TRUST PROCEDURE FOR UNDERTAKING
CLINICAL AUDIT

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AUTHOR: Clinical Audit Department
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PROCEDURE SUMMARY
These procedural guidelines establish the governance arrangements and responsibilities for clinical audit in the Trust. This procedure provides a framework through which the clinical audit programme will be defined and delivered. It will ensure a consistency in the process across the Trust that is understood by all Trust staff and will clarify their individual responsibilities. This will ensure that the principles set out in the Policy for Undertaking Clinical Audit are translated into continuous clinical quality improvement.

The Trust monitors the implementation of and compliance with this procedure in the following ways:
External Audit as scheduled

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The Director responsible for monitoring and reviewing this procedure is Executive Nurse.
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PROCEDURAL GUIDELINE FOR UNDERTAKING CLINICAL AUDIT

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PROCEDURAL FOR UNDERTAKING CLINICAL AUDIT

Assurance Statement

The purpose of these procedural guidelines is to establish the governance arrangements and responsibilities for clinical audit in the Trust. This procedure provides a framework through which the clinical audit programme will be defined and delivered. It will ensure a consistency in the process across the Trust that is understood by all Trust staff and will clarify their individual responsibilities. This will ensure that the principles set out in the Policy for Undertaking Clinical Audit are translated into continuous clinical quality improvement.

1.0 INTRODUCTION

1.1 The following procedure and appendices sets out the process for registering, gaining approval and carrying out effective clinical audit in the Trust. This procedure should be read in conjunction with the Trust Policy on undertaking a Clinical Audit.

2.0 WHAT IS CLINICAL AUDIT?

2.1 Clinical audit is a systematic review that answers the question:

‘Are we doing what we should be doing in the way we should be doing it’?

2.2 The clinical audit process:

- measures practice against agreed standards
- identifies any problems or deficits in compliance to those standards
- implements any changes in practice necessary to achieve the standards
- reviews, to measure whether practice has improved

2.3 The Clinical Audit Department (CAD), which is part of the Executive Nurse Directorate, is available to offer advice and support for clinical audit in the Trust.

3.0 INVOLVING SERVICE USERS

3.1 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. Where possible, service users should be involved in clinical audit.
4.0 ETHICAL APPROVAL

4.1 Clinical audit proposals are not usually required to be submitted to a Research Ethics Committee. However, if there is any doubt, staff should seek the approval of the Trust’s Research Governance Steering Group.

4.2 Audits involving service user interviews or questionnaires further advice is available through the Patient Advisory and Liaison Service.

5.0 PROTECTION OF DATA

5.1 All clinical audit activity must take account of the General Data Protection Regulation (2016) and the Caldicott Principles (1997). This means, for example, that data should be adequate, relevant, not excessive, accurate, and collected for the specific audit purposes only.

5.2 Data must be held securely in line with Trust Policy/Procedure Records Management, Confidentiality and Records Management Storage & Retention. Operational and Clinical Audit Department project leads must ensure that any paper clinical audit data is held in a locked cupboard when not in use and all electronic data is password protected.

5.3 The patient’s name and NHS number (which is considered patient identifiable) must not generally be used on raw data being used for data entry and analysis. Where it is necessary to know to whom data refers project leads must define a process to anonymise the case/s.

5.4 The Records Management: NHS Code of Practice (2006) requires “audit records” to be retained for a period of five years. This applies to clinical audit reports and results. However the Trust requires that all raw data should be destroyed as confidential waste as soon as the final report has been disseminated/approved.

6.0 DEVELOPMENT OF THE TRUST CLINICAL AUDIT ANNUAL FORWARD PRIORITY PROGRAMME

6.1 A Priority Clinical Audit Annual Forward Programme will be developed as priority work for the organisation from the following sources:

- Relevant National Audits
- Locality operational senior managers and service quality groups identified priority clinical audits
- Commissioner’s requirements and Quality Accounts
- CQC Registration Standards
- NICE, National Enquiries, etc.
- Trust priority audits including audits arising from complaints or serious incidents
6.2 The Head of Clinical Effectiveness will develop the draft annual forward clinical audit programme in consultation with the Medical Director, Executive Directors & Executive Nurse in conjunction with other Trust senior corporate and operational managers.

6.3 The draft forward priority programme will be shared with the relevant Executive Director for their approval and following this be presented to the CG & QC for final approval and ratification.

6.4 The Trust’s Clinical Audit Department (CAD) will focus on delivery of this planned priority programme as its primary plan of work.

6.5 Urgent projects identified by the Executive Team or from external bodies such as the Clinical Commissioning Groups (CCG’s) during the financial year will be added to the priority forward programme and supported by CAD as required.

6.6 Details of any potential risks, level of compliance with expectations of the standards will be presented to the relevant locality/localities operational service quality groups. The Chairs of operational locality groups will ensure any further reporting progression identified is escalated to the senior management teams (SMT) and Clinical Governance and Quality Group (CG&QG) as necessary.

7.0 PROCESS FOR THE TRUST’S CLINICAL AUDIT ANNUAL FORWARD PRIORITY PROGRAMME

7.1 Each national or priority clinical audit will have an appointed clinical project lead, nominated by the Director responsible for services being audited when this is necessary.

7.2 Participation in the national audits, including those developed by the Prescribing Observatory for Mental Health (POMH) will use the nationally validated tools.

7.3 For audits on the priority programme; NICE provides a variety of clinical audit tools, these include ready-to-use criteria, including exceptions, definitions and data source suggestions. In addition NICE quality standards are sets of specific, concise statements and associated measures for achievable, high-quality, cost-effective care, covering the treatment and prevention of different diseases and conditions.

7.4 Other priority clinical audit tools will be drafted via consultation between the clinical project lead, and the Clinical Audit Department project lead. These will use nationally agreed standards of practice or local Trust policies and procedures to inform development of criteria. As they will have experts from clinical services and clinical audit involved in their development these tools will be assumed to be robust providers of evidential needs of the organisation.

7.5 CAD will work with the appointed clinical project lead to ensure the agreed audit tool is piloted when necessary to ensure it is fit for purpose and achieves identified aims. CAD will support the clinical project lead to ensure that the
audit data collection is completed and clear results are prepared and reported appropriately, using the Trust template (Appendix 2), and that the report includes a relevant action plan.

7.6 Where possible clinical audit reports will be presented by the clinical project lead or a nominated colleague to relevant senior committees as appropriate, either in a draft version where further advice is being sought in relation to developing an action plan or the finalised version when this has already been completed.

7.7 CAD will ensure that all national and Trust priority clinical audit reports are disseminated to all relevant operational service quality groups via their monthly clinical audit summaries. The local operational groups will be provided with details of recommendations and also details of any potential risks identified in order that the Chair can escalate any concerns up to the (SMT) and Clinical Governance & Quality Group and from there to the Quality Committee, a Board sub-committee, when necessary.

7.8 The CG&QG will receive quarterly reports provided by CAD. In this manner it is expected that learning from clinical audit, and clarity about outcomes, is shared throughout all levels of Trust services.

8.0 PROCESS FOR CARRYING OUT TRUST ANNUAL FORWARD NATIONAL AND PRIORITY PROGRAMME CLINICAL AUDITS

8.1 A pilot of the audit tool is required unless it is a validated tool i.e. developed by POMH or other national audit organisers, or has been previously used in the organisation.

8.2 The audit clinical project lead and Clinical Audit Department (CAD) project lead need to ensure that the tool is suitable and appropriate for collecting the data being audited i.e. will answer the areas under review, and any necessary amendments required.

8.3 Where necessary following data collection completed forms will be sent to CAD for collation and results preparation and analysis, with due care being taken in regard to protecting the data during transit in line with the Trust information governance policy and expectations.

8.4 CAD will prepare a draft report (using Trust template Appendix 5) where this is required; including identifying any potential risks found in the audit. This will be shared with the clinical project lead/s who will work with the CAD lead to define an appropriate action plan. This work is CAD’s priority and a named member of the team will provide all necessary support to the clinical project lead.

8.5 For local or low priority audits, not on the priority program, the draft report this will be the responsibility of the clinical project lead, using the clinical audit report template, to complete this and ensure that they identify any potential risks and an action plan.
8.6 Recommendations in clinical audit reports, in particular those related to the standards being audited, should be given a priority rating (high/medium/low) in line with Appendix at the beginning of the audit process.

8.7 To formulate the action plan each recommendation from the audit must be considered and relevant actions identified. Action plans for all audits should be SMART (Specific, Measurable, Achievable, Relevant and Time bound). Action plans will detail who is taking responsibility for each recommendation/action and the expected completion date. Action plans will be shared with relevant senior committees, such as the Medicine Management Group, and relevant operational service quality groups and amendments made where this is felt to be appropriate.

8.8 If re-audit is felt to be necessary the audit action plan should identify a re-audit date. This re-audit timeframe should depend on the time scale agreed for the actions to be completed and the level of risk identified. For audits where a high level of compliance against the standard is provided, it may not be necessary to re-audit for 2 or 3 years.

8.9 Every national and priority clinical audit will be shared with the relevant Executive Director for them or a nominated delegate to approve prior to full dissemination.

8.10 Final reports from the national and priority programme will be sent to all relevant operational service quality groups in order that learning from clinical audits can be widely shared throughout the Trust.

8.11 All projects on the annual forward national and priority programme will have summary details of the audit, including potential risks presented to the CG&QG, reading the full audit reports where this is felt to be appropriate to enhance understanding of issues. The Clinical governance and quality group will also be responsible for monitoring implementation of action plans for national and priority clinical audits which CAD will support via quarterly reports to the group.

8.12 Projects from the national and priority programme will have the final reports presented at appropriate Committee(s) / Group(s) e.g. Executive Team, Medicine Management Group as necessary. This will be identified as part of the action plan.

8.13 CAD will monitor and regularly report on progress with national and priority clinical audits to the Senior Management Teams via reporting structures.

8.14 CAD will ensure that final reports for all national and priority clinical audits are published via a link in the Trust's emailed daily staff communication ‘Trust Today' and loaded onto the Trust’s intranet. In this way the Trust seeks to share learning from clinical audit with the widest possible population of staff.

8.15 Clinical teams will be responsible for making any necessary changes or improvements to practice as a result of the audit, and this should be monitored by the relevant operational service quality groups. CAD will support this requirement by monitoring and regularly reporting to these groups on the completion of action plans identified in all national and priority clinical audit reports for services relevant to that group. CAD will also monitor and
report regularly to relevant committees and operational service quality groups on the implementation of action plans necessary for individual teams following clinical audits.

8.16 Unless otherwise indicated by the audit lead, all audits will be scored as follows:
- Above 90% - Green - Compliant
- 75%-90% - Amber - Improvement needed
- Less than 75% - in red - no robust systems evidenced by audit; action plan required.

8.17 Additionally to the clinical audit department program, Clinical audit will be conducted to meet trust requirements for Medicines Management and Infection Control; these will be overseen and managed by the specialist team for Infection Control and the Chief Pharmacist who will decide scope, frequency and provide reports as required.

9.0 REGISTRATION PROCESS FOR LOCAL CLINICAL AUDITS AND SERVICE EVALUATIONS

9.1 Operational service quality groups will be expected to identify a forward programme of audit priority requirements as part of the Trust’s forward planning process. These priority audits will be approved by the relevant Executive Director and are then able to access the full support of the Trust’s Clinical Audit Department (CAD).

9.2 The locality operational service quality group should expect relevant clinicians interested in carrying out clinical audits to focus on these projects in the first instance. Ideally, only after these local priority audits have been completed should individual clinician’s interest projects, which are relevant to the service, be considered for approval.

9.3 Clinical audit proposals relating to medications will require approval from the Medicines Management Group. All other local audits will require approval from either the practice supervisor or the operational service quality group. These groups will have overall responsibility for outcomes from the audit. Additionally, clinical audit or service evaluations involving patient questionnaires or interviews will need to evidence they have sought guidance from the PALS service.

NB: When approving audits, Managers and Consultants should be aware of their responsibility to supervise audits and the amount of time that will need to be spent on the audit and the effect this could have on the service.

9.4 Once approval has been given, evidence of this and all proposal paperwork (including evidence of PALS if required) relating to the audit will be checked and registered with the Clinical Audit Department using a project proposal form (Appendix 1) which can be obtained from them or from the Intranet.

9.5 A draft audit tool should be developed to support the audit proposal. Ideally this would be a previous tool used within the Trust, or a local adaptation of a nationally validated tool such as POMH or NICE audit criteria. If these are not appropriate then a newly developed draft tool can be developed. The project
proposal and proposed tool must then be presented by the clinical project lead to the relevant group or supervisor for approval.

9.6 Evidence of approval to be forwarded with the proposal and audit tool to the Clinical Audit Department for registration. Evidence of approval can be via minutes, signed document or e-mail.

9.7 The Clinical Audit Department will keep a log of all local clinical audit projects underway in the Trust. Encouraging the completion of audits, in particular the preparation and presentation to colleagues of the findings. Presentations and reports will highlight any identified potential risks and an achievable action plan.

9.8 CAD will report on progress with implementation of the action plan to the relevant operational service quality group via regular monthly reports.

9.9 It should be noted that any routine management audits carried out by team managers, which review documentation or practice on a weekly/monthly basis or in supervision do not need to be registered as clinical audits, however records should be kept within the team of issues and actions carried out to address these. (If in doubt, please check with the Clinical Audit Department)

9.10 It should be expected that any clinical audit project will generally be completed within 12 months of registration after which it will be withdrawn, notification will be sent to the approver and no further reminders will be sent by CAD.

**10.0 PROCESS FOR CARRYING OUT LOCAL CLINICAL AUDITS**

10.1 Once registered data collection should take place within timeframes identified in the project proposal as it is important that local clinical audits are carried out within an acceptable time frame to enable results to inform current practice.

10.2 The clinical project lead will produce a clinical audit report (Appendix 2) or slide set and ensure that an action plan is developed via discussion of the results with clinical and other colleagues as appropriate. The findings should be forwarded to the CAD with the SMART action plan at the earliest opportunity. The clinical project lead must, as a minimum, present the clinical audit report to their practise area, peers. Ideally this would be via presentation at the Local Quality and Safety groups. However, it is also important to share the audit findings and outcomes with any relevant teams and committees as identified including other teams and services that the results could affect. CAD will support this by sending out local reports to other relevant operational service quality groups for their information if this is agreed with the local clinical project lead.

10.3 It should be expected that any clinical audit project will generally be completed within 12 months of registration after which it will be withdrawn, notification will be sent to the approver and no further reminders will be sent by CAD.
10.4 Clinical teams will be responsible for making any necessary changes or improvements to practice, and this should be monitored by the relevant operational service quality group. CAD will support this requirement by monitoring completion of action plans identified in all local clinical audit reports and reporting regularly to the operational service quality groups.