

Ethics and Clinical Audit and Quality Improvement (QI) — A Guide for NHS Organisations

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Clinical audit tool to promote quality for better health services



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1 Introduction

The Healthcare Quality Improvement Partnership (HQIP) is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Our purpose is to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales.

Clinical audit may be defined as “a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Put more simply, clinical audit is all about measuring the quality of care and services against agreed standards and making improvements where necessary.”¹

In order to facilitate this, HQIP have funded the development of a number of clinical audit support tools to help local teams deliver local clinical audit activity. They are intended to be used as reference material or toolkits to help with the clinical audit process.

This document should be read in conjunction with other relevant tools produced as part of this collection by HQIP.

The importance of ethics in clinical audit and quality improvement (QI) activities

Many people think that there is no need for ethics oversight of clinical audits or QI activities. However, there are several reasons why NHS organisations should have an ethical oversight system for clinical audit and QI including:²⁻⁴

- Clinical audit or QI activities can potentially impose burdens on or risks to patients or carers. Some activities may benefit some patients at the expense of others or may not represent priorities based on risk-benefit analysis from a patient care perspective. Ethical oversight is needed to avoid these possibilities.
- Clinical audits or QI activities can create potential conflicts of interest when findings indicate shortfalls in care attributable to lack of resources. The ethical duties of a healthcare organisation to all its patients need to be considered formally in such situations.
- Some healthcare professionals are not trained in clinical audit or QI methods. Audits or QI projects they carry out may be poorly designed and unlikely to yield useful results, in which case the activity is not ethically justified.
- Clinicians, intentionally or unintentionally, can avoid the research ethics review process by designating a project as a clinical audit or QI study rather than as research. Patients can be put at risk if this happens.
- True research on the quality improvement process itself may not be recognised as research and may not have appropriate oversight.
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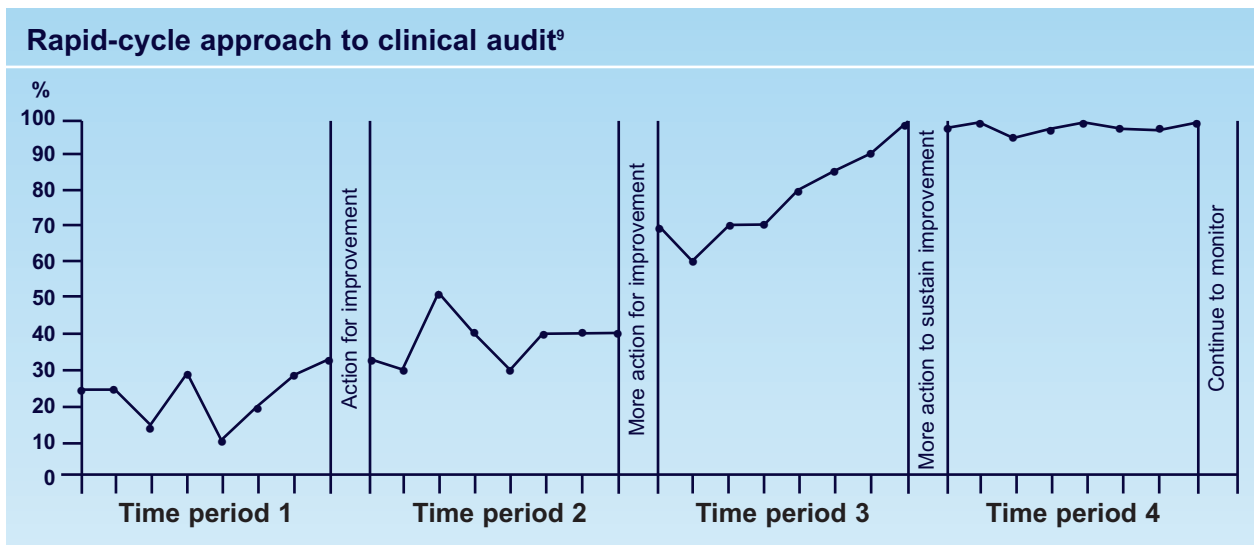
The key terms — ethics, clinical audit and quality improvement activities

The terms as used in this guidance are defined in the box.

Ethics	The inquiry into certain situations and into the language used to describe them; the kind of situations referred to are those that have led or may lead to harms or benefits to others. ⁵
Clinical audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery. ¹
Quality improvement	Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. ¹ For quality improvement to occur, the information produced by quality assessment [data collection] must be translated into systematic improvements in healthcare practices. ⁶

Clinical audit has shifted to a QI process

Clinical audit has shifted from a quality assurance to a quality improvement process.¹ In a QI approach to clinical audit, data collection to compare actual practice to measures of good practice is repeated rapidly to test the effect of different change interventions.⁷ QI feeds back measurements rapidly and leads to quick modifications in the care process or outcome being measured, with the goal of achieving needed improvement. This measure–act–measure–act–measure process to demonstrate improved and sustained compliance with measures of good practice is shown in the diagram that follows. The science of QI is developing rapidly and QI methods, including clinical audit, are constantly evolving.⁸



Differentiating between research and clinical audit

Distinguishing between research and clinical audit or QI should no longer be the basis for deciding whether or not an activity requires ethics review for three reasons:

- Studies have demonstrated that research and clinical audit or QI studies cannot be distinguished in a reliable or valid way.¹⁰
- There are a number of other ethics issues related to clinical audit that are beyond the consideration of the design of an individual project.
- Some QI initiatives are truly research on the quality improvement process, that is, 'hybrid' projects that do require research ethics review.²

Ethics issues in a clinical audit or QI programme

Clinical audit and QI activities can be decentralised, fragmented and ad hoc, with little priority setting that is based on an analysis of benefits and risks for patients. Also, organisations can have an inadequate structure in place to ensure that clinical audits and QI activities actually lead to sustained improvements in the quality and safety of patient care.¹¹ Ethical principles should be applied to an NHS organisation's clinical audit or QI programme, as explained in the box.

Principle	Explanations
Provide benefit (beneficence) and avoid harm (non-maleficence)	<p>Clinical audits and QI activities need to be managed effectively to ensure that patients actually benefit from the work and that patients are not put at any risk through the activities.</p> <p>Priorities for carrying out clinical audits or QI activities need to reflect a benefit-risk analysis from a patient care perspective. Healthcare resources should be directed at activities that will achieve the most benefit for patients or will minimise the risk of harm to patients.</p>
Be fair and equitable (justice)	<p>All healthcare professions need to participate in clinical audit or QI activities.</p> <p>All patient groups and types of conditions need to be covered in the programme over time.</p> <p>All clinical services need to participate in clinical audits or QI activities.</p>

An NHS organisation's annual clinical audit report can be used to demonstrate consistency with these ethics principles.

Possible ethics issues in an individual clinical audit or QI activity

There are three stages at which clinical audit or QI activities should be reviewed to identify any possible ethics issues:

- as a proposal
- following analysis of data gathered
- following action.

The possible reasons for review are in the box.

Stage	Reason for review
Proposal	<ul style="list-style-type: none">• Is there a situation in the proposal that requires ethics review? (See the screening questions on page 6.)• Is the proposed design and measures of the quality or safety of care or service valid and is the method for data collection likely to produce reliable data?• Does the subject of the clinical audit or QI activity itself have any ethical implications, and if so, are the proposed design and measures completely consistent with the organisation's formal policy on the subject?
Following analysis of data	<p>Do the findings of the clinical audit or QI activity:</p> <ul style="list-style-type: none">• pose any risk for patients whose care was reviewed in the clinical audit or for other similar patients, for example, if care was not provided consistent with good practice?• identify any patients for whom a life-threatening or quality-of-life threatening shortcoming in care occurred?• disclose any data that could be used to identify any patient or any practitioner?• reveal any clinically significant departure from usual clinical care?
Following action	<ul style="list-style-type: none">• Has the action taken been effective in achieving needed improvement?• Are patients at risk if care continues to be inconsistent with the measures used in the clinical audit or QI study?

Questions that could be used to screen proposed clinical audit or QI activity for ethics issues are in the box on the next page.

Possible ethics screening questions for proposals for clinical audits or QI activities

Will the proposed clinical audit or QI activity:

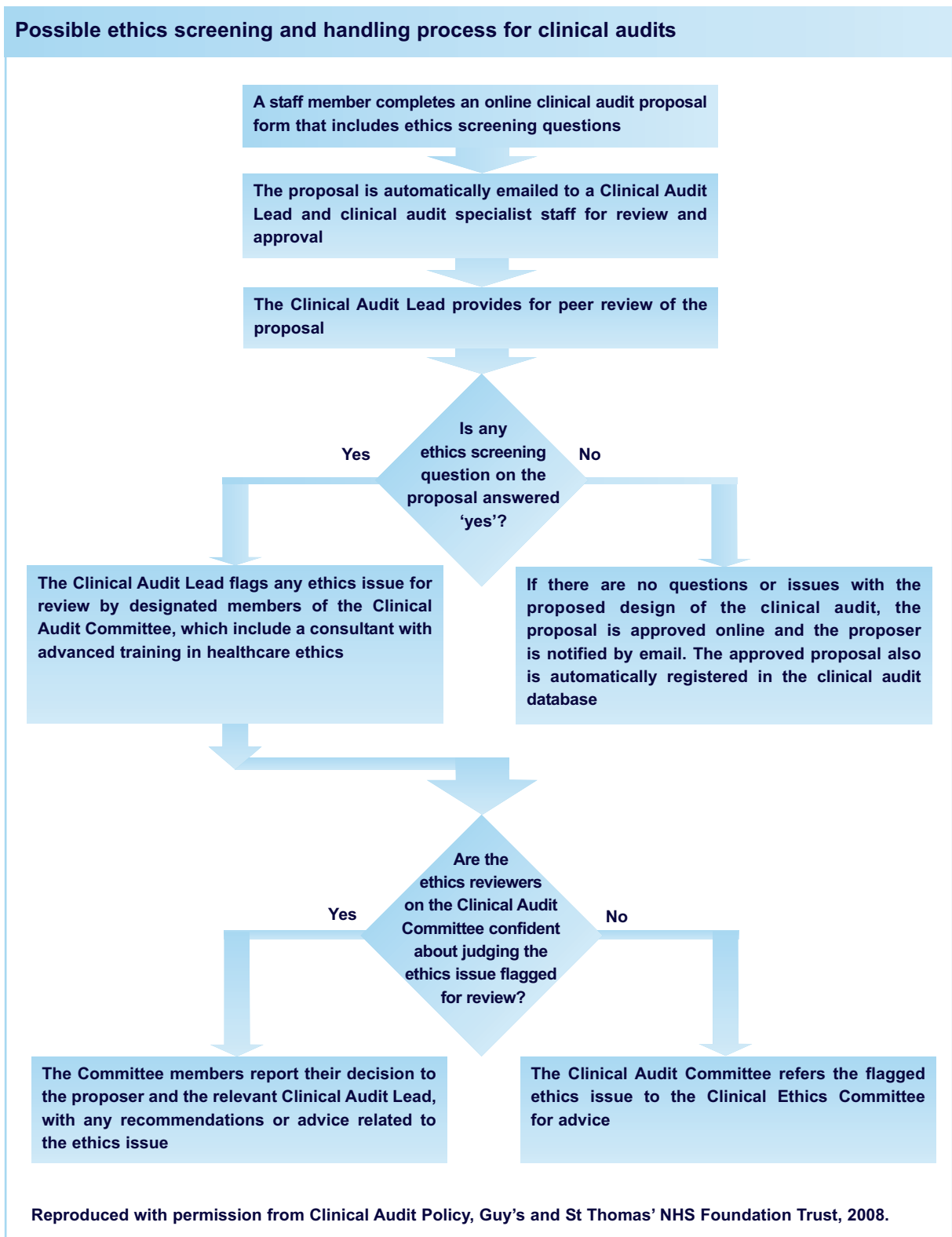
- infringe on any patient's rights or risk breaching any patient's confidentiality or privacy?
- pose any risk for or burden on a patient beyond those of his or her routine care?
- involve any clinically significant departure from usual clinical care?
- gather any information about any patient other than information that is ordinarily collected as part of providing routine care for the patient?
- collect data directly from any patient or carer, and if so, could the activity subject a patient or carer to more than a minimal burden or risk if it requests sensitive information or is time consuming?
- collect or disclose any data that could be used to identify any patient or any practitioner?
- have someone carrying out the activity who does not normally have access to patient's records? People who normally have access to patients' records include clinical staff providing direct patient care and staff employed to support clinical audit or QI activities when a duty of confidentiality is included in their job descriptions.
- involve a potential conflict of obligation to individual patients or to all patients such as if the activity involves a trade-off between cost and quality?
- involve the use of any untested clinical or systems intervention or testing an hypothesis?
- allocate any interventions differently among groups of patients or staff, for example, in implementing a change in practice?

Each NHS organisation needs to consider how to provide for routine screening of proposals for clinical audits or QI activities. Some options for ways an organisation could identify ethics issues are in the box.

Option	Explanation
Include questions that 'screen' for possible ethics issues on the organisation's clinical audit or QI project proposal form	The person completing the proposal form could check if any possible ethics issue could arise in the clinical audit or QI activity. If the proposer identifies a possible ethics issue, a 'special' review of the proposal would be arranged.
Provide guidance on screening clinical audit or QI project proposals	The person or people who review(s) proposals for a clinical audit or QI activity, such as a clinical audit lead or a clinical audit committee, could use guidance provided to decide if there is a possible ethics issue in the work being proposed.
Rely on clinicians or reviewers to decide for themselves if the proposed clinical audit or QI activity requires review from an ethics perspective	The person completing or reviewing the proposal for a clinical audit or QI activity could decide that the work represents a possible ethics issue that requires special review.

Flagging ethics issues as part of the normal process for carrying out clinical audit or QI

Many NHS organisations already have a clinical audit or QI activity proposal submission process in place. Many also have a process for registration of clinical audits and QI projects in a database. An example of how ethics screening and review could be added to these processes is in the box.



Organisational arrangements for ethical oversight of clinical audit or QI

Clinical audit and QI activities require ethical oversight by a responsible individual or group that is accountable to senior management and the governance of the organisation.¹¹ Individuals acting in isolation should not carry out clinical audits and QI activities. Groups or teams acting on behalf of the organisation should be carrying out the work.⁸ Professional and management leaders' roles should include creating a culture of quality and safety improvement throughout the organisation to ensure that when clinical audit or QI is done, it is done the right way.

“The standards expected of audit in terms of design, data collection and analysis should be at least as high as for research, if only because audit potentially leads to change more often than research does and often much greater change.”¹²

An NHS organisation can establish ethical oversight of clinical audits and QI activities in one or more of the following ways:

- have clinical directors or service managers or Clinical Audit or Quality Improvement Leads assume responsibility for screening proposals and referring those that require further consideration to a designated individual or group
- have the director who is organisationally accountable for clinical audit and quality improvement assume responsibility for ethical oversight of these activities
- assign ethical oversight to a committee or group which is accountable to the governance structure, such as a clinical audit committee, quality improvement committee, patient safety committee, clinical policy committee or an ad hoc group.

A research ethics committee can be asked for an opinion on an ethics-related issue in a clinical audit or QI project proposal. However, there are several reasons why this is not the best solution to oversight of clinical audit and QI including that:

- Clinical audit and QI activities are part of an overall quality and patient safety improvement strategy that should be integrated into the operations of an NHS organisation. Clinical audits or QI activities should not be viewed as individual projects, but as the heart of the operations of the organisation. These projects need to be strategically selected and completed as part of the commitment by the organisation to improve the quality and safety of patient care.¹¹
- Research ethics committees:
 - were not created to assess projects that involve changing practices and systems in the delivery of patient care
 - are often overworked and backlogged
 - don't necessarily have the knowledge and expertise to evaluate clinical audits or QI activities.
- Staff might be discouraged from carrying out clinical audits or QI projects if they perceive that a project might involve the amount of paperwork and the delays associated with ethics review of research.

Contents for a policy on ethics and clinical audit and QI

NHS organisations should have a policy on ethics and clinical audit and QI that should include reference to the contents in the box.

Who is responsible and accountable for ethical oversight of clinical audit and all quality and safety improvement programmes and activities in the organisation including reference to the following:

- the responsibility and accountability of the individual taking the lead for a clinical audit or QI project
- the responsibility and accountability of the director or manager of a clinical service for clinical audits and QI projects being carried out in the service
- the responsibility of the named person or group that is accountable for ethical oversight of clinical audit and QI on behalf of the organisation

How proposals for clinical audits and QI activities and findings of initial and repeat data collection are to be screened for possible ethics issues

Screening criteria to be used to identify potential ethics issues in an individual clinical audit or QI activity

How proposals for clinical audit or QI projects that involve a potential trade-off between quality and safety and cost, such as changes in access to services, are to be reviewed

How actual ethics issues in a clinical audit or QI activity are to be reviewed, by whom and through what process

How data are to be collected and analysed to maintain confidentiality and anonymity of the patients and staff whose care is reviewed in a clinical audit or QI activity

How patients are informed of the clinical audit and QI processes and activities in the organisation

How patient permission or consent is to be obtained when participation in a clinical audit or QI activity represents more than minimal burden or risk to patients

Action to be taken if a clinical audit or QI activity reveals that shortcomings in patient care may represent a life-threatening or quality-of-life-threatening situation for one or more patients

How staff are informed about ethical oversight of clinical audit and QI activities

How clinical audits and QI projects are monitored to ensure adherence to the organisation's policies relating to these activities

How submissions for publication of work on clinical audits or QI activities are to be handled

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