audit programme on service user care.

12.2 Monitoring effectiveness of the policy

This Clinical Audit Policy will be reviewed every two 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 it’s application will be assessed. Information and results from clinical audit systems, adverse incidents, user feedback and external clinical audits / reviews will be used to inform this assessment. This will be performed by the Clinical Audit Department in association with the RCGG, NCEP and IGG.

13 REFERENCES

14  **APPENDIX A. MEMBERSHIP OF RCGC AND NCEP**

14.1  **NICE and Clinical Effectiveness Committee**
- Medical Director
- Deputy Director of Nursing & Integrated Governance
- Consultant Psychiatrist, Early Intervention Service
- Consultant, CAMHS
- Clinical Lead, Psychological Therapies
- Chief Pharmacist
- Governance Manager, North Division
- Governance Manager, South Division
- Service Manager Older Persons
- Head of Research and Clinical Effectiveness
- Clinical Audit Manager
- Clinical Effectiveness Coordinator
- Equality & Diversity Manager
- Head of Performance and Information
- Clinical Lead for Service Line Management
- Service Lead, Occupational Therapy

14.2  **Risk and Clinical Governance Committee**
- Deputy Director of Nursing & Integrated Governance
- Clinical Psychology Services Manager
- Child Safeguarding Lead
- CNS: Infection Prevention and Control/Physical Health
- Complaints Manager
- Training/MVA Lead
- Head of Patient Safety
- Governance Manager, North Division
- Medical Director
- Clinical Lead – SLM & Service Improvement
- Specialist Services Interim Directorate Manager
- Governance Manager, South Division
- Health, Safety and Emergency Planning Manager
- Mental Health Law Manager
- Chief Pharmacist
- Head of Estates and Facilities
- Head of Research and Clinical Effectiveness
- Trust Solicitor
- Maintenance Manager
Clinical Audit Project Application Form

A form must be completed for all clinical audit projects involving patient information irrespective of whether support is required from the Clinical Audit department. Please email the completed electronic copy of this form to clinicalaudit.penninecare@nhs.net where it will be considered for approval. Not audit can commence prior to approval from the Clinical Audit Department. This is to ensure that:

- Audits undertaken are of a consistently high standard.
- There is adherence to the NHS Code of Confidentiality which incorporates the Caldicott principles.
- Clinical audits are not being duplicated unnecessarily.
- Integrated governance standards are being met.

Note: Please save a copy of this document before completing it. Do not complete it directly when opened from the intranet as any changes may not be saved.

Audit title

Contact details of project leads
Note: Projects will not be accepted without sponsorship from a senior member of staff/management approval.

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Person undertaking project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td></td>
</tr>
<tr>
<td>Job title:</td>
<td></td>
</tr>
<tr>
<td>Team / location:</td>
<td></td>
</tr>
<tr>
<td>Correspondence address:</td>
<td></td>
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<tr>
<td>Contact number:</td>
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<td>Email:</td>
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**Project rationale**

**Please identify the reason for undertaking this project:**

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<thead>
<tr>
<th>Reason</th>
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<tr>
<td>National requirement</td>
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<tr>
<td>Mental Health Act</td>
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<tr>
<td>NICE / NSF / NPSA</td>
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<tr>
<td>Care Quality Commission</td>
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<tr>
<td>Royal College / Professional body</td>
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<tr>
<td>Trust priority / Audit calendar</td>
<td></td>
<td></td>
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<tr>
<td>Complaint / PALS issue</td>
<td></td>
<td></td>
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<tr>
<td>New service / Business plan</td>
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<tr>
<td>Local concern</td>
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<tr>
<td>Re-audit</td>
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<tr>
<td>Other (specify below)</td>
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**Which areas will participate in the audit?**

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<tr>
<th>Area</th>
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<tr>
<td>Trustwide</td>
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<td>Mental Health Services</td>
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<td>Tameside</td>
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<td>All boroughs</td>
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<td>Community Services</td>
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<td>Oldham</td>
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<td>All boroughs</td>
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**Service line**

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<tr>
<th>Service Line</th>
<th>Inpatient</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Older peoples</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Adult</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>CMHTs</td>
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<tr>
<td>CAMHS</td>
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<tr>
<td>RHSD</td>
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<tr>
<td>Drug &amp; Alcohol</td>
<td></td>
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<tr>
<td>Psychological therapies</td>
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<tr>
<td>Other, please specify</td>
<td>☐</td>
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</tr>
<tr>
<td>All service lines</td>
<td>☐</td>
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</tr>
</tbody>
</table>

**Please indicate here which service(s) will be audited:**
### Methodology

#### Patient/Staff Sample
Clearly specify your inclusion criteria.

<table>
<thead>
<tr>
<th>Sample size:</th>
<th>Estimate size of total population (that the above sample is drawn from):</th>
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<tbody>
<tr>
<td>Method of sample selection, e.g. random, clustered:</td>
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<tr>
<td>Specify retrospective or prospective time period that sample will fall into:</td>
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<tr>
<td>From:</td>
<td>N/A</td>
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Who will be responsible for collecting the data? When will data collection occur?

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If data is to be returned to the Clinical Audit Department for inputting and analysis, how will this be done?

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</table>

When will the final report be ready?
Please note: the Trust Report Template must be used and a copy must be submitted to the Clinical Audit Department for approval and wider dissemination of the findings. If a report is not supplied by the date indicated below, the Department will contact you and the audit sponsor for an update.

<p>| | |</p>
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</table>

If areas for improvement are identified an action plan must be developed and included in the final report – this must be in the Trust approved format and the template can be found at the end of the Trust Report Template.

Will you require support from the Clinical Audit Department?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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If Yes, what assistance will be required:

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<tbody>
<tr>
<td>Sourcing evidence/Literature review</td>
<td>Data analysis</td>
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<tr>
<td>Identifying standards</td>
<td>Presentation design</td>
</tr>
<tr>
<td>Proforma design</td>
<td>Report writing</td>
</tr>
<tr>
<td>Data entry</td>
<td>Disseminating results</td>
</tr>
<tr>
<td>Database design</td>
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</tbody>
</table>
It is expected that the person undertaking the project will take responsibility for case note retrieval (if required), data collection and participating in the production of the audit report.
Clinical Audit Project Standards Form
This section of the form must be completed alongside the Clinical Audit Project Application Form. The purpose of this section is to detail the specific standards that the audit will be measuring practice against.

Standards
Clearly outline the standards you will measure practice against.

- Standards are explicit measures of the aspect of care by which you will compare actual practice against best practice. Standards should be based upon the evidence of best care from the literature (e.g. policy or guidelines), professional or other organisations.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Source (detail specific policy(s) or guidelines etc)</th>
<th>Section / page number</th>
<th>Proforma question number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Example of a good audit standard:</strong> The NHS number must be included in all clinical correspondence (Target 100%)</td>
<td>Records Management Policy V4 Ref C020</td>
<td>Section 11.3 Page 17</td>
<td></td>
</tr>
<tr>
<td><strong>Example of an inappropriate audit standard:</strong> To investigate how many patients presented to our service with X (problem or condition)</td>
<td>This does not measure against a specific criterion and is not an appropriate standard</td>
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<tr>
<td>Standard</td>
<td>Source (detail specific policy(s) or guidelines etc)</td>
<td>Section / page number</td>
<td>Proforma question number</td>
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<tr>
<td>Standard</td>
<td>Source (detail specific policy(s) or guidelines etc)</td>
<td>Section / page number</td>
<td>Proforma question number</td>
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<td>22</td>
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</tbody>
</table>
Declaration

Please email the completed electronic copy of this form to clinicalaudit.penninecare@nhs.net.

By submitting this clinical audit application you agree to the following terms and conditions:

1. To conduct the audit (once approved) in a timely fashion.
2. Ensure that data is collected in accordance with the methodology identified.
3. Participate in the production of an audit report. This will include writing an introduction and summarising the audit findings.
4. Nominate a replacement audit lead if you should leave the Trust before the completion of the project.
5. Accept responsibility for developing an action plan in response to the audit findings, and implementing changes recommended in the action plan, if applicable.
6. Adhere to data protection requirements and Caldicott principles, and ensure all audit data remains anonymous and is only used for the purpose of this project.

For Clinical Audit Department use only:

<table>
<thead>
<tr>
<th>Date application form received in the department:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All questions and documentation provided? (including relevant policy/guidelines and draft proforma)</td>
</tr>
<tr>
<td>Audit project number:</td>
</tr>
<tr>
<td>Which CQC outcome(s) and indicators does this audit support?</td>
</tr>
<tr>
<td>Further comments:</td>
</tr>
</tbody>
</table>
APPENDIX C. CLINICAL AUDIT REPORT TEMPLATE

Clinical Audit Title

Note:
The purpose of clinical audit is to inform change and in order to ensure this, it is essential that all audit results are written up into a formal report. The purpose of a clinical audit report is to provide a medium which brings together the aim, methodology, project findings and recommendations.

It is vital that an audit report is written in a structured, comprehensive and clear manner using a professional approach in order to achieve maximum clarity and impact. As such, this template has been developed to ensure that the Trust has a consistent mechanism to present audit results. Audit reports which do not follow this template will be rejected.

Audit Lead: name and position

<table>
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<tr>
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<tbody>
<tr>
<td></td>
<td>Number must be allocated by the Clinical Audit Department</td>
</tr>
<tr>
<td>Data collection period</td>
<td>Month and year – month and year</td>
</tr>
<tr>
<td>Date report produced</td>
<td></td>
</tr>
<tr>
<td>Service location</td>
<td></td>
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</table>
Contents page

A list of headings for each section in a clinical audit report is required. The requirements for each of these sections are outlined below. Your report should cover the following sections:

- Executive summary
- Introduction
- Aims and objectives
- Criteria and standards
- Methodology
- Results
- Conclusion
- Recommendations
- Action plan
- References
- Dissemination
- Appendices
Executive summary

The purpose of this section is to give the reader a clear and concise overview of the audit project as a whole. It can also double up as an abstract to be circulated as a pre-cursor to the full report to people who do not need a full copy of the report.

The executive summary should include a summarised version of the introduction/background, aims and objectives, key findings and recommendations.

As a rough guide, the executive summary should be no longer than one A4 page in length. You will find this section much easier to write once the rest of the report has been written, so it is always best to complete this section at the end.

All clinical audit executive summaries will be included in the Clinical Audit Annual Report.
Introduction/Background

In this section you need to include the reason for choosing your audit topic. It should give the background information on the audit topic in general, in order to give the reader an overview and a basic understanding of the subject matter. You may be auditing a particular guideline as the clinical audit topic area because it has been the subject of recent clinical incidents.

E.g. Following a recent complaint, it has been decided to conduct a clinical audit into the management of patients with Parkinson’s disease. The local guideline currently in use follows the NICE recommendations in CG035: Parkinson’s disease.

Aim

This should be a clear and concise statement which outlines the aims of what the audit hopes to achieve.

E.g. This audit aims to assess the extent to which current practice meets the NICE guideline CG035: Parkinson’s disease.

Objectives

These should be the specific aims for the audit. They should specify how the overall aim of the clinical audit is to be achieved.

E.g. Identify the length of wait for an outpatient appointment for patients referred with suspected Parkinson’s disease.

Criteria and standards

The standards and the source of the standards used should be detailed in this section.

Methodology

The methodology describes the approach, process and procedures carried out during the audit. The basic principles should be that the description of the methodology is sufficient to allow the audit to be replicated by someone who had no prior involvement or knowledge of it. As a minimum it should contain the following information:

1. Population

What was the population audited? What were the inclusion and exclusion criteria?

2. Sample size
   - There should be a 95% confidence interval and 5% margin of error in relation to the audit results. If your sample size does not enable this level of data validity and an inadequate sample size was used, this must be justified here.
3. Sampling technique

In this section the sampling technique, such as simple random sampling, systematic random sampling, stratified random sampling should be detailed and a justification where appropriate.

4. Data collection

- Was a proforma/data collection tool used to collect the data?
- How was the sample of patients identified? Retrospectively - from clinical records? Or prospectively - at the time the audit occurred? for example at a clinic, was there any patient group excluded? (e.g. under 18’s), the dates the audit occurred over.
- Who collected the data and over what time period?

5. Data analysis

How were the data analysed (e.g. Excel or SPSS etc.) and by whom?

6. Data validity

Were any steps undertaken to ensure the validity of the data collected or the subsequent analysis?

Results

The results section should only present the facts; any interpretation of the findings should be saved for the discussion section.

Graphs, figures and tables are usually the best way to present data as they are easily understandable, please refer to the Clinical Audit Data Validity and Analysis Standard Operating Procedure for advice in relation to the most appropriate choice of chart for a particular type of data set.

Results should show the number and percentage of compliance against each criteria/standard. If it is appropriate, you could show trends over time especially if it is a re-audit, or you could show a comparison to other Trusts/national standards etc. The results do not have to be sophisticated statistical analysis; they should be presented in an appropriate manner for your readers. Please ensure that each table/graph has a number and a title, e.g. Table 1: People with suspected Parkinson’s disease seen within 6 weeks of referral over time.

Discussion

Here you need to highlight the most pertinent findings from the audit. Give reasons to explain any trends, or any unexpected results. For example, From the 1st January, the new ‘fast-track’ clinic for people with suspected Parkinson’s disease was opened. This has had a demonstrable effect on compliance with the standard, increasing it from 10% (n=25) to 40% (n=100) compliance in one quarter.
Conclusion

In this section there needs to be a short paragraph summarising the project. For example, This audit has demonstrated that overall compliance with the NICE standards for the management of patients with Parkinson’s disease is of an acceptable standard. New initiatives such as the new ‘fast-track’ clinic have had a demonstrable effect in improving compliance.

Recommendations and action plans

This is the most important part of the report. You need to identify what needs to happen to improve practice or care. Most projects should include ‘conduct a re-audit’ as one of the recommendations to ensure that improvements have occurred. Ensure that all recommendations are SMART format — Specific, Measurable, Achievable, Realistic and Timely — as the Trust will be monitored by external agencies on its ability to deliver against these. It may be worth circulating a draft report to the relevant staff or discussing it at a project steering group meeting prior to agreeing the recommendations. These recommendations once agreed need to be put into an action plan with the name of the person responsible for ensuring that the recommendation is completed within the time period agreed. A sample action plan has been devised on the next page to assist you.
## Action plan template

<table>
<thead>
<tr>
<th>Area of concern</th>
<th>Action point</th>
<th>Priority level 1–4 (1 = Highest) Based on risk</th>
<th>Standard required (i.e. 100% of patients should have…..)</th>
<th>Comment</th>
<th>Responsible individual</th>
<th>Target completion date</th>
<th>Evidence of action point implementation</th>
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### SMART

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<th>Measurable</th>
<th>Achievable</th>
<th>Realistic</th>
<th>Timely</th>
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</thead>
<tbody>
<tr>
<td>Actions should specify what they need to achieve</td>
<td>It should be possible to measure whether an action is being met or not</td>
<td>Actions set should be achievable and attainable</td>
<td>Actions should realistically be achievable with the resources available</td>
<td>All actions must have an achievable deadline date which, without senior management approval, should not be changed. Any amendments must be clearly documented and must be accompanied by a justification</td>
</tr>
</tbody>
</table>
Acknowledgements

Thanks to other staff or departments who have been involved in the audit.

References

List of publications referenced in the project. References should follow the Vancouver referencing style (for examples, see clinical audit style sheet).

Dissemination

List of who the final report will be disseminated to – this could include individuals and groups / committees. Please ensure if you include individuals you put their name and job title.

Appendices

Clinical audit proforma/data collection tool should be included as an Appendix to allow other people to repeat the audit.