HQIP
Healthcare Quality Improvement Partnership

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

February 2017

Author:
Nancy Dixon, Healthcare Quality Quest

Next review:
February 2019

 Design: Pad Creative www.padcreative.co.uk

Do you need to print this document? Please consider the environment before printing.

Contents

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.

TOP TIPS

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)	Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings[2, 3] Systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups[4] For QI to occur, the information produced by quality assessment [data collection] must be translated into systematic improvements in healthcare practices[5]
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	An obligation to respect the rights of people to make choices concerning their own lives, for example, by disclosing information to: • Enable people to make decisions • Foster their decision-making • Avoid assuming controlling influence on their decisions Also recognising the right of a person to decline having information about choices and not to make choices on behalf of the person	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 Seeking patients' informed consent
Beneficence	An obligation to act in ways that: • Benefit others • Prevent harm, including removing circumstances that could lead to harm	Meeting a duty of care to provide patient care that is consistent with known good practice

Non-maleficence	An obligation not to: • Harm others • Impose risks of harm Assuming a standard of due care, that is, taking sufficient and appropriate action to avoid causing harm to a person	Maintaining confidentiality of information about patients, and providing privacy for patients 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)
Justice	An obligation to: • Treat others fairly • Distribute scarce resources fairly • Respect people's rights and morally acceptable laws	Avoiding being selective about patients who receive care or a substantial improvement in care Avoiding wasting resources that could be used to better purpose

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 review[2]

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: • 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: • 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 patients[10]
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.

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

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 data[18]
- 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 audit*[i] at *HQIP Criteria and indicators of best practice in clinical audit*[ii] *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

TOP TIPS

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* 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 undertaken[16] 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 projects[16]
- 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 findings[102]

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 care[10]
- 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 care[10]
- 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

TOP TIPS

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	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 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 review[96]
Disseminate organisational policies and guidance for QI and clinical audit projects	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] Examples of possible policies could include: • 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	Arrange for consideration of the ethical implications of a QI project that: • Has the sole purpose of controlling or reducing costs • Represents a potential conflict of interest in the provision of services to patients[16, 107] 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]
Include carrying out QI and clinical audit projects in job descriptions and performance appraisals for all clinical staff	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 reviewed[16-18]
Teach staff about the organisation's policies and systems for identifying and managing ethics issues in QI and clinical audit projects	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]

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

TOP TIPS

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]

References

1. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 4th ed. Oxford: Oxford University Press; 1994.

2. Baily MA, Bottrell M, Lynn J, Jennings B. The Ethics of Using QI Methods to Improve Health Care Quality and Safety. Hastings Cent Rep 2006;36:S1–40.

3. Lynn J, Baily MA, Bottrell M, Jennings B, Levine RJ, Davidoff F, Casarett D, Corrigan J, Fox E, Wynia MK, Agich GJ, O'Kane M, Speroff T, Schyve P, Batalden P, Tunis S, Berlinger N, Cronenwett L, Fitzmaurice JM, Dubler NN, James B. The ethics of using quality improvement methods in health care. Ann Intern Med 2007;146:666–73.

4. Quality improvement. Health Resources and Services Administration. US Department of Health and Human Services. Available at: *www.hrsa.gov/quality/toolbox/methodology/qualityimprovement/index.html*. Last accessed 3 September 2016.

5. Fox E, Tulsky JA. Recommendations for the ethical conduct of quality improvement. J Clin Ethics 2005;16(1):61–71.

6. National Institute for Clinical Excellence. Principles for Best Practice in Clinical Audit. Abingdon: Radcliffe Medical Press; 2002.

7. Lo B, Groman M. Oversight of quality improvement. Focusing on benefits and risks. Arch Intern Med 2003;163(12):1481–6.

8. Bellin E, Dubler NN. The quality improvement-research divide and the need for external oversight. Am J Public Health 2001;91(9):1512–7.

9. Dubler N, Blustein J. Bhalla R, Bernard D. Information participation: an alternative ethical process for including patients in quality-improvement projects. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp. 69–87. Available at: *www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf*. Last accessed 3 September 2016.

10. O'Kane ME. Do patients need to be protected from quality improvement? In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp. 89–99. Available at: *www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf*. Last accessed 3 September 2016.

11. Jennings B, Baily MA, Bottrell M, Lynn J. Introduction. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp. 1–5. Available at: *www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf*. Last accessed 3 September 2016.

12. Human Research Ethics Committee, Faculty of Health Sciences, University of Cape Town. Manual of Standard Operating Procedures, Appendix A, Ethics Guidelines for Audit and Quality Improvement Activities, October 2009. Available at: *www.healthresearchweb.org*. Last accessed 3 September 2016.

13. Gerrish K, Mawson S. Research, audit, practice development and service evaluation: Implications for research and clinical governance. Practice Development in Health Care 2005;4(1):33–9.

14. Ethics approval of research. BMJ. Available at: *www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/ethics-approval-research*. Last accessed 3 September 2016.

15. Barton A. Monitoring body is needed for audit. BMJ 1997;315:1465.

16. Bottrell MM. Accountability for the conduct of quality-improvement projects. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp.129–144. Available at: www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf. Last accessed 3 September 2016.

17. Carr ECJ. Talking on the telephone with people who have experienced pain in hospital: clinical audit or research? J Adv Nurs 1999;29(1):194–200.

18. Casarett D, Fox E, Tulsky JA. Recommendations for the Ethical Conduct of Quality Improvement. A report of the National Ethics Committee of the Veterans Health Administration. Available at: www.ethics.va.gov/docs/necrpts/NEC_Report_20020501_Ethical_Conduct_of_Quality_Improvement.pdf. Last accessed 3 September 2016.

19. Cheung D, Sandramouli S. The consent and counselling of patients for cataract surgery: a prospective audit. Eye 2005;19:963–71.

20. Doyal L. Preserving moral quality in research, audit, and quality improvement. Qual Saf Health Care 2004;13:11–2.

21. Hill Y, MacGregor J. Is clinical audit under threat? Nurs Manage 1999/2000:6(8):6.

22. Hughes R. Is audit research? The relationships between clinical audit and social research. Int J Health Care Qual Ass 2005;18(4):289–99.

23. Kinn S. The relationship between clinical audit and ethics. J Med Ethics 1997;23:250–3.

24. Layer T. Ethical conduct recommendations for quality improvement projects. J Healthc Qual 2005;25(4):44–6.

25. Lowe J, Kerridge I. Implementation of guidelines for no-CPR orders by a general medical unit in a teaching hospital. Aust N Z J Med 1997;27(4):379–83.

26. National Ethics Advisory Committee. Ethical Guidelines for Observational Studies: Observational research, Audits and Related Activities. Revised edition. Wellington: Ministry of Health; 2012. Available at: www.neac.health.govt.nz/system/files/documents/publications/ethical-guidelines-for-observational-studies-2012.pdf. Last accessed 3 September 2016.

27. Nelson WA. Proposed ethical guidelines for quality improvement. Healthc Exec 2014;Mar-Apr;29(2):52, 54–5.

28. Sehdev SS, Wilson A. Hospital care given in the event of a miscarriage: views of women and their partners, and an audit of hospital guidelines. Journal of Clinical Excellence 2000;2:161–7.

29. Holm MJ, Selvan M, Smith ML, Markman M, Theriault R, Rodriguez MA, Martin S. Quality improvement or research: defining and supervising QI at the University of Texas MD Anderson Cancer Center. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp.145–¬68. Available at: www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf. Last accessed 3 September 2016.

30. Cave E, Nichols C. Clinical audit and reform of the UK research ethics review system. Theor Med Bioeth 2007;28(3):181¬–203.

31. Cretin S, Lynn J, Batalden PB, Berwick DM. Should patients in quality-improvement activities have the same protections as participants in research studies? JAMA 2000;284(14):1786.

32. Davidoff F. Publication and the ethics of quality improvement. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp. 101–6. Available at: www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf. Last accessed 3 September 2016.

33. Morris PE, Dracup K. Quality improvement or research? The ethics of hospital project oversight. Am J Crit Care 2007;16:424–6.

34. Perneger TV. Why we need ethical oversight of quality improvement projects. Int J Qual Health Care 2004;16(5):343–44.

35. Wade DT. Ethics, audit, and research: all shades of grey. BMJ 2005;330:468–73.

36. Boult M, Maddern GJ. Clinical audits: why and for whom. ANZ J Surg 2007;77:572–8.

37. Rix G, Cutting K. Clinical audit, the case for ethical scrutiny? Int J Health Care Qual Ass 1996;9(6):18–20.

38. Smith R. BMJ's preliminary response to the need for ethics committee approval (letter). BMJ 2000;320:713.

39. Brown LH, Shah MN, Menegazzi JJ. Research and quality improvement: drawing lines in the grey zone (editorial). Prehosp Emerg Care 2007;11:350–1.

40. Hagen B, O'Beirne M, Desai S, Stingl M, Pachnowski CA, Hayward S. Innovations in the Ethical Review of Health-related Quality Improvement and Research: The Alberta Research Ethics Community Consensus Initiative (ARECCI). Healthc Policy 2007;2(4):1–14.

41. Lynn J. When does quality improvement count as research? Human subject protection and theories of knowledge. Qual Saf Health Care 2004;13:67–70.

42. Wise LC. Ethical issues surrounding quality improvement activities. J Nurs Adm 2007;37(6):272–8.

43. Markman M. The role of independent review to ensure ethical quality-improvement activities in oncology: a commentary on the national debate regarding the distinction between quality-improvement initiatives and clinical research. Cancer 2007;110(12):2597–600.

44. Reynolds J, Crichton N, Fisher W, Sacks S. Determining the need for ethical review: a three-stage Delphi study. J Med Ethics 2008;34:889–94.

45. Driscoll A, Currey J, Worrall-Carter L, Steward S. Ethical dilemmas of a large national multi-centre study in Australia: time for some consistency. J Clin Nurs 2008;17(16):2212–20.

46. Lindenauer PK, Benjamin EM, Naglieri-Prescod D, Fitzgerald J, Pekow P. The role of the Institutional Review Board in quality improvement: a survey of quality officers, Institutional Review Board chairs, and journal editors. Am J Med 2002;113:575–9.

47. Maxwell DJ, Kaye KI. Multicentre research: negotiating the ethics approval obstacle course (letter). Med J Aust 2004;181(8):460.

48. Wilson A, Grimshaw G, Baker R, Thompson J. Differentiating between audit and research: postal survey of health authorities' views. BMJ 1999;319:1235.

49. Whicher D, Kass N, Saghai Y, Faden R, Tunis S, Pronovost P. The views of quality improvement professionals and comparative effectiveness researchers on ethics, IRBs, and oversight. J Empir Res Hum Res Ethics 2015;10(2):132–44.

50. Candib LM. How turning a QI project into 'research' almost sank a great program. Hastings Center Report 2007;37:26–30.

51. Choo V. Thin line between research and audit (commentary}. Lancet 1998;352:337–8.

52. Doezema D, Hauswald M. Quality improvement or research: a distinction without a difference? IRB 2002;24:9–12.

53. Goodyear-Smith F, Arroll B. Audit or research? N Z Med J 2001;114:499–502.

54. Miller FG, Emanuel EJ. Quality improvement research and informed consent. N Engl J Med 2008;358(8):765–7.

55. Neff MJ. Institutional Review Board consideration of chart reviews, case reports, and observational studies. Respir Care 2008;53(10):1350–3.

56. Palevsky PM, Washington MS, Stevenson JA, Rohay JM, Dyer NJ, Lockett R, Perry SB. Improving compliance with the dialysis prescription as a strategy to increase the delivered dose of hemodialysis: an ESRD network 4 quality improvement project. Adv Ren Replace Ther 2000;7(4 Suppl 1):S21–30.

57. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, Sexton B, Hyzy R, Welsh R, Roth G, Bander J, Kepros J, Goeschel C. An intervention to decrease catheter-related bloodstream infections in the ICU. N Engl J Med 2006;355(26):2725–32.

58. Savel RH, Goldstein EB, Gropper MA. Critical care checklists, the Keystone Project, and the Office for Human Research Protections: a case for streamlining the approval process in quality-improvement research. Crit Care Med 2009;37(2):725–8.

59. Snijders RJ, Noble P, Sebire N, Souka A, Nicolaides KH. UK multicentre project on assessment of risk of trisomy 21 by maternal age and fetal nuchal-translucency thickness at 10–14 weeks of gestation. Fetal Medicine Foundation First Trimester Screening Group. Lancet 1998;352(9125):343–6.

60. Health Research Authority. Defining research; 2009, revised June 2016. Available at: www.hra.nhs.uk/documents/2016/06/defining-research.pdf. Last accessed 3 September 2016.

61. Ogrinc G, Nelson WA, Adams SM, O'Hara AE. An instrument to differentiate between clinical research and quality improvement. IRB 2013;35(5):1–8.

62. Casarett D, Karlawish JHT, Sugarman J. Determining when quality improvement initiatives should be considered research. JAMA 2000;283(17):2275–80.

63. Alberta Research Ethics Community Consensus Initiative (ARECCI) Network. ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects; 2008. Available at: www.aihealthsolutions.ca/arecci/guidelines/. Last accessed 3 September 2016.

64. Alberta Research Ethics Community Consensus Initiative (ARECCI) Network. ARECCI Ethics Screening Tool; 2005, revised 2008. Available at: www.aihealthsolutions.ca/arecci/screening/132382/5e9f2b8dc46f8c07c2839223948b2003. Last accessed 3 September 2016.

65. Babalis K, Harnett E, Steinhoff K. Implementation of the process of ethical review of improvement activities at the Children's Hospital at Westmead. BMJ Qual Saf 2011;20(4):366–71.

66. Cooper JA, McNair L. How to distinguish research from quality improvement. J Empir Res Hum Res Ethics 2015;10(2):209–10.

67. De Lusignan S, Liyanage H, Di Iorio CT, Chan T, Liaw ST. Using routinely collected health data for surveillance, quality improvement and research: framework and key questions to assess ethics, privacy and data access. J Innov Health Inform 2016;22(4):426–32.

68. Goldman B, Dixon LB, Adler DA, Berlant J, Dulit RA, Hackman A, Oslin DW, Siris SG, Valenstein M. Rational protection of subjects in research and quality improvement activities. Psychiatr Serv 2010;61(2):180–3.

69. Henry B. Making a decision about your project: is it quality improvement or research? Can Oncol Nurs J 2014;Spring 24(2):118–120.

70. Hicks RW. Maintaining ethics in quality improvement. AORN J 2016;103(2):139-41.

71. Hill SL, Small N. Differentiating between research, audit and quality improvement: governance implications. Clin Gov 2006;11(2):98–107.

72. Hockenberry M. Quality improvement and evidence-based practice change projects and the Institutional Review Board: is approval necessary? Worldviews Evid Based Nurs 2014;11(4):217–8.

73. Human Research Ethics Committees. Quality Improvement & Ethical Review: A Practice Guide for NSW, 21 November 2007. Available at: wwwo.health.nsw.gov.au/policies/gl/2007/pdf/GL2007_020.pdf. Last accessed 3 September 2016.

74. Raval MV, Sakran JV, Medbery RL, Angelos P, Hall BL. Distinguishing QI projects from human subjects research: ethical and practical considerations. Bull Am Coll Surg 2014;99(7):21–7.

75. Rees M. Ethics and studies in human beings: research, service evaluation or audit. Maturitas 2009;64(4):199–200.

76. Somers A, Mawson S, Gerrish K, Schofield J, Debbage S, Brain J. The Simple Rules Toolkit: an educational tool designed to help staff differentiate between clinical audit, research and service review activities. Available at: *www.clahrc-cp.nihr.ac.uk/wp-content/uploads/2012/07/Simple-Rules-Toolkit_2.pdf*. Last accessed 3 September 2016.

77. Taylor HA, Pronovost PJ, Faden RR, Kass NE, Sugarman J. The ethical review of health care quality improvement initiatives: findings from the field. Issue Brief (Commonw Fund) 2010;95:1-12.

78. Taylor HA, Pronovost PJ, Sugarman J. Ethics, oversight and quality improvement initiatives. Qual Saf Health Care 2010;19(4):271–4.

79. Research Ethics Committees (RECs). NHS Health Research Authority. Available at: *www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs/*. Last accessed 3 September 2016.

80. Abbasi K, Heath I. Ethics review of research and audit (editorial). BMJ 2005;330:431–2.

81. Grifiths P. But who decides when review is needed? (eletter). BMJ 2005; 26 February. Available at: *www.bmj.com/rapid-response/2011/10/30/who-decides-when-review-needed*. Last accessed 3 September 2016.

82. Weiserbs KF, Lyutic L, Weinberg J. Should quality improvement projects require IRB approval? (letter). Acad Med 2009;84(2):153.

83. Lemaire F. Informed consent and studies of a quality improvement program (letter). JAMA 2008; 300:1762.

84. 84. Siegel MD, Alfano S. The ethics of quality improvement research. Crit Care Med 2009;37(2):791–2.

85. Nelson WA, Gardent PB. Ethics and quality improvement. Healthc Exec 2008;23(4):40–1.

86. Nerenz DR, Stoltz PK, Jordan J. Quality improvement and the need for IRB review. Qual Manag Health Care 2003;12(3):159–70.

87. Seddon M, Buchanan J. Quality improvement in New Zealand healthcare. Part 3: achieving effective care through clinical audit. N Z Med J 2006;119(1239):U2108.

88. Tapp L, Edwards A, Elwyn G, Holm S, Eriksson T. Quality improvement in general practice: enabling general practitioners to judge ethical dilemmas. J Med Ethics 2010;36:184–8.

89. Tapp L, Elwyn G, Edwards A, Holm S, Eriksson T. Quality improvement in primary care: ethical issues explored. Int J Health Care Qual Assur 2009;22(1):8–29.

90. WMA Declaration on Guidelines for Continuous Quality Improvement in Health Care. Adopted by the 49th World Medical Assembly, November 1997 and amended October 2009. Available at: *www.wma.net/en/30publications/10policies/g10/index.html*. Last accessed 3 September 2016.

91. Hagger L, Woods S, Barrow P. Autonomy & audit — Striking the balance. Med Law Int 2004;6(2):105–16.

92. Meenan G, Taylor D. Unexpected outcomes and ethical considerations arising out of an audit of management of paediatric urinary tract infection. J Clinical Governance 2001;9:5–9.

93. Kofke WA, Rie MA. Research ethics and law of healthcare system quality improvement: the conflict of cost containment and quality. Crit Care Med 2003;31(Suppl):143–52.

94. Regulation 20: Duty of candour. Care Quality Commission. Available at: *www.cqc.org.uk/content/regulation-20-duty-candour*. Last accessed 3 September 2016.

95. Somers A, Stephenson T. Managing untoward findings from clinical audit — keeping the can of worms under control. Bulletin of the Royal College of Pathologists 2004;126:11–4.

96. Paxton R, Whitty P, Zaatar A, Fairbairn A, Lothian J. Research, audit and quality improvement. Int J Health Care Qual Assur 2006;19(1):105–11.

97. Wynia MK, Kurlander MK. Physician ethics and participation in quality improvement: renewing a professional obligation. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp. 7–27. Available at: *www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf*. Last accessed 3 September 2016.

98. General Medical Council. Good medical practice, March 2013, updated April 2014, pp. 10. Available at: *www.gmc-uk.org/static/documents/content/GMP_.pdf*. Last accessed 3 September 2016.

99. Diamond LH, Kliger AS, Goldman RS, Palevsky PM. Commentary: Quality improvement projects: how do we protect patients' rights? Am J Med Qual 2004;19(1):25–7.

100. James BC. Quality-improvement policy at Intermountain Healthcare. In: Jennings B, Baily MA, Bottrell M, Lynn J, editors. Health Care Quality Improvement: Ethical and Regulatory Issues; 2007, pp. 169–76. Available at: *www.thehastingscenter.org/wp-content/uploads/Health-Care-Quality-Improvement.pdf*. Last accessed 3 September 2016.

101. Nelson WA, Neily J, Mills P, Weeks WB. Collaboration of ethics and patient safety programs: opportunities to promote quality care. HEC Forum 2008;20(1):15–27.

102. Johnson N, Vermeulen L, Smith KM. A survey of academic medical centers to distinguish between quality improvement and research activities. Qual Manag Health Care 2006;15(4):215–20.

103. Low-Beer TS. Ethics committee review of medical audit: a personal view from the United Kingdom. Sex Transm Infect 2001;77(1):72.

104. Koschnitzke L, McCracken SC, Pranulis MF. Ethical considerations for quality assurance versus scientific research. West J Nurs Res 1992;14(3):392–6.

105. Finkelstein JA, Brickman AL, Capron A, Ford DE, Gombosev A, Greene SM, Iafrate RP, Kolaczkowski L, Pallin SC, Pletcher MJ, Staman KL, Vazquez MA, Sugarman J. Oversight on the borderline: quality improvement and pragmatic research. Clin Trials 2015;12(5):457–66.

106. Fiscella K, Tobin JN, Carroll JK, He H, Ogedegbe G. Ethical oversight in quality improvement research: new approaches to promote a learning health care system. BMC Med Ethics 2015;16(1):63.

107. Rie MA, Kofke WA. Nontherapeutic quality improvement: the conflict of organisational ethics and societal rule of law. Crit Care Med 2007;35(2 Suppl):S66–84.

108. Stirrat GM, Johnston C, Gillon R, Boyd K. Medical ethics and law for doctors of tomorrow: the 1998 Consensus Statement updated. J Med Ethics 2010;36(1):55–60.

Further information is available at: www.hqip.org.uk

ISBN NO 978-1-907561-20-7

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
Registration No. 6498947
Registered Charity Number: 1127049

February 2017. Next review date: February 2019