

Guide to managing ethical issues in quality improvement or clinical audit projects





Author:
Nancy Dixon, Healthcare Quality Quest

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Key points

Ethics is about the inquiry into situations that have led or may lead to harm or benefits to others.

Quality improvement (QI) describes systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings.

Clinical audit is a QI process.

Many people think that only research studies involve ethics review. However, any activity that poses a risk of psychological or physical harm to a patient should have ethical consideration, including a QI project or a clinical audit.

It can be difficult to distinguish between research, QI or clinical audit projects.

There are published tools available to help people distinguish between a research and a QI project.

A poorly designed QI project or clinical audit is itself an ethical issue because the project is unlikely to achieve valid and reliable assessment, and may not produce improvements in the quality or safety of patient care.

Action to consider

Ensure that robust processes are in place to:

- Screen proposals for QI projects and clinical audits to identify and act on any possible ethical issues embedded in a project
- Consider the findings of measurement in QI projects and clinical audits to identify and act on any possible ethical issues revealed through data collection
- Check on the effectiveness of actions taken to achieve needed improvements in care via valid and reliable measurement

Ensure that the QI and clinical audit programme:

- Involves all professions working in the organisation and all clinical services
- Uses a systematic approach for setting priorities for QI or clinical audit projects
- Includes all patient groups and types of conditions
- Manages the projects being undertaken

Ensure that the organisation has designated:

- Who is accountable for ensuring that ethical issues in QI and clinical audit projects are identified, considered and addressed. Options could include: directors of clinical

services; a QI, clinical audit or clinical governance director; or a designated committee

- The role of leads of QI projects or clinical audits in identifying and addressing any ethics issues in these activities

Consider the following organisational systems to oversee possible ethical issues in QI or clinical audit projects:

- Provide a corporate register of QI and clinical audit projects
- Disseminate organisational policies and guidance for QI and clinical audit projects
- Provide for ethical consideration of a QI or clinical audit project that is designed to contain or control or reduce costs
- Include carrying out QI and clinical audit projects in job descriptions and performance appraisals for all clinical staff
- Teach staff about the organisation's policies and systems for identifying and managing ethics issues in QI and clinical audit projects
- Track completion of QI and clinical audit projects
- Review potential publication of QI or clinical audit projects

Ensure that research on QI methods or interventions is subject to formal ethics review

Introduction

Who this guide is for

This guide is for the following people involved in QI, clinical audit and clinical governance:

- Leads
- Managers and specialist staff that support teams and projects
- Committee Chairs and members
- Clinical directors and service managers
- Staff that are carrying out a QI or clinical audit project
- A committee or individual that is responsible for ethics and ethical decision-making

How the guide is intended to help

This guide is intended to help those responsible to review and develop arrangements for effective ethics oversight of QI and clinical audit activities, as required. It focuses on QI and clinical audit and describes:

- What's involved in ethics and how ethics principles may apply
- Why healthcare organisations should provide for ethical oversight
- The difficulty in distinguishing between a research and a QI or clinical audit project as the basis for ethical review
- The stages in projects when ethical oversight should be carried out
- How to screen projects for ethics issues
- The structure and systems needed in a healthcare organisation for ethical oversight
- How to assess and improve current arrangements for ethical oversight

The content in the guide is derived from an extensive search and review of published literature on ethics and QI or clinical audit carried out by Healthcare Quality Quest. The full review is available at www.hqq.co.uk.

What’s involved in ethics and QI or clinical audit

Key terms and their meanings

The terms used in this guide are defined in the box.

Term	Meaning
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 harm or benefits to others ¹
Quality improvement (QI)	<p>Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings^{2, 3}</p> <p>Systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups⁴</p> <p>For QI to occur, the information produced by quality assessment [data collection] must be translated into systematic improvements in healthcare practices⁵</p>
Clinical audit	A QI process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, followed by the implementation of change. Aspects of the structure, process, 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 ⁶

Ethical principles

Ethical principles usually considered in healthcare settings also apply to QI and clinical audit. An explanation of the principles and how they apply to healthcare generally is in the box.¹

Ethical principle	Meaning	Example applied to healthcare
Autonomy	<p>An obligation to respect the rights of people to make choices concerning their own lives, for example, by disclosing information to:</p> <ul style="list-style-type: none"> • Enable people to make decisions • Foster their decision-making • Avoid assuming controlling influence on their decisions <p>Also recognising the right of a person to decline having information about choices and not to make choices on behalf of the person</p>	<p>Providing information to patients about their treatments or procedures in ways that are sufficiently complete and comprehensible. The information must include associated benefits and risks so that patients can make informed choices about proposed treatments or procedures</p> <p>Seeking patients’ informed consent</p>
Beneficence	<p>An obligation to act in ways that:</p> <ul style="list-style-type: none"> • Benefit others • Prevent harm, including removing circumstances that could lead to harm 	<p>Meeting a duty of care to provide patient care that is consistent with known good practice</p>

Non-maleficence	<p>An obligation not to:</p> <ul style="list-style-type: none"> • Harm others • Impose risks of harm <p>Assuming a standard of due care, that is, taking sufficient and appropriate action to avoid causing harm to a person</p>	<p>Maintaining confidentiality of information about patients, and providing privacy for patients</p> <p>Avoiding the intentional or unintentional imposition of a risk of harm to a patient (e.g. by failing to monitor a patient in accordance with the severity of their condition)</p>
Justice	<p>An obligation to:</p> <ul style="list-style-type: none"> • Treat others fairly • Distribute scarce resources fairly • Respect people's rights and morally acceptable laws 	<p>Avoiding being selective about patients who receive care or a substantial improvement in care</p> <p>Avoiding wasting resources that could be used to better purpose</p>

Why there is concern about ethics and QI and clinical audit

The gaps between evidence-based practice and actual patient care delivered in healthcare organisations are well documented.⁷ Healthcare professionals and organisations have an ethical obligation to close the gap in implementation of best known practice and to overcome patient care quality and safety shortcomings.^{8–10}

Disciplined and focused improvement efforts can increase the effectiveness and safety of healthcare, and therefore, can be seen as an ethical imperative in healthcare services.¹¹ Failure to undertake improvement projects could be harmful if the lack of participation perpetuates unsafe, unnecessary or ineffective clinical practice.¹²

Widely accepted ethical standards are in place for many activities carried out in healthcare organisations, such as medical treatment and research. However, arrangements for ensuring that QI and clinical audit projects conform to appropriate ethical standards seem to be fragmented, and such standards have not been clearly or thoroughly described.^{13, 14}

Many people think that only research studies require ethics review and that a QI project or a clinical audit, which may involve using data that have been previously captured for patient care, cannot have ethical implications. However, this assumption may not be justified.¹⁵ Any activity that poses a risk of psychological or physical harm to any patient should have ethical consideration, including a QI project or a clinical audit.¹⁶

Healthcare organisations should provide ethical oversight of QI projects and clinical audits because:

- Patients or carers can potentially experience burdens or risks through their participation in these activities^{2, 3, 17–28}
- Some patients may benefit at the expense of others^{2, 3, 18, 29}
- Projects undertaken may not represent priorities for improving care based on risk-benefit analysis from a patient care perspective^{2, 3, 18}
- These activities can create potential conflicts of interest when findings indicate shortfalls in care. The ethical duties of a healthcare organisation to all its patients need to be considered formally in such situations^{5, 7, 18, 24, 30–35}
- Some projects are not carried out properly, and therefore, are unlikely to benefit patients or patient care. If QI or clinical audit projects are poorly designed and unlikely to yield useful results, the activity is not ethically justified^{2, 3, 8, 17, 18, 23, 36–38}
- Clinicians, intentionally or unintentionally, can avoid the research ethics review process by designating a project as a QI project or clinical audit rather than as research. Patients could be put at risk in this circumstance^{18, 24, 32, 39–42}
- True research on QI interventions or the QI process itself may not be recognised as research, and therefore, may not have appropriate ethics review²

Although QI and clinical audit projects have a different intent and focus, the requirement for ethical consideration and oversight of QI activities should be no less stringent than what is mandated for clinical research.⁴³

Differentiating research and QI as a basis for ethics review

The importance of identifying research properly

Ethics review of proposed research studies is required because, while there should be clinical equipoise (i.e. there is genuine uncertainty whether a treatment will be beneficial) there is risk that the person may receive a treatment that is not optimal or may even be harmful. Participation in research is voluntary, and therefore each participant in a research study is entitled to choose whether or not to be a research participant.^{2, 41} It is very appropriate that people who volunteer to participate in research are safeguarded through effective ethical review of proposed research projects.

It has become important to attempt to distinguish between research, clinical audit and QI projects to ensure that each activity has the appropriate type of ethics review or ethical oversight.

The problem of reliable differentiation

Studies have demonstrated that Research Ethics Committees, medical directors, QI practitioners and journal editors are not consistent in reaching decisions as to whether a proposed project represents research or a QI project.⁴⁴⁻⁴⁹ Clinicians in different countries have experienced misunderstanding by colleagues as well as by authorities as to what constitutes research as opposed to a QI project.^{41, 50-59}

Concepts that are used to differentiate between research and QI and clinical audit

A number of concepts have been suggested as the basis for differentiating between research and QI or clinical audit, such as purpose, systematic approach, production of generalisable new knowledge, treatment or allocation, intention to publish, and focus on human participants.^{60, 61} These concepts have not been validated as reliably discriminating between research and QI studies. However, as QI studies become more popular and sophisticated, many of these concepts can potentially apply to both research and QI studies.^{3, 7, 9, 10, 41-43, 52, 54, 62}

Tools to distinguish between QI and research

A number of tools have been developed to help practitioners decide if the activity they propose is a QI project or a research study, and whether or not the project requires ethics review. An example of questions asked to contribute to making a decision is in the box on the following page^{61, 63-78}

Questions to decide if an activity needs a research ethics review ⁶¹		
Will the activities of the project occur within the standard of care?	If NO	There should be a research ethics review
Is there risk to the participants?	If YES, determine: <ul style="list-style-type: none"> The nature of the risk such as threat to privacy or confidentiality of health information, or physical, psychological, emotional, social or financial risk Whether or not participants will be involved in an informed consent process that describes the risks carefully 	Based on the nature of the risk and whether or not informed consent is intended, there should be a research ethics review
Is the project primarily intended to generate generalisable knowledge?	If YES	There should be a research ethics review
Does the project involve vulnerable populations?	If YES, determine: <ul style="list-style-type: none"> The nature of the risk such as threat to privacy or confidentiality of health information, or physical, psychological, emotional, social or financial risk Whether or not participants will be capable of being involved in an informed consent process that describes the risks carefully 	Based on the nature of the risk and whether or not informed consent is intended, there should be a research ethics review

Conclusion: Research requires ethics review and QI and clinical audit require ethical oversight

Research requires ethics review by a Research Ethics Committee in order to safeguard the rights, safety, dignity and well-being of the participants. The committee gives an opinion about the proposed participant involvement and whether the research is ethical.⁷⁹

Many people think that only research studies require ethics review and that QI and clinical audit projects do not require any ethical consideration. Three points contribute to understanding that QI and clinical audit require ethical oversight:

1. Distinctions between the types of activities are blurred and can be ambiguous, unhelpful and arbitrary^{7, 13, 18, 30, 35, 40, 44, 46, 52, 80-82}

2. A healthcare organisation has an ethical duty to manage the conduct and to act on the findings of QI and audit projects to benefit patients¹⁰
3. Some QI projects are truly research on the QI process, these are called 'hybrid' projects.^{2, 83, 84} Research on the QI process itself or on organisational or practice interventions intended to bring about improvements in patient care, often referred to as 'implementation science', should be subject to research ethics oversight (See the [section on research on QI methods or interventions](#).)

A summary of definitions and types of ethical actions is in the box, overleaf.

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Activity	Research	Quality improvement	Clinical audit
Formal definition	The attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods	Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings	A QI process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change
Nature of the activity	Generating hypotheses and verifying scientifically a predicted, but not necessarily proven, relationship between or among variables such as clinical processes and outcomes	Using quantitative or qualitative data to identify problems in the delivery of care and their causes and act to achieve improvement in an aspect of care	Comparing actual patient care to the type of care that represents best practice and act on the findings to achieve improvement in delivering best practice
Ethics involvement	Requires Research Ethics Committee review	Should have oversight of projects to identify and address any ethical issues	Should have oversight of projects to identify and address any ethical issues

Also see *Defining Research* at www.hra.nhs.uk/documents/2016/06/defining-research.pdf.

Managing possible ethical issues in individual QI or clinical audit projects

Process to review proposals

There could be some situations or circumstances in a QI project or clinical audit that requires ethical consideration before the project has started.

Many healthcare organisations already have a well-established process for reviewing proposals for clinical audits, and these processes can be used to identify any possible ethical issues related to the topic or the design of a clinical audit. Ethical issues also could arise when data collection for a clinical audit reveals that patients are at risk because they don't receive appropriate, effective or timely care. If action is not taken to improve the quality or safety of care, the continuous risk to patients may become an organisational ethical issue.

Organisations may not have similar arrangements for reviewing QI project proposals. Staff members are encouraged to develop and carry out QI projects, often without a definite framework to follow that would ensure that any ethical issues embedded in a project are identified and managed appropriately.

Screen project proposals

The questions in the box have been derived from the literature to identify circumstances in which the topics of possible clinical audit or QI projects should be screened.^{5, 7, 8, 10, 15-18, 20-24, 26, 30, 31, 33, 34, 36, 37, 42, 44, 62, 85-90}

Further explanation follows overleaf.

Questions to guide the decision on QI or clinical audit projects that should be screened for possible ethics issues

Does the proposed QI or clinical audit project have any of the following ethical issues that need consideration before starting the project?

Infringe on any patient's rights?

Yes No

Risk breaching any patient's confidentiality or privacy?

Yes No

Place a burden on a patient beyond those of his or her routine care?

Yes No

Involve any clinically significant departure from usual clinical care?

Yes No

Involve a potential conflict of obligation, for example, a trade-off between quality and cost, to patients?

Yes No

Involve the use of any untested clinical or systems intervention?

Yes No

Allocate any interventions differently among groups of patients or staff?

Yes No

Provide no direct benefit to patients or patient care?

Yes No

If the answer to any of these questions is yes, the project should have ethical consideration.

Infringing patient rights — Review any activity that limits or restricts patients’ rights to make choices about their healthcare, such as restricting access to evidence-based practice.

Risk breaching confidentiality or privacy — Review any of the following situations: collecting or disclosing data that could be used to identify any patient; using such small sample sizes that individual patients can be identified; or having someone collect data who does not normally have access to patients’ information or records.

Placing a burden on a patient beyond those of his or her routine care — Review the following types of activities: A patient is required to spend additional time for data collection, provide samples not essential for care or attend extra clinic or home visits; a vulnerable person is required to participate directly; or a patient is asked to answer more than a minimal number of factually based questions or to provide sensitive information.

Involving any clinically significant departure from usual clinical care — Review an activity that varies from accepted current clinical practice or that causes any disruption in the clinician-patient relationship.

Involving a potential conflict of obligation to patients — Review any activity that considers a trade-off between cost and quality for individual patients or a group of patients.

Involving the use of any untested clinical or systems intervention — Consider the risk patients could face if an activity involves implementing a new practice that is not already established.

Allocating any interventions differently among groups of patients or staff — Review if different groups of patients are to be assigned to interventions or treatments or patients are to be recruited to participate in an activity.

Providing no direct benefit to patients or patient care — Review any activity that does not directly benefit the patients participating to ensure that the risk to patients is acceptable.

A proposal for a QI or clinical audit project should reflect the following:

- The explicit intention to improve the quality or safety of patient care
- Quantitative or qualitative measures of quality that are valid and likely to produce reliable data¹⁸
- Data collection and analysis methods that are as rigorous as those that are used in research and undertaken to the highest professional standard^{17, 37}
- Supervision by someone who has been trained to carry out QI or clinical audit projects
- That a team of people have access to consultative advice on the design and conduct of the project^{3, 91}

Check the quality-of-care measures for projects on topics with ethical implications

Clinical audits or QI projects that are on topics that themselves have ethical implications must have well-defined approved standards or policies as the basis for the project.^{19, 25, 28} Quality-of-care measures should be considered carefully to ensure consistency with approved standards or policies. Examples of such topics could include:

- End-of-life care
- Do-not-resuscitate decisions
- Conformance with advance directives
- Patient understanding of information given as part of the consent process
- Healthcare-related decision-making for patients who lack mental capacity
- Care of women who experience a miscarriage or stillbirth

Review the design

A project that is poorly designed is a waste of time and is unlikely to result in improvements in the quality of patient care.³⁸ A project that does not use scientifically valid methods or is unlikely to provide scientifically credible evidence should not be carried out.^{8, 23, 36} Individual practitioners working at

local level may decide on a topic for a clinical audit or QI project, and how to undertake the project, without consultation with colleagues or other stakeholders. The conduct of projects by individuals without oversight can raise questions about the validity and ethicality of some projects being carried out.²⁶

*'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.... Every study, whether audit or research, should have some prospect of succeeding in its stated aim. The lower the likelihood of an investigation achieving its goal, the less risk or burden that the patient should bear, and generally the more it should be subjected to external ethical scrutiny.'*³⁵

For guidance on good practice in clinical audit, see [New principles of best practice in clinical auditⁱ](#) at [HQIP Criteria and indicators of best practice in clinical auditⁱⁱ](#) [Guidance](#).

For checklists on the design and conduct of clinical audits and QI projects, see [Guide for clinical audit leads](#) at www.hqip.org.uk.

Action to consider

Ensure that there is a robust process to screen proposals for QI projects and clinical audits to identify and act on any possible ethical issues embedded in a project



TOP TIPS

Review reports

After data have been collected and acted on in a QI or clinical audit project, a report should be prepared and submitted to those responsible for overseeing QI and clinical audit processes in the organisation. As part of the oversight process, the findings of the project should be reviewed and a judgement made about the effectiveness of action taken to achieve improvements in the quality or safety of patient care.

Consider findings of measurement of current practice

The circumstances listed in the box overleaf have been derived from the literature to indicate when the consequences to the health of patients should be assessed and action taken accordingly.^{5, 7, 18, 24, 26, 30-36, 42, 86, 87, 92, 93}

i Burgess, R. Moorhead, J. New Principles of Best Practice in Clinical Audit, 2011.

ii HQIP, Best Practice in Clinical Audit, 2016.

Questions to guide whether the findings of QI or clinical audit projects should be screened for possible ethics issues

Do the findings from a QI or clinical audit project represent any of the following ethical issues?

A serious risk for patients whose care was measured or for similar patients, for example, if care actually provided was inconsistent with evidence-based practice?

Yes No

A patient for whom a life-threatening or quality-of-life threatening shortcoming in care happened, for example, if a patient with a diagnosis requiring specialist treatment was not referred for treatment?

Yes No

Data that could be used to identify any patient included in the project?

Yes No

Patients experience a clinically significant departure from usual and standard clinical care, for example, if patients require a follow-up assessment, but there is no evidence that the follow-up took place?

Yes No

If the answer to any of these questions is yes, the implications for the patients involved should be assessed.

If a QI or clinical audit project unexpectedly reveals that a patient has experienced a serious incident that has had or could have an important effect on their health or quality of life, the organisation has an obligation to ensure that the incident is disclosed to the patient.⁹⁴ In addition, the organisation has an obligation to ensure that further measurement of actual practice is carried out to verify that the system or process involved has been improved and that the situation is unlikely to recur.⁹⁵

Check on effectiveness of actions implemented

QI and clinical audit projects aim to improve or maintain the quality or safety of patient care. However, there is a risk that the proposed changes taken to achieve improvements will be ineffective or even possibly harmful.³⁴ Therefore, changes in patient care or service delivery need to be risk assessed to pre-empt what could go wrong during the implementation of a change and to identify what to do if it does.¹³

QI or clinical audit projects that do not achieve needed changes to the provision of patient care may fail to meet the ethical responsibilities of healthcare professionals and

organisations to improve quality.¹⁶ If a project indicates that effective practice is not now being provided to patients, it would be unethical to continue to provide substandard care and to withhold improvements in practice from patients.^{37, 38} On the other hand, lessons learned about the clinical impact and outcomes of successful projects that have achieved substantial improvements should be disseminated within the organisation in order to promote organisational learning and spread the implementation of improvements.⁹⁶

Action to consider

Ensure that:

- There is a robust process to consider the findings of measurement in QI projects and clinical audits to identify and act on any possible ethical issues revealed through data collection
- The effectiveness of actions taken to achieve needed improvements in care is demonstrated through valid and reliable measurement



TOP TIPS

Managing possible ethics issues in a QI or clinical audit programme

There are five ethical issues related to a QI or clinical audit programme. Healthcare professionals and organisations should provide for reviewing programmes to ensure that the

issues are addressed. The bases for systems that should be in place in healthcare organisations are explained in the sections following the box.

1. All healthcare professions participate

It has been acknowledged that all healthcare professionals have a responsibility to provide the best possible patient care. This professional responsibility could be interpreted to mean that not being involved in QI or clinical audit could be a breach of a professional code of conduct.^{23,97} Each healthcare professional's duty to prevent harm to patients through his or her acts or omissions extends to the duty to participate in QI or clinical audit projects.⁹¹⁻⁹⁸

2. All clinical services involved

All clinical directorates and services should have an active QI and clinical audit programme that has the overall aim of achieving improvements in the quality or safety of patient care.

3. A systematic approach to setting priorities

Setting priorities for QI or clinical audit projects can be influenced by a number of factors, such as commissioner and regulatory requirements and expectations, resources

available to support the work, pressure from patient groups, or the perceived ease or difficulty attached to carrying out work on a particular subject.⁸⁹ For example, in some organisations, there is a perception that topics for clinical audits have tended to focus on satisfying external pressures rather than on the integrity of clinical services' self-measurement and self-regulation.²² An ethical approach to QI and clinical audit would include a system for setting priorities for projects based on a risk-benefit analysis of disease burden and patient need.¹⁸

4. All patient groups and types of conditions included

The ethical principle of justice and fairness suggests that no patient group should be excluded from the possibility of inclusion in a QI or clinical audit project. Criteria used to define patient groups to be included or excluded (for example, patient characteristics such as gender, race, ethnicity, age or disease site, or staff characteristics, such as profession or role in a healthcare organisation) need to be justified.²⁹ In addition, the potential burdens or risks and the potential benefits of QI or clinical audit projects should be distributed fairly across the population of patients who are served by the healthcare organisation.¹⁸

5. Projects are managed

In many healthcare organisations, QI and clinical audit projects are decentralised, fragmented, not supervised, under-resourced and ad hoc.^{10, 88} Arrangements should be in place for the management of these projects that include;

oversight of ethical issues; the quality of the design; implementation of the work; information sharing, and the resources allocated to each project.⁹⁶

Action to consider

Ensure that the QI and clinical audit programme:

- Involves all professions working in the organisation and all clinical services
- Uses a systematic approach for setting priorities for QI or clinical audit projects
- Includes all patient groups and types of conditions
- Manages the projects being undertaken



Managing ethics and QI and clinical audit in a healthcare organisation

Organisational structure for oversight

It may not always be clear who is accountable for the effective conduct of QI and clinical audit projects, and who is responsible for ensuring that ethical issues are identified, considered and addressed.^{18, 24} Therefore, a healthcare organisation needs to ensure that these projects have appropriate oversight as part of the clinical governance arrangements in the organisation.^{10, 18, 24, 29, 33, 99, 100} The ethical oversight structure also should include the organisation's patient safety programme because these activities also can involve risks to patients.¹⁰¹

Oversight should protect patients from ad hoc or poorly conceived projects and should ensure that the organisation has a robust strategic programme that is achieving substantial improvements in the quality and safety of patient care.¹⁰

Designate leadership and individual responsibility

Most healthcare organisations have appointed leads for clinical audit that are responsible for leading and overseeing clinical audits in their services or directorates. (See [Guide for clinical audit leads](http://www.hqip.org.uk/resources/guide-for-clinical-audit-leads/) at www.hqip.org.uk/resources/guide-for-clinical-audit-leads/)

It is less clear, however, if leaders for QI work are designated in clinical services and directorates, and if such individuals have training in leading staff to carry out QI projects and to oversee their effectiveness.

An individual or a team undertaking a QI or clinical audit project should inform a designated QI or clinical audit lead or an appropriate clinical supervisor or manager that the project is being undertaken¹⁶ and seek approval or authorisation for the project. Individual members of staff may not recognise when a project includes an ethics-related issue.³⁰

Assess organisational oversight structure

Many healthcare organisations have a Clinical Audit or Clinical Effectiveness Committee that oversees the conduct of local and national clinical audits. However, such a committee may not include the oversight of QI projects in its terms of reference. Mechanisms could include any or all of the options in the box below.

Possible organisational mechanisms for overseeing ethics issues in QI and clinical audit projects

- Directorate or department or service heads assume responsibility for screening QI project proposals and for referring those that require further assessment of any ethical issue to a designated individual or group. These senior managers also should assume responsibility for the effectiveness of actions taken as part of projects^{16, 102}
- A director for QI, clinical audit and/or clinical governance assumes responsibility for oversight of QI and clinical audit projects¹⁶
- A designated committee, accountable to the governance structure of the organisation, assumes responsibility for the oversight of QI and clinical audit projects, including the screening of proposals for projects and the review of findings¹⁰²

Some organisations have considered that a Research Ethics Committee can be asked to oversee QI and clinical audit projects from an ethics perspective^{7, 18, 102–104} Another suggestion has been that the Chair of a Research Ethics Committee could be asked for guidance in relation to ethical issues in QI or clinical audit projects and could authorise projects that involve no more than minimal risk to patients.^{12, 55} However, a number of reasons have been given for not involving a Research Ethics Committee in QI and clinical audit activities including the following:

- There are significant differences between research and QI or clinical audit with regard to the obligations of a healthcare organisation.^{30, 45} Research is an optional activity in a healthcare organisation. No individual or organisation is obligated to carry out research,⁸ however QI and clinical audit processes, on the other hand, are ethically intrinsic to the provision of care, a morally and legally mandatory activity that should be integrated into the operations of a healthcare organisation.^{8, 90} QI and clinical audit activities should not be viewed as a set of staff projects, but as the heart of the operation of a healthcare organisation, representing its commitment to improve the quality and safety of patient care¹⁰
- Individuals who are leading QI or clinical audit projects need to take responsibility for leading changes in practice needed to achieve improvements; this responsibility cannot be delegated to a Research Ethics Committee to oversee. Research Ethics Committees do not exist to assess projects that involve changing practices and systems in the delivery of patient care.¹⁰ Therefore, QI and/or clinical audit leads need to also assume responsibility for identifying and managing any ethics issues related to the projects^{10, 18, 24, 29, 33, 88, 99}
- Research Ethics Committees are often overworked and have lengthy backlogs.^{3, 5, 10, 40} Given the urgency of improvement in the quality and safety of healthcare, it is counterproductive to contemplate delays in the important business of redesigning the quality and safety of patient care¹⁰

- Research Ethics Committees may lack the knowledge and expertise needed to evaluate QI or clinical audit projects^{5, 30, 40}
- Staff members who are now involved and committed to carrying out QI or clinical audit projects could be discouraged from undertaking such projects in the first place if they could experience barriers such as additional paperwork, alongside delays and frustrations associated with Research Ethics Committee review before the work on a project could begin.^{3, 32, 40} The typical Research Ethics Committee process could have a ‘chilling effect on studies that could substantially improve error-prone systems and that expose participants to risks no greater than those incurred during routine patient care’⁴⁶

Action to consider

Ensure that the organisation has:

- Designated someone who is accountable for ensuring that ethical issues in QI and clinical audit projects are identified, considered and addressed. Options could include: a director of clinical service; a QI, clinical audit or clinical governance director; or a designated committee
- Confirmed that it is the role of the leads of QI projects or clinical audits to identify and address any ethics issues in these activities



Organisational systems for oversight of QI and clinical audit projects

Healthcare organisations need several systems in place to support the oversight of QI and clinical audit projects, particularly to identify and manage any ethics issues in the projects. Examples of systems that might be needed are in the box below.

Possible organisational systems for overseeing ethics issues in QI and clinical audit projects	
Provide a corporate register of QI and clinical audit projects	<p>Register QI projects or clinical audits using the organisation's intranet, to enable staff members who are carrying out a project to quickly and easily provide information about the project</p> <p>Include a short series of questions in the organisation's proposal template that would flag whether or not the proposed project could include any ethics issues that require further review⁹⁶</p>
Disseminate organisational policies and guidance for QI and clinical audit projects	<p>Share organisational policies to provide guidance for staff members on the proper design and conduct of QI and clinical audit projects and when ethics oversight of a project may be needed^{105, 106}</p> <p>Examples of possible policies could include:</p> <ul style="list-style-type: none"> • How data are to be collected and analysed to maintain confidentiality and anonymity of the people whose care is measured • Information to patients about QI and clinical audit activities and the use of their personal health information in these activities • When patient permission or consent is needed for participation in a project • How a proposal is screened for ethics issues and the levels and types of review of any ethics issues • Action to be taken if a serious incident involving a patient is revealed through a QI or clinical audit project
Provide for ethical consideration of a QI or clinical audit project that is designed to contain or control or reduce costs	<p>Arrange for consideration of the ethical implications of a QI project that:</p> <ul style="list-style-type: none"> • Has the sole purpose of controlling or reducing costs • Represents a potential conflict of interest in the provision of services to patients^{16, 107} <p>Patients may need to be protected from projects that are primarily intended to curtail essential services without clinical justification, or to substitute therapies when evidence is lacking that intended outcomes can be achieved safely^{7, 46, 104}</p>
Include carrying out QI and clinical audit projects in job descriptions and performance appraisals for all clinical staff	<p>Refer to an expectation that staff members will participate in QI and clinical audit projects in job descriptions, performance appraisals and continuing development programmes, including that any projects involving an ethics issue will be reviewed¹⁶⁻¹⁸</p>
Teach staff about the organisation's policies and systems for identifying and managing ethics issues in QI and clinical audit projects	<p>Inform staff, through induction and training sessions, about QI and clinical audit processes and of the organisation's policies and systems for screening proposals for QI and clinical audit projects. Include identifying and managing ethics related to the activities^{18, 24, 101, 108}</p>

Track completion of QI and clinical audit projects	Develop and implement a system for tracking progress in the conduct of QI and clinical audit projects ¹⁸ Monitor projects for non-compliance with approved policies ¹⁰¹ and ensure that any failure to conduct a project in accordance with approved policies is reported as an incident ¹⁶
Review potential publication of QI or clinical audit projects	Provide for appropriate review for individuals who wish to publish a QI or clinical audit project ^{16, 101} Some journals still require evidence that an ethics review has been carried out on a QI or clinical audit project prior to the conduct of the project. With a routine ethics screening process in place for all proposals for QI or clinical audit projects, this requirement can be deemed to have been met

Action to consider

Consider the following organisational systems to oversee possible ethical issues in QI or clinical audit projects:

- Provide a corporate register of QI and clinical audit projects
- Disseminate organisational policies and guidance for QI and clinical audit projects
- Provide for ethical consideration of a QI or clinical audit project that is designed to contain or control or reduce costs
- Include carrying out QI and clinical audit projects in job descriptions and performance appraisals for all clinical staff
- Teach staff about the organisation's policies and systems for identifying and managing ethics issues in QI and clinical audit projects
- Track completion of QI and clinical audit projects
- Review potential publication of QI or clinical audit projects

Research on QI methods or interventions

Recognising research about QI

QI and clinical audit projects focus on translating existing knowledge about best practice, derived from research and other forms of evidence-based information, into routine clinical practice. They provide important information on how to apply existing knowledge and implement changes that may be needed to achieve the best possible clinical outcomes.⁷² These types of projects may be seen as 'routine' QI or clinical audit projects.¹⁰⁵

Changes in practice resulting from QI or clinical audit projects often involve routine operational interventions. Examples might include: clarifying or redefining clinical policies or procedures based on evidence-based practice; training staff to implement new policies or procedures; implementing a new form of routinely recording patient care interventions; or changing a process of care to eliminate steps that don't contribute to providing quality care.

More complex QI projects can involve changing major systems that support the delivery of care or service or devising completely novel interventions to achieve improvements in the quality of care or service. Such projects may be seen as 'non-routine' QI activities.¹⁰⁵ It can be unclear how much risk is involved in these projects, particularly for individual or groups of patients who may experience the major systems change or novel intervention. These types of projects should have ethical oversight by an organisational mechanism that provides for appropriate risk assessment for patients and considers the balance of benefits to patients in comparison to possible risks.

A third type of activity involves the testing of alternative systems or methods for organising or delivering care. This

type of activity most appropriately should be identified as QI research. Such projects typically involve patients accessing care or services that differs from established best practice or usual clinical care, and therefore, meet criteria that define a research study.

These QI research projects require formal ethical committee application and review. The results of the interventions being tested in the research are unknown, and therefore, patients are at risk of not receiving care that will benefit them.

Action to consider

Ensure that research on QI methods or interventions is subject to formal ethics review



TOP TIPS

Seeking ethics review of QI research

The appropriate mechanism for ethics review of QI research proposals in a healthcare organisation is the established Research Ethics Committee. However, to provide the most effective review of QI research proposals, ethics committees should either develop expertise in assessing QI research or include individuals with such expertise on the committee.⁴³

Summary

Healthcare organisations are strongly encouraged to support staff in carrying out QI projects and clinical audits. These activities are essential to support the continuous improvement of the quality and safety of patient care. Organisations that do not proactively support the QI process may be subjecting patients to unnecessary risks associated with not receiving care that is consistent with established best practice.

In many healthcare organisations, clinical audits have been subject to regular corporate oversight through clinical audit leads or committee reviews of proposals for clinical audits, registration of clinical audits in corporate databases and regular presentation of clinical audits at clinical meetings. However, QI activities may not yet be subject to the same types of oversight through effective and appropriate corporate structures and systems. Without such oversight of individual QI projects or the QI process across a healthcare organisation, those responsible cannot know that all work carried out in the name of QI meets ethical principles.

In summary, ethical principles applied to the concept of QI should include that every project or activity or clinical audit meets the following criteria:^{3, 27}

- **Favourable benefit/risk balance** — The QI project or clinical audit should limit risks, such as breaches in confidentiality of privacy, for patients and maximise benefits to patients and patient care. When a project involves more than minimal risks to patients, patients must be fully informed of the project and consent to participation

- **Scientifically valid** — The QI project or clinical audit must be well-designed and methodologically sound, producing demonstrated evidence of the positive effects on patients or patient care resulting from any changes in practice, processes or systems that are implemented as part of the project
- **Equitable and reflecting priorities** — QI projects or clinical audits should include all clinical services, patient conditions and professional groups, and should reflect a systematic approach to setting priorities for improvement of the quality or safety of care or service
- **Value** — The anticipated improvement from the QI project should justify the effort in the use of time and resources
- **Awareness of conflict of obligation to patients** — If a QI project or clinical audit is concerned with or related to reducing the cost of care or allocating services or care, the design and methodology for the project or audit should be carefully reviewed to ensure that care or service provided to patients is not compromised from an ethics perspective

Corporate oversight of QI and clinical audit projects should require individuals or teams carrying out the projects to specify carefully: the objectives to be achieved; methodology; intended benefits and potential risks; and the value of the activity to patient care.²⁷ The process of thinking through the activity is likely to enhance the credibility of the QI or clinical audit project and reduce the likelihood that a poorly developed project is carried out.²⁷

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6th Floor, 45 Moorfields, London, EC2Y 9AE

T 0207 997 7370 F 0207 997 7398

E communications@hqip.org.uk

www.hqip.org.uk

Registered Office: 70 Wimpole Street, London W1G 8AX

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