

Clinical audit strategy

1 Purposes and outcomes of this strategy

1.1 Purposes

The purposes of this strategy are to:

- define a standardized approach to carrying out clinical audits to be followed by staff working in all professions and clinical specialties in ..., consistent with current evidence of best practice in clinical audit
- facilitate a shared understanding of the purpose of clinical audit and the clinical audit process among all staff working in ...
- ensure that ... has an active ongoing defined clinical audit programme that is made up of audits that are appropriate and effective and that support ...'s commitment to continuously improve the quality and safety of care and services for patients and other service users
- facilitate the sharing and dissemination of good practice as demonstrated through clinical audits across professions and services in ...
- ensure that doctors or other professionals in training who work in ... meet requirements for the completion of clinical audits as part of their training
- clarify responsibilities for carrying out the clinical audit programme among staff, managers and the ... Committee
- clarify responsibilities and accountabilities for approving and acting on the clinical audit programme and individual clinical audits carried out in ...
- inform staff carrying out clinical audits about data protection requirements to be followed in carrying out clinical audits in ...
- ensure that ethical issues in clinical audits are recognized and handled appropriately by ...
- ensure that the corporate board for ... can be accountable for ...'s execution of an ongoing clinical audit programme and knowing about and addressing known shortcomings related to patient care as revealed through clinical audits, as appropriate.

1.2 Outcomes

The intended outcomes of this strategy are evidence that:

- There is a robust clinical audit programme being implemented in ... on an ongoing basis.
- The clinical audit process is being carried out consistent with best practice in clinical audit.
- Good practice in comparison with national and professional guidance that is relevant to the operation of ... is being provided or improvements are being made in the provision of patient care in response to findings of clinical audits.
- Roles, responsibilities and accountabilities for the clinical audit programme and clinical audits carried out in ... are clear and are being implemented.
- Doctors and other healthcare professionals in training are supported to meet their requirements for participation in clinical audit.

2 Definitions

2.1 Clinical audit

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit measures and the implementation of change.¹

The word clinical refers to any activity that involves direct patient care, and includes audits carried out by doctors, nurses or allied healthcare professionals or by multiprofessional teams.

2.2 Clinical team

For purposes of this process, a clinical team is a professional or specialty group. Such teams assume responsibility and accountability for the completion of clinical audits in the relevant specialty or service.

2.3 Clinical audit process

The clinical audit process involves the following steps. A clinical team:²

- agrees on an important subject for clinical audit and the intent of the audit

- agrees to how the audit will be carried out, including the objective(s) of the audit, the population or sample to be included and the data collection strategy
- agrees to the precise measures of the quality or safety of patient care or service. The clinical audit measures may incorporate agreed national or local standards or evidence of good clinical practice, where available, or consensus among appropriate colleagues in the absence of agreed standards or evidence.
- uses the clinical audit measures as the basis for collecting data on day-to-day practice
- evaluates the findings and any cases or events that did not meet patient care quality or safety expectations
- *if the findings show that the clinical audit measures are being met*, gives feedback on good practice to those involved and acts to maintain good practice
- *if the findings show that the clinical audit measures are not being met*:
 - analyses the problems revealed and finds their root causes
 - takes action to eliminate or minimize the causes of the problems
 - measures again when action is taken to see if practice is improved.

The clinical audit process is shown in the diagram in Attachment A.

2.4 Lead(s) for specific clinical audits

The lead(s) for a specific clinical audit is(are) the member(s) of staff who will do the work involved in carrying out a specific clinical audit. The work involved in carrying out a specific clinical audit may be shared among members of staff or when some stages are completed, the audit may be handed over to other members of staff to continue the work. If the clinical audit covers more than one profession or specialty, the overall lead(s) must be agreed when the Clinical Audit Proposal is prepared and submitted for approval.

2.5 Clinical audit programme

For purposes of this policy, a clinical audit programme is a document that identifies the following:

- the subjects of clinical audits to be carried out in ... over the next year

- the specific objectives for each clinical audit. The objectives should reflect how the clinical audit relates to the quality or safety of patient care, for example, confirm that best practice (as defined by a guideline, policy, protocol, etc) is being followed, or increase the percentage of patients who receive care that represents best practice.
- a very brief explanation of why the subject was selected for the clinical audit, such as affects many patients, represents higher than usual risk, is currently a problem, is a national or organizational requirement, represents high cost, represents the potential for improving clinical effectiveness of the service, etc
- key milestones for completion of the clinical audit, for example, by quarter. An example could be: for first quarter, discussion and agreement by the team to the design for a clinical audit; for second quarter, completion of data collection and analysis for that audit; for third quarter, analysis of causes or problems revealed and action planned for that audit; for fourth quarter, action implemented and repeat data collection to demonstrate if the action was effective for that audit.
- the name of the individual(s) leading the clinical audit.

A clinical audit programme should include the following:

- national or regional clinical audits in which ... intends to participate, if any
- clinical audits for which participation is required of ... because of any of the following:
 - requirements of the ..., such as a clinical audit on the completeness of documentation in patient records or completeness of required consents
 - clinical audits that are intended to demonstrate compliance with guidance published by ...
- clinical audits required by ... because of a risk situation, a perceived problem or an intention in ... to achieve improvement in an aspect of patient care, for example, hand washing
- clinical audits being carried out by professionals in training, such as Foundation Programme Trainees, Specialty/Specialist Registrars, trainee pharmacists or others, as part of their training or professional development requirements
- clinical audits selected by staff members as being important to the specific service or specialty.

3 Process for carrying out specific clinical audits

The process for carrying out a specific clinical audit in ... is as follows.

3.1 Completion of Clinical Audit Proposal form

The lead(s) for a specific clinical audit agrees to carry out the work involved in carrying out a clinical audit, including the following:

- designing the clinical audit, including the objective(s), stakeholders, population or sample to be included and data collection strategy
- formulating the specific measures to be used in the audit
- developing a data collection protocol and tools as needed
- collecting and collating data as needed
- providing for data protection requirements relating to clinical audit to be met through the data collection, collation, presentation and reporting stages of the audit
- reviewing or arranging for the review of cases that were not consistent with the clinical audit measures to learn why care was not consistent with expectations
- identifying any problems in practice revealed by the clinical audit and analysing the root causes of the problems
- taking action or recommending action to be taken to address the root causes of problems identified
- repeating or arranging for the repeating of data collection when action is taken, in order to learn if the action has been effective in improving practice.

The person(s) serving as lead(s) for a specific clinical audit completes ...'s Clinical Audit Proposal form and submits the form for approval to the Clinical Audit Lead for the specialty or service.

3.2 Review of the Clinical Audit Proposal

The Clinical Audit Lead may arrange for review of the Clinical Audit Proposal and will communicate the decision following such review to the lead(s) for the audit, including any comments about how the proposal needs to be changed to enhance the appropriateness and/or effectiveness of the proposed clinical audit.

Alternatively, the Clinical Audit Proposal could be considered as an item of business at a meeting where clinical audits are usually discussed, and the group discussion could determine whether or not the clinical audit is approved as proposed or requires amendment.

Feedback to the originator of a proposed clinical audit should be documented in correspondence or meeting minutes. Approval of a proposed clinical audit is indicated by signature of the Clinical Audit Lead.

3.3 Completion of Clinical Audit Report

Upon completion of the work involved in the clinical audit, the lead(s) for the specific clinical audit should complete a report on the audit. The report should be submitted to the relevant clinical service director and manager, to any relevant committees and to the Clinical Audit Lead.

The individuals receiving the report should take particular notice of the effectiveness of actions taken to achieve any improvements shown as indicated by the clinical audit and the need for further actions to be taken.

A copy of the completed Clinical Audit Report should be sent to ...'s clinical audit/governance department for completion of registration purposes.

4 Process for developing and carrying out a clinical audit programme

The process for developing and carrying out ...'s clinical audit programme is as follows.

4.1 Development of clinical audit programme

The Clinical Audit Committee (or equivalent) will issue guidance within ... relating to ...'s clinical audit programme. The guidance will include reference to the following:

- national or regional clinical audits in which ... has agreed to participate for the following year
- requirements for clinical audit imposed by the ... or other regulatory body or approved by the Clinical Governance Committee for ...
- national guidance for which evidence of implementation is needed in the coming year

- how clinical audits can be selected for relevance to the clinical service or team
- the specific documentation to be submitted on the clinical audit programme, including the timetable for carrying out the clinical audits.

4.2 Monitoring of completion of clinical audit programme

The Clinical Audit Lead will monitor completion of ...’s clinical audit programme, including checking if clinical audits are being carried out in accordance with the planned timetable, and what interventions are needed, if any, to keep the programme on schedule.

4.3 Reporting on clinical audit programme

The Clinical Audit Lead should prepare brief regular reports to the clinical audit committee and to the ... committee on the completion of the clinical audit programme.

5 Data protection requirements relating to clinical audit

The following actions will be implemented in regard to data protection requirements related to clinical audit, consistent with ... requirements.³

5.1 Informing patients about the use of personal health information

... informs patients that their personal health information will be used for clinical audit and quality improvement purposes through reference to the subject in the patient information material about care in The patient information material briefly describes the clinical audit process and its contribution to the quality and safety of patient care.

5.2 Anonymization of clinical audit data

All data collected for clinical audit purposes in ... will be anonymized through the use of randomly assigned codes at the time of data collection. No patient or professional identifiable data will be reported for any clinical audit at any time.

6 Ethics issues relating to clinical audit

Any clinical audit or quality improvement activity that involves any of the following situations or circumstances will be submitted to the ... committee for review of the ethics issues represented by the situation or circumstance:³

- Information is being collected for the clinical audit that is beyond the information collected as part of routine patient care.
- The clinical audit poses any risk for or burden on a patient beyond those of his/her routine care.
- The clinical audit includes a moderate or major departure from current typical clinical care, for example, in implementing a significant change in practice.
- The clinical audit infringes on patients' rights in any way.
- The clinical audit breaches or could breach any patient's confidentiality or privacy through the way that data are to be collected, stored, collated or analysed, or collects any data that could be used to identify any patient or practitioner.
- Patients or carers are being subjected to more than minimal burdens or risks, for example, by the completion of a lengthy survey questionnaire or direct interview.
- The clinical audit involves the use of any untested clinical or systems intervention or interventions or proposed changes in practice are to be allocated differently among different groups of patients, for example, by consultant or by GP practice.
- The person(s) carrying out the clinical audit has(have) no ongoing commitment to improvement of patient care, for example, are external to

7 Dissemination of clinical audit activities

The ... committee will be responsible for ensuring that the following are communicated regularly to the staff working in ...:

- the clinical audit programme and progress on carrying out the programme
- findings of clinical audits, both of good practice and where improvements in practice need to be made
- changes in practice being implemented as a consequence of clinical audits and evidence of the effectiveness of the changes in practice learned through repeating the data collection for clinical audits
- good practice in clinical audit and how to carry out a clinical audit the right way.

8 Doctors and healthcare professionals in training

Foundation Programme trainees (at F1 and F2 levels), specialist or specialty registrars, trainee pharmacists, and any other healthcare professionals in training who are assigned to work in ... will be supported in carrying out clinical audit properly.

9 Responsibilities and accountabilities for the clinical audit

The following are responsibilities and accountabilities for clinical audit in

9.1 All staff

All staff working in ... are expected to participate in ...'s clinical audit programme, including to accept responsibility for carrying out or acting on individual clinical audits.

9.2 Lead(s) for specific clinical audits

The individual(s) designated to take the lead for carrying out a specific clinical audit is responsible for the following:

- carrying out the clinical audit consistent with section 2.3 in this document
- completing and submitting the Clinical Audit Proposal form for the audit to the Clinical Audit Lead
- completing and submitting the Clinical Audit Report for the audit to the relevant clinical service director and manager and to the Clinical Audit Lead, as well as to the Clinical Audit/Governance Department for completion of registration purposes.

9.3 Clinical Governance Director

...s director for clinical governance is responsible for carrying out the following in regard to clinical audit:

- supporting the implementation of the approved clinical audit programme
- getting reports of all clinical audits being carried out in ... through relevant committees or directors or managers or through the Clinical Audit/Governance Department
- proactively learning if further action needs to be taken to achieve improvement in practice as indicated by the clinical audit findings, following

discussion of the causes of problems and actions taken or needed within the clinical team

- assuming responsibility for taking actions needed as indicated by clinical audit findings, which are outside the scope of authority of the clinical team, including forwarding the need for actions to more senior levels of management as needed
- reporting back to the lead(s) for a specific clinical audit and the clinical team on the status of actions referred to operational management and senior management, on a timely basis.

9.4 Clinical Audit Lead

The individual who assumes responsibility for clinical audit in the specialty or profession assumes responsibility for directing clinical audit in the specialty or profession.

9.5 ... Committee

The ... Committee is responsible and accountable for the following:

- reporting regularly on progress in the completion of approved clinical audits in the clinical audit programme
- noting if action is taken as needed on clinical audit findings, and calling lack of action to the attention of the operational management of

10 Support for implementation of this strategy

The following forms of support will be provided to implement this strategy:

- clinical audit proposal and clinical audit report templates for use by staff serving as leads for clinical audits
- guidance on ...'s clinical audit programme and the clinical audit process as defined in this strategy
- training for staff to carry out the clinical audit process, as needed
- technical assistance for staff carrying out clinical audits, as needed.

11 References

1. Adapted from National Institute for Clinical Excellence. *Principles for Best Practice in Clinical Audit*. Abingdon UK: Radcliffe Medical Press; 2002, p. 1.
2. Dixon N. *Getting Clinical Audit Right to Benefit Patients*. Romsey UK: Healthcare Quality Quest; 2008, p. 4.
3. Dixon N, Pearce M. *Clinical Audit Manual*. Romsey: Healthcare Quality Quest; 2008.