HQIP
Healthcare Quality
Improvement Partnership

Review of Ethics Issues related to Clinical Audit and Quality Improvement Activities

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Clinical audit tool to promote quality for better health services

Contents

Introduction

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

Clinical audit may be defined as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery".[1]

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

This document should be read in conjunction with the following:

- the separate glossary provided
- other relevant tools produced as part of this collection by HQIP.

Abstract

Purposes The ethical duty of healthcare practitioners and healthcare organisations to carry out quality improvement (QI) activities, including clinical audit, is established. However, the potential ethics issues associated with these activities aren't always recognised and handled effectively. As clinical audit and QI activities become increasingly more sophisticated, it is becoming inappropriate to use the distinction between research and clinical audit or QI as the basis for deciding if an activity needs ethical review. The purposes of this review of ethics issues related to clinical audit and QI activities were to identify: ethics issues related to clinical audit or QI; circumstances relating to the clinical audit or QI process or activities for which a review of possible ethics issues should be carried out; and healthcare organisational ethical oversight structures and systems for clinical audit and QI.

Method A literature review was carried out to find and analyse publications that referred to any of the following: ethics issues related to clinical audit or QI; clinical audit or QI activity-related circumstances for which a review of ethics issues is needed; and structures, mechanisms or processes in healthcare organisations for reviewing and resolving ethics issues related to clinical audit or QI.

Findings A number of ethics issues related to clinical audit and QI were identified, occurring at three stages in the clinical audit or QI process: proposal development and approval; data collection and analysis; and assessment of the effectiveness of actions taken in response to findings. There are also ethics issues that relate to a clinical audit or QI programme in a healthcare organisation. A variety of structural, systems and process oversight options are available to enable a healthcare organisation to be accountable for identification and appropriate handling of ethics concerns related to clinical audit or QI. The use of the commonly accepted definition of research is being challenged as the basis for deciding if a proposed activity requires ethics review.

Conclusions It is no longer appropriate to use a distinction between research and clinical audit or QI as the basis for deciding if an ethics review of a proposed study is needed. Ethics screening questions should be applied to proposals for all clinical audit and QI activities to ensure that the activities benefit and avoid or minimise risk to patients. Healthcare organisations should have robust structures, mechanisms and processes in place for oversight of clinical audits and QI projects in order to protect patients and avoid waste of scarce healthcare resources.

1 Background

Clinical audits that use existing information already collected as part of routine patient care have been seen as posing no risk to patients except the risk of breach of confidentiality or privacy.[2, 3] Therefore, traditionally, no provision for ethics oversight has been made for clinical audits and similar projects.[4–8] However, as clinical audits evolve into more sophisticated QI activities, formal QI studies can be confused with research[9–11] and there can be controversy on how patient care quality and safety improvement studies are to be handled from a research ethics perspective.[12–18] Also, other ethics issues related to clinical audit and QI have emerged in addition to confidentiality and privacy and there is a need for healthcare organisations to recognise and handle appropriately the ethics issues that relate to these activities.[19]

In view of the evolution of clinical audit into a quality improvement process[1] and the development of related QI initiatives, healthcare organisations have to ensure that there are robust oversight mechanisms in place to safeguard patients whose care is assessed in clinical audit and QI activities and to avoid waste of scarce healthcare resources.

2 Purposes

The purposes of the review of ethics issues related to clinical audit and QI activities were to identify:

- ethics issues related to clinical audit or QI recognised in published literature
- circumstances relating to the clinical audit or QI process or individual clinical audit or QI activities for which a review of possible ethics issues should be carried out
- structures, mechanisms or processes in healthcare organisations for reviewing and resolving ethics issues related to clinical audit or QI suggested in the literature.

3 Method

3.1 Search strategy

The following sources were used to find publications related to ethics and clinical audit or quality improvement: PubMed, Ovid and ProQuest databases; Agency for Healthcare Research and Quality (AHRQ) and the National Library for Health (NLH) websites, and Google search engine. The terms used were 'ethics and clinical audit' or 'ethics and quality improvement' along with health care (or healthcare). No limit was placed on the years searched. Reference lists in publications retrieved were scanned for additional relevant publications. In addition, 61 publications on ethics in health care were retrieved from the Healthcare Quality Quest (HQQ) library.

3.2 Inclusion and exclusion criteria

Publications were read and selected to be abstracted for the review if they referred to any of the following:

- one or more ethics issues related to clinical audit or QI
- circumstances or situations relating to clinical audit or QI processes or activities for which a review of ethics issues should or might be considered
- structures, mechanisms, systems or processes for reviewing and resolving ethics issues related to clinical audit or QI in a healthcare organisation
- rationale for distinguishing between research and clinical audit and other QI activities as a basis for determining if an ethics review is required.

3.3 Abstracting information from the publications

A standardised abstract form was developed for the review. Publications were abstracted by one reviewer and abstracts were validated by a second reviewer for a random sample of publications.

4 Defining ethics and clinical audit

For purposes of this review, the key terms of ethics, clinical audit and quality improvement (QI) are defined in the table.

Table 1. Definitions of key terms

Ethics	The inquiry into certain situations and into the language employed to describe them; the kind of situations referred to are those that have led or may lead to harms or benefits to others.[20]
Clinical audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.[19]
Quality improvement	Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings.[13, 17] For quality improvement to occur, the information produced by quality assessment [data collection] must be translated into systematic improvements in healthcare practices.[21]

4.1 Ethics principles applied to health care

Ethics is a generic term for various ways of understanding and examining morality. Four principles derived from moral theory are: autonomy, beneficence, non-maleficence and justice. An explanation of each principle[20] and examples of their application to health care are in the table on the next page.

Table 2. Ethics principles applied to health care

Principle	Meaning	Examples
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, to foster their decision-making and not to assume controlling influence on their decisions; also recognising the right of a person to choose 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 about associated benefits and risks of the treatments or procedures so that patients can make informed choices about proposed treatments or procedures Seeking patients' informed consent to treatments or procedures
Beneficence	An obligation to act in ways that benefit others and in ways that 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, that is, care that is known to benefit patients
Non-maleficence	An obligation not to harm others and not to 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 patients' information and patients' privacy Avoiding the intentional or unintentional imposition of a risk of harm to a patient, for example, by failing to monitor a patient in accordance with the severity of the patient's condition
Justice	An obligation to treat others fairly, distribute scarce resources fairly and 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

4.2 Clinical audit as a quality improvement (QI) process

Clinical audit has been described as a systematic process of establishing best practice, measuring care against criteria, taking action to improve care and monitoring to sustain improvement.[1] The original aim of clinical audit as a tool for clinical quality assurance was to review patient care in comparison to standards, identify any problems, find the root causes of poor practice and eliminate them, and evaluate actions directed at correcting the problems.[22–24]

Clinical audits that followed this understanding often involved retrospective assessment of the adequacy of treatment or the achievement of intended outcomes, using information in patient records and other routine records of patient care as the basis for measurement of actual practice.[25] This description of a traditional approach to clinical audit positioned audit as a ***quality assurance*** activity.[22, 26]

The definition of clinical audit that is currently accepted in the NHS has shifted clinical audit to a ***quality improvement process***.[1] The new emphasis on implementing changes to achieve improvements has significant implications. The Tavistock ethical principles for everybody involved in health care included the principle of improvement, which states that improving health care is a serious and continuing responsibility.[27]

> "Improvement — This principle means that it isn't good enough to do well. We must aspire to do better, recognising the escalating rate of new knowledge, the rapid advances in technology, that patients want to be partners, and that our healthcare systems are too complex, giving too much room for error and waste. Being serious about improvement (rather than simply paying lip service) means learning the skills of improvement, being willing to accept and even encourage change, and recognising that improvement is never ending. Most health professionals have not mastered the improvement skills, and many resist change."[27]

The emphasis on quality improvement should shift the way clinical audit is carried out. In a QI approach to clinical audit, repeated data collection is used to test different change interventions, including redesigning processes and systems, in order to improve the performance of a clinical service in comparison to measures of good practice.[28] Clinical audit as a QI process should involve members of a team working together to introduce best practices and make them routine, using quantitative feedback on the effects of changes on processes and outcomes.[12] QI implies a more holistic approach to improving the quality of patient care, can involve the patient in defining quality and is more than the sum of discrete audited parts of a service.[29]

The primary intent of QI is to provide all patients with the best possible care.[30] The defining element of QI is the use of measurement and feedback aimed at changing care practices; there is a deliberate aim to improve and the effects of change are monitored.[16] QI tests change on a small scale, using measurement and feedback to create learning opportunities, change care practices and sustain improvements.[4, 25, 31] It is a sequential, dynamic process involving ongoing cycles that measure clinical practice compared with evidence-based benchmarks of best practice, and then devise and try out strategies to improve implementation of best practice.[16, 21, 32–37] QI feeds back measurements rapidly to the care system, leading to further quick modifications in the care process or outcome being measured, with the ultimate goal of achieving an intended improvement.[16, 24, 38]

QI activities emphasise testing interventions, typically changes in processes or systems, within a healthcare organisation. For example, the widely accepted Plan–Do–Check–Act (P–D–C–A) or Plan–Do–Study–Act (P–D–S–A) cycle for quality improvement was described by Shewhart[39] and later Deming[40] as a scientific approach to achieving improvement. In the cycle, the Plan phase provides hypotheses for change; the Do phase is a trial; the Check phase is the measurement of success or failure of the trial; and the Act phase allows drawing conclusions and adapting and/or extending change.[40–43] QI assumes that the quality and safety of patient care are largely influenced by organisational systems and can look like a type of practical problem solving, an evidence-based management style or the application of a theory-driven science of how to bring about system change.[13, 17] The study of causal relationships in QI is explicitly for the purpose of changing local processes to improve quality for those immediately affected by the processes.[43]

The field of QI is progressing rapidly, and the concept of QI is constantly evolving.[44] Efforts are increasingly being directed toward improving the quality and safety of patient care and ensuring that care provided is clinically effective.[45] Therefore, the design and conduct of clinical audits is becoming and will become more sophisticated.[25, 46]

5 Findings

5.1 The obligation to carry out clinical audit and QI

Given the well-documented gap between actual care and evidence-based practice and the shortcomings in patient safety in healthcare organisations,[47] doctors, nurses, allied health professionals and healthcare organisations have an ethical obligation to close the gap in implementation of best known practice and overcome patient safety shortcomings.[4, 24, 26, 48]

Patients are harmed and their opportunity to heal is reduced when the quality of care provided to them is not what it could be. Patients are 'human subjects' who may receive health care that is not safe and effective.[24] Also, some patients may benefit at the expense of others or QI activities may waste scarce healthcare resources.[49] Disciplined and focused QI efforts can increase the effectiveness and safety of health care.[49] Properly conducted, QI can itself be seen as an ethical imperative in health care, something from which both professionals and patients benefit and in which they should cooperate.[49] However, if there is an ethical responsibility to undertake QI efforts, there is also a responsibility to manage and conduct QI effectively to be sensitive to the rights and interests of patients. [24, 49]

The ethical obligations of healthcare organisations derive from multiple sources as follows: [4, 48]

- The health care organisation is a natural extension of medical practice and, so being, is bound by professional oaths and ethics, including codes of practice, to promote the patient's best interests. The compact of trust between patient and doctor encompasses the expectation that the care provided will be characterised by skill, judgement, attention and concern. The health care organisation demonstrates this concern through a rigorous, continuous quality improvement process.
- The healthcare organisation is a distinct moral agent with responsibilities separate from and in addition to those of the individuals who make up the organisation.
- In the social contract between patients and professionals, society has traditionally granted professionals the responsibility to act as guardians of patient health, in exchange for which professionals are obligated to practice according to accepted standards and promote patient well-being through assessing and improving the quality of care. A similar social contract with health care organisations is becoming explicit.

QI activities are thus more systematic and deliberate expressions of normal, ongoing healthcare management and operations.[45]

5.2 Why there is concern about ethics and clinical audit or QI

QI activity is essential among professionals and healthcare organisations and has brought benefits for patients.[44] Yet, while widely accepted ethical standards exist for other activities in the clinical arena, including medical treatment and research, the arrangements for ensuring that clinical audit and QI activities conform to appropriate ethical standards are fragmented, lack clarity and have not been clearly or thoroughly articulated.[21, 23, 40, 42] The ethics of clinical audit has been a neglected area[46–48] and the assumption that audit or analysing previously collected data is never unethical may not be justified.[2] Governance of clinical audit is less explicit than governance of research.[23]

Ethical issues arise in QI because attempts to improve the quality of care for some patients may sometimes inadvertently cause harm, may benefit some patients at the expense of others, or may waste scarce healthcare resources.[13, 17, 49] Ethical issues also arise because some activities aimed at improvement have been interpreted as a form of medical research in which patients are used as subjects[13, 49] and differing standards for distinguishing between QI and research may lead to different conclusions by those making the distinction.[53] Although QI activities have a different focus, the requirement for ethical conduct and ethical oversight of these initiatives should be no less stringent than that mandated for clinical research.[38]

5.3 Differentiating research and clinical audit or QI as a basis for ethics review

5.3.1 The importance of identifying research properly

Clinical research requires participants in the research to take the chance that they will receive a treatment that is not optimal or may even be harmful.[30] Researchers are under no obligation to see to it that an intervention found as a result of their research to be effective will be implemented or continued for those who participate in the study.[30] Participants in research receive no direct benefit from that research.[48] Participation in research, therefore, is voluntary; each participant is entitled to choose whether to be a research subject.[16] It is very appropriate that people who volunteer to participate in research are safeguarded through effective ethics reviews of proposed research projects.

It has become important to attempt to distinguish between research and clinical audit or QI activities to avoid the possibility that clinicians, intentionally or unintentionally, might 'game' the existing system of protection for participants in a research study by designating a project as a clinical audit or QI study rather than as research.[16, 28, 30, 34, 44, 54–55] By so doing, they avoid bureaucratic, time-consuming and frustrating processes of review of research proposals, including requirements for informed consent of the participants.[30, 34, 44]

5.3.2 The problem of reliably differentiating between research and clinical audit or QI

Studies have demonstrated that research ethics committees, medical directors, quality improvement practitioners, and journal editors are not consistent in reaching decisions on whether a proposed project represents research or quality improvement.[56–59] QI practitioners' perspectives on ethical oversight of QI activities differ from those expressed in the literature.[60] Clinical staff may not be aware of any clinical audit monitoring processes, including for ethics issues, in place in their healthcare organisation.[50]

Few healthcare organisations report having formal policies or guidelines related to the review or approval of quality improvement projects.[61] In addition, clinicians in different countries have experienced misunderstanding with authorities as to what constitutes research versus a quality improvement project.[9, 62–63]

Examples of the difficulty clinicians have experienced in differentiating between research and clinical audit or QI projects are summarised in the table.

Table 3. QI projects later determined to be research

An argument made about why the first four projects were determined to be research was that the results were published or presented at professional meetings and thus the projects represented attempts to derive generalisable knowledge, a defining feature of research.

The two–state end stage renal disease (ESRD) 'clinical audit' that was later determined to be research — The 'quality improvement' project involved gathering and analysing routinely collected data on end dialysis laboratory values for all dialysis centres in two states in the USA. The centres with the lowest average end dialysis lab values were given feedback about their performance. They were provided with intensive education on the quality improvement process and required to develop and implement a QI plan. After 9 months, repeat data collection showed some improvement. The team carrying out the project published a report about the project[10] because they learned that improvement in the lab values was resulting from physicians prescribing longer than necessary dialysis times, which counterbalanced a tendency for the dialysis centres to deliver shorter dialysis times than prescribed. The publication aimed to alert readers to watch for creating compensating errors since counterbalancing errors do not create reliable excellence.[16] Some time after the publication appeared, the USA Government's Department of Health and Human Service's Office for Human Research Protections (DHHS–OHRP) determined that the project met the definition of human subjects research and was not exempt from review as a research project.

The state-wide QI project on central line-associated bloodstream infections in ICU that was later determined to be research — A 'patient safety' project to evaluate the use of a patient safety programme and a checklist to reduce the rate of central line–associated bloodstream infections was carried out in 103 intensive care units in the USA state of Michigan. The ICU-based patient safety programme was intended to improve the 'culture of safety'. The checklist was intended to ensure that the following five evidence-based procedures were followed during catheter insertion: hand washing; using full barrier precautions; cleaning the skin with chlorhexidine before insertion; avoiding the femoral site if possible; and removing unnecessary catheters as soon as possible. A report of the project showed an up to 66% reduction in rates of catheter-related blood stream infection that was maintained throughout the 18-month study period. Following publication,[10] the DHHS–OHRP determined that the project should not have been exempt from full review as a research project; each hospital should have reviewed the project as a research project; and informed consent from the 'subjects' should have been obtained.[14]

The QI project on Chlamydia screening that was later determined to be research — A 'quality improvement' project was carried out to evaluate the use of urine tests rather than cervical samples to diagnose Chlamydia in an emergency department. The project was later determined by the DHHS–OHRP to be a research project.[9]

The clinical audit on family planning that was later determined to be research — A retrospective review of clinical records of consecutive patients seen at an abortion clinic was carried out. Data collected included preconception contraception and why this failed (including whether a patient had stopped taking combined oral contraceptives in response to fears raised by publicity regarding venous thromboembolism); risk factors of venous thromboembolism; and post-termination contraception. Prior to publication, the project was determined to be research by the Ethics Committee of the Health Research Council in New Zealand.[64]

The clinical audit on assessment of risk of Down's Syndrome that was later questioned as being research — A multicentre project on assessment of risk of trisomy 21 by maternal age and fetal nuchal-translucency thickness at 10–14 weeks of gestation was published as an "audit of results from a clinical service." The report compared the prevalent method of detecting women at a high risk of carrying a fetus with trisomy 21 (Down's Syndrome) which involved a combination of the maternal age and a second-trimester maternal serum biochemistry with an emerging method, which combined maternal age with a nuchal-translucency thickness ultrasound scan at the end of the first trimester. Following publication,[65] there was criticism of the report on the basis that it was research that should have been subject to ethics review. The journal in which the project was published commented on a "quandary about where the line should be drawn between research and audit." [66]

The mechanism developed to govern ethical conduct in one important area — human subjects research — could have the perverse, if unintended, consequence of interfering directly with an equally important ethical imperative in another area — that is, unceasing efforts by healthcare professionals to make clinical care safer and more effective.[13]

5.3.3 Concepts used to differentiate research and clinical audit and QI

The National Research Ethics Service (NRES) has published guidance that differentiates among research, clinical audit and service evaluation (see Appendix 1).[5] The NRES identifies four key discriminants among the activities: intent; treatment; allocation; and randomisation.

Whether or not these concepts or other concepts associated with research are sufficient to differentiate research and clinical audit and QI for ethics review purposes is being questioned. Research and clinical audit have many similarities. They both start with a question, both expect the answer to change or influence clinical practice, both require formal data collection on patients, and both depend on using an appropriate method and design to reach sound conclusions.[67] How key research concepts can apply to clinical audit or QI is illustrated in the table on the next page.

Table 4. How clinical audit and QI relate to key research concepts

Research concept	How clinical audit and QI relate to the concept
Purpose or intent	Projects may be intended for more than one purpose. For example, a project may be designed to improve healthcare operations in a particular setting as well as to produce knowledge that can be applied in other settings. Also, the purpose may change over time such as when a QI project unexpectedly yields results that are worthy of publication.[44, 47]
Focus on improvement of patient care	Both research and QI help improve patient care.[25] The public good of research lies not in the contribution it makes to generalisable knowledge per se, but in the subsequent improvement in the treatment and care of future patients that results from the application of that knowledge. Thus in terms of the relevant ethical considerations, the purpose of research is more appropriately expressed as the improvement of healthcare for future patients. Exactly the same can be said of the purpose of clinical audit.[46]
Systematic	Clinical audits and QI studies are routinely systematic in nature, using quantitative and qualitative methods to better understand processes of care and measuring the impact of interventions intended to improve patient outcomes.[18, 25, 61, 68]
Generalisable new knowledge	Clinical audits and QI studies can produce generalisable knowledge of interest outside the local healthcare organisation.[9, 24, 36, 48, 61] If a QI project's insights are taken to be generalisable whenever they might be expected to apply to any other people or situations, then almost every QI activity will qualify.[17] The results of virtually all QI interventions are generalisable to lesser or greater degrees. QI data can be of direct interest to those who participate in a project; however, the data also may be generalisable to others in the same organisation and perhaps to other organisations.[32] Not all research produces or aims to produce new knowledge. A research project may simply set out to confirm what was found previously or try to disprove what was believed previously to be the case. Much research finds nothing conclusive but this failure to produce new knowledge does not stop it being research.[52]
Intent to publish	No one can know that a project will be worth publishing at the start.[16] There are occasions when information obtained from an audit may contribute knowledge on the effectiveness of services.[64] Often a quality improvement project began simply as an effort to improve health care locally and the fact that the work came up with a generalisable message that might merit publication is a bonus.[69] The level of dissemination of a piece of work does not determine whether it is audit or research.[3] The rule of thumb that defines the possibility of publication as a trigger for research ethics committee review provides no added value to the patients whose treatment provided the focus of the QI intervention. It also creates an important barrier to the dissemination of knowledge that could save lives and improve the care experience for millions of other patients.[24]

	The situation that has faced those who publish clinical audits or QI initiatives is that publication has suggested that the content is intended to be generalisable and if the content is intended to be generalisable, it must by definition be research.[70]
Focus on human subjects	The current system for obtaining approval for a project makes the presumption that research projects are always about interventions with patients.[71–72] Clinical audits and QI initiatives are about how patient care is delivered, that is, how processes and systems in organisations work.[12]
	The distinction between QI and research can be made by asking whether the project is about one or the other of two fundamentally different kinds of processes — natural processes or man-made processes. Research involves gathering and analysing data to increase enduring knowledge of a universal, natural process or perhaps to discover new natural processes, particularly about the nature and functions of human beings and their environment.[17, 43] QI involves gathering and analysing data about how a current standard of care that represents existing knowledge is implemented through organisational processes or systems.[17] The study of causal relationships in QI is explicitly for the purpose of changing local processes and systems to improve quality for those immediately affected by the processes or systems.[43]

5.3.4 The way forward — no point to differentiating research and clinical audit and QI as a basis for ethical review

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

- The distinctions between the two types of activities are blurred and can be ambiguous and unhelpful, particularly as QI initiatives become more scientific.[2, 23, 34, 44, 46–47, 57, 67, 73–76] For ethics review purposes, the distinction between research and clinical audit is arbitrary,[9, 77–78] and the activities cannot be distinguished for this purpose in a reliable or valid way.[67]
- There are other ethics issues related to clinical audit that are beyond consideration of the design of an individual clinical audit or QI initiative as a project.
- Some QI initiatives are truly research on the quality improvement process, that is, 'hybrid' projects.[13] Research on the QI process itself should be subject to research ethics oversight.[13]

Instead of focusing on the distinction between research and clinical audit or QI, healthcare organisations should focus on assuring that the rights and interests of all patients involved in all these activities are adequately protected.[44] The move is needed from a rule-based system (if it's research, it requires ethical review) to a principles-based one (if it has ethical implications, it requires review).[78] The key ethical issue is not the classification of a project as research or clinical audit or QI, but the balance of benefits and harms in any project.[47]

5.4 Why a clinical audit or QI programme should have an ethics review

Five ethics issues related to overall clinical audit or QI programmes have been identified as:

- participation of all healthcare professions in clinical audit and QI activities
- coverage of all patient groups and types of conditions
- assurance that all clinical services are carrying out clinical audits or QI activities
- a systematic approach to setting priorities for clinical audits or QI activities
- effective management and conduct of clinical audit and QI activities.

First, it has been acknowledged that all healthcare professionals have a responsibility to provide the best possible care, which could be interpreted to mean that not to be involved in audit is a breach of a professional code of conduct.[79, 80] The duty of care of each healthcare professional to prevent harm coming to others through his or her acts or omissions extends to the duty to participate in clinical audit.[81] The inclusion or exclusion of professionals in the clinical audit process raises important ethical issues, not least in terms of representation and the promotion of fair working practices.[36] It is important for audit to be conducted in ways that maximise professonals' obligations towards one another, and in doing so, may improve the quality of clinical audit.[36]

Second, the moral principle of justice and fairness suggests that no patient group should be excluded from the possibility of inclusion in a clinical audit or QI activity. Any criteria used to delineate inclusions or exclusions (eg, patient characteristics such as gender, race, ethnicity or disease site, or staff characteristics such as profession or role within the organisation) need to be justified.[35] Also, the potential burdens or risks as well as the potential benefits of the activities should be distributed fairly across the population of patients served by the healthcare organisation.[44]

Third, all clinical services should have an active clinical audit and QI programme with the aim of achieving improvements in the quality of patient care. Given the concern to inform patients of possible harms, "perhaps providers who do not monitor quality should be required to inform patients that no systematic improvement efforts are underway and they are thus at risk of receiving suboptimal care"[82] because "the real risk from QI lay in the absence rather than presence of QI."[83]

Fourth, priority setting may be influenced by a number of influences including: external requirements and expectations; resources available to carry out the work; pressures from patients and their representatives; or the perceived ease or difficulty of carrying out work on a particular subject.[84] There is a perception that clinical audits tend to focus on satisfying external pressures rather than on the integrity of self-observation and self-regulation.[36] A system for setting priorities needs to include analysis of benefits and risks to patients in the current system of healthcare delivery and whether or not the proposed activities respond to the risk–benefit analysis.[44]

Finally, if there is an ethical responsibility to undertake QI efforts, there is also a responsibility to manage and conduct QI effectively and well. Unfortunately, QI activities in many organisations are decentralised, fragmented, and ad hoc, with little priority setting, inadequate structures to ensure the long-term success of the activities, and lacking a reliable structure of management of and accountability for quality.[24]

5.5 When a *proposal* for clinical audit or QI activity should have an ethics review

5.5.1 Situations in proposals that require ethics review

Principles and criteria have been suggested to identify a clinical audit or QI activity that should have an ethics review at the proposal stage. The principles relate directly to the moral principles described earlier not being followed.[34, 46] They include:

- There is a benefit to existing or future patients or others that outweighs potential burdens or risks.[2, 21, 33, 44, 54, 67, 82–83, 85]
- Each patient's right to self-determination is respected.[21, 33, 44, 48, 54, 85–86]
- Each patient's privacy and confidentiality are preserved.[21, 33, 44, 54, 85]
- The activity is fairly distributed across patient groups.[21, 44, 54]

If a clinical audit or QI activity is likely to involve more than minimal burdens or risks to patients or others or the risks or burdens are uncertain, problematic or controversial, written permission or informed consent by the participants is needed and the activity should have an ethics review. [21, 32, 47, 54, 87]

Criteria for reviewing a proposal for a clinical audit or QI activity have been suggested to identify circumstances in which an ethics review is needed. The criteria indicate that a clinical audit or QI activity should be reviewed if:

- There is a risk of a breach of confidentiality of patient information or patient privacy, including by the use of very small sample sizes.[6, 21, 28, 33, 44, 47, 52, 54, 79, 84, 86, 88–90]
- Data are being obtained that are additional to the data normally or routinely gathered in the delivery of patient care.[6, 90]
- Data are being obtained directly from patients and the process may be intrusive for patients, for example, questionnaires that involve patients' personal feelings or that require more than 5–10 minutes to complete, or focus groups, particularly if there is:[8, 36, 44, 51–52, 54, 79, 83, 86, 88–91]
  - a need for the consent or permission of the patients, carers, health care providers or organisations involved
  - planned collection or disclosure of identifiable personal information about any individual
  - disclosure of de-identified information to a third party where permission to disclose this information was not specified at the time of collection of the information or would not fall within the reasonable expectations of the individuals whose information is involved.
- Data are being collected by someone who is not part of the clinical care team, does not have a professional obligation of confidentiality, or is not employed to support QI-related activities. Work being done as part of a course of study should be subject to review if the person carrying out the work is not part of the clinical team or does not have a professional obligation of confidentiality.[6, 52, 90, 92–93]
- The activity involves a deviation from current normal (accepted, local) clinical practice.[2, 6, 8, 19, 32, 37, 44, 47, 55, 67, 90, 94]
- There is any disruption to the clinician-patient relationship.[21, 44, 47, 54]
- The activity might reveal non-compliance constituting a "remediable adverse event".[95]

- There are additional risks or burdens on patients or others because of the activity.[2, 21, 32, 43–44, 46–47, 54, 67, 82, 86, 90, 96–97] Burden includes the additional time and effort required of patients or others in data collection; taking additional tissue samples; extra clinic or home visits; or considerable time giving information.[67]
- The activity involves a potential conflict of obligation to individual patients or to all patients, such as if the activity involves a trade-off between cost and quality.[24, 44, 54, 67, 98]
- There is an allocation of treatment for different groups with or without randomisation or any form of selective or untested intervention or testing of an hypothesis.[4, 37, 44, 47, 52, 55, 89]
- The activity involves specific recruitment.[21, 44, 54–55]
- The patients involved in the activity won't directly benefit from the knowledge to be gained.[19, 32, 44, 54]
- There is an intention at the start of the project to publish or to use any personal health information in the publication.[8, 52, 55]
- The activity or initiative involved is new and not already established.[44, 52, 54]

Examples of guidance and tools used to review proposals for research, clinical audit, QI study or service evaluation are in appendices 2–9.[19, 29, 44, 74, 90, 99–102]

5.5.2 Ethics issues related to the proposed design and methodology of a clinical audit or QI activity

In addition to the principles and criteria for reviewing a proposal for a clinical audit or QI activity, it has been recognised that poorly conceived clinical audits or QI projects are a waste of everyone's time and are not likely to result in any improvement of care.[103] If a project is going to be futile or doesn't use scientifically valid methods or won't yield scientifically credible evidence, it shouldn't be carried out.[4, 79, 94] Local practitioners often decide what needs to be audited and how a clinical audit should be carried out. The development of clinical audit activity in this way can raise questions as to the validity and ethicality of some studies being undertaken.[52]

Clinical audits and QI projects should be well designed and the measures they use should be reliable and valid.[44] The activities should be carried out by well-supervised staff who have adequate training on audit or QI methods and access to consultative advice. [23, 44] The methods used in a clinical audit or QI project need to be as rigorous as those of research if the activity and findings are to be valid, reliable and credible, and clinical audits should be undertaken to the highest professional standard.[19, 52, 86]

> "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. Interestingly, one consequence of this rule would be that much current audit and NHS routine data collection would require ethical scrutiny because they are rarely likely to achieve their stated goals and the costs and risks are often not small."[67]

5.5.3 Ethics-related subjects of a clinical audit or QI activity

If a clinical audit or QI activity is being carried out on a clinical subject that itself has ethical implications, the design of the clinical audit or QI activity has to be consistent with what is agreed to be ethical practice. Examples of subjects of such clinical audits could include end-of-life care, do-not-resuscitate policies, patient understanding of information given as part of the consent process, handling decision making for patients who lack mental capacity, or miscarriage.[104–107]

5.6 When *findings* of a clinical audit or QI activity should have an ethics review

Of the principles and criteria considered at the proposal stage, several are applicable following the collection of data for a clinical audit or QI activity. The findings of data collection should be considered from an ethics perspective if they:

- pose any risk for patients whose care was reviewed in the clinical audit or for other similar patients, for example, if care was not provided consistent with good practice [2, 21, 30, 43–44, 46–47, 54, 67, 82, 90, 96–97]
- identify any patients for whom a life-threatening or quality-of-life threatening shortcoming in care occurred[108]
- disclose any data that could be used to identify any patient or any practitioner[21, 44, 54]
- reveal any clinically significant departure from usual clinical care.[2, 6, 8, 19, 37, 44, 47, 55, 67, 90, 94]

If a clinical audit or QI activity has unexpectedly revealed that a patient has experienced an adverse event that could have been prevented, the organisation has a responsibility to disclose the event to the patient if the event has had or could have an effect on the patient's health or quality-of-life. In addition, the organisation has a responsibility to carry out further measurement to verify that the system or process involved in the event has been improved and that the event is unlikely to recur.[95]

5.7 When *the effectiveness of action taken* on a clinical audit or QI activity should have an ethics review

Having better knowledge of what constitutes good clinical practice is not a guarantee that it will be adopted or that it will actually improve practice in all settings.[109] One contribution of the QI process is that it examines how a local practice environment shapes or influences the implementation of knowledge locally and, through the examination of variation in that local practice, helps to identify where and how practice might be improved.[109] While clinical audits and QI projects aim to improve or maintain the quality of patient care, those in charge cannot be sure that the intervention will be effective. A risk exists that the proposed innovation will be ineffective or even harmful.[97] Therefore, risk assessment of changes in patient care or service delivery needs to be carried out to pre-empt what could go wrong in the implementation of a change and identify what to do if it does.[23]

Clinical audits or QI activities that do not address needed changes to systems fail to meet the ethical responsibilities of healthcare professionals and institutions to improve quality.[83] Minimal changes in clinical practice would rarely require specific ethical consideration; however, moderate changes, such as the introduction of an integrated care pathway, might need ethical review because the change may be ineffective. Major change should always have ethical scrutiny.[67]

If the audit or QI project is carried out effectively, it measures conformance with clinical practices that are known to be effective. Therefore, if the audit or project indicates that the effective practice is not being provided to patients, it would be unethical to continue to provide substandard care and to withhold improvements from patients.[52, 83] If action is to be taken on the findings of audit that affect patient care, should there not be ethics checks and balances in place?[52]

> "Clinical audit should be part of an integrated programme ... aimed at showing that there is an improvement in the quality of the care given to patients, not just that audit is going on. Occasionally audits indicate the need for change and are not acted upon. This could be due to inaction by the clinicians or the clinical team or to the lack of resources made available by the provider (time, staff, equipment, costs, etc) to implement the changes. Inaction of this kind has far-reaching consequences in terms both of professional codes of conduct and of business constraints of trusts or other healthcare providers."[79]

5.8 How a healthcare organisation should handle ethics and clinical audit or QI

5.8.1 Individual responsibility designated

An individual who takes the lead for a clinical audit or QI project should inform an appropriate manager that the project is being undertaken[83] and seek approval of or authorisation for the project. In the absence of such reporting, the individual assuming responsibility for a project may not recognise when an ethics review is required.[46]

It may not always be clear who is ultimately accountable for the appropriate conduct of a given clinical audit or QI project and who has the authority to assure that applicable ethical standards are followed.[44, 54] Therefore, healthcare organisations need to provide that an individual is designated as responsible for the ethical conduct of each clinical audit or QI activity.[44, 54]

5.8.2 Organisational structure for oversight of clinical audit or QI

QI activities, including clinical audit, require ethical oversight by a responsible structure in a healthcare organisation that is accountable to senior management and the governance of the organisation and is ultimately publicly accountable.[24, 33, 35, 96, 110] Oversight will protect patients from ad hoc or poorly conceived projects. It also will ensure that the organisation has a vigorous and strategic agenda to improve the quality and safety of patient care.[24]

Ideally, this agenda should be managed cooperatively by the clinical and management leadership of the organisation, reporting to the board through a committee that oversees clinical audit and QI throughout the organisation.[24]

Management responsibility for all activities that relate to QI and take place within a healthcare organisation is important[48] because these activities should not be carried out by individuals acting in isolation.[44] Groups or teams acting on behalf of the organisation should be carrying out the work.[44] To be effective, the activities must have organisational support, particularly providing authority to act to respond to findings of data collection.[44] Professional and management leaders' roles should include creating the culture of quality and safety improvement throughout the organisation to ensure that when QI is done, it is done right.[83]

The individual or group that oversees ethics in clinical audit and QI activities on behalf of the organisation should be capable of providing an independent review of such activities.[111] The individual or group should define and implement systems for reviewing proposals for clinical audits and QI activities, oversee the findings and ensure that effective actions are implemented in response to findings. The organisational mechanism(s) could include one or more of the following:

- department heads assuming responsibility for screening proposals and referring those that require further assessment to a designated individual or group and for the effectiveness of actions taken[19, 61, 83]
- the director responsible for clinical audit or QI, such as a quality improvement director[83]
- the organisational structure that governs quality management or improvement[24, 44]
- a committee or group, accountable to the governance of the healthcare organisation,[61] which could be any of the following: quality improvement or quality improvement review committee,[33–34, 44, 74, 83] clinical audit committee,[2] ethics (not research ethics) committee,[34, 44, 46, 54, 67, 90, 97, 112] peer review committee,[19, 38, 52] joint quality improvement and research ethics committee,[4, 47, 49, 76, 83, 113] patient safety committee,[43] clinical policy committee,[43] special group[34] or ad hoc group of ethicists.[19]

The review mechanism needs to ensure that individuals with knowledge about QI principles and processes and ethical standards for QI processes are involved.[44, 54, 83] The process carried out should be designed to determine that clinical audit or QI activity projects:[38, 48]

- are well designed and justify the use of resources
- ensure patient safety and do not pose more than minimal risk to patients and if they do, appropriate provision is made for informed consent
- ensure appropriate provision is made for anonymous and confidential data collection
- do not overly burden patients or staff
- realise benefits to patient care
- ensure that those assuming responsibility for the project have the authority to implement actions in response to the findings.[48]

A research ethics committee can be asked to review clinical audit or QI activity proposals routinely or in cases where a possible ethics issue may exist.[7, 44, 47, 61, 73, 87, 98] However, there may be several reasons why research ethics committees are not the best solution to the oversight of clinical audit and QI:[24, 33 49, 89]

- There are significant differences between research and clinical audit or QI[46] in relation to obligations of a healthcare organisation. Research is an optional activity in a healthcare organisation, whereas QI is ethically intrinsic to providing care.[4] Research falls into the category of an ethically permissible rather than a morally and legally mandatory activity. Society supports research to advance knowledge; however, no particular individual or organisation is obligated to perform research.[4]

  Clinical audit and QI activities, on the other hand, should be part of an overall quality and safety improvement strategy that is integrated into the operations of the healthcare organisation. Clinical audits or QI activities should not be viewed as a set of projects, but as the heart of the operations of the healthcare organisation. These projects need to be strategically selected and completed as part of the commitment by the organisation to improve the quality and safety of patient care.[24]

- Individuals who take the lead for clinical audit or QI activities should take responsibility for leading changes in practice needed to achieve improvements and they should also assume responsibility for ethics issues related to the work. Research ethics committees were designed to consider the impact of research on research participants; they were not created to assess projects that involve changing practices and systems in the delivery of patient care.[24]
- Research ethics committees are often overworked and backlogged.[21, 24, 34, 54] Given the urgency for improvement in the quality and safety of health care, it is counterproductive to contemplate delays in the important business of redesigning the quality and safety of patient care.[24]
- As currently constituted, research ethics committees may lack the required knowledge and expertise to evaluate clinical audits or QI activities.[21, 34, 46]
- Many people now involved and committed to carrying out QI projects could be discouraged from undertaking such projects in the first place if barriers such as additional paperwork, delays and frustrations associated with research ethics committee review were experienced before the work on improvement could begin.[30, 34, 54, 68] The research ethics committee process could have a "chilling effect on studies that could substantially improve error–prone systems and that expose subjects to risks no greater than those incurred during routine patient care" and could unintentionally lead to patients being harmed.[57]
- In the UK, giving ethical approval for clinical audit or QI projects may put a research ethics committee beyond its indemnity coverage.[19]

5.8.3 Organisational systems for oversight of clinical audit or QI

Healthcare organisations should promote proactively the ethical conduct of clinical audit or QI activities using a systematic approach.[44] Systems should provide for screening proposals for clinical audits or QI activities independent of the individual leading or carrying out the work in order to identify any risks or burdens that the project will involve for patients or staff, and provide for an appropriate level of review of any project that involves more than minimal risk or burden beyond those inherent in normal clinical care.[44, 89]

Examples of organisational systems include the following:

- registering clinical audits or QI activities electronically with the clinical audit or quality improvement department. A web-based interface could allow the individual initiating a project to quickly provide information about the audit or QI activity, which would include answers to a series of questions that would flag whether or not the proposal requires an ethics review and at what level of review. The electronic registration process would enable monitoring and following up on findings and the effectiveness of actions taken as part of the audit or QI activity. It would also broaden staff awareness of the standards for the ethical practice of clinical audit or QI.[83]
- promulgating organisational standards, policies and procedures, or guidance for all types of QI projects to ensure that patients and staff are protected and clinical audits and QI projects are carried out consistent with ethics review systems in the organisation.[17, 47, 54, 74, 79, 83] The standards or policies can provide for efficient screening of proposals for projects for their purpose, level of risk or burden to patients or staff and the intended process for gathering and handling personal health information.[34, 43, 74, 111]

Examples of standards, policies, procedures or guidance could include the following: how data will be collected and analysed to maintain confidentiality and anonymity of the participants in the clinical audit or QI project; informing patients about clinical audit or QI activity; making clear when patients have a choice about their participation and when a need for patient permission or consent is needed;[85] screening criteria to be used for ethics issues and the levels and types of review of any issues; and action to be taken if an adverse event to a patient is revealed through a clinical audit or QI project.[95]

- providing for standards relating to and ethics review of any project that is designed to contain or control costs, particularly if this is the sole purpose of the project or if the project is initiated by managers of clinical services or represents a potential conflict of interest. [38, 83, 107, 114]

  For example, patients may need to be protected from initiatives that are primarily intended to reduce length of stay or use of healthcare services or substitute therapies when evidence is lacking that intended outcomes can be achieved safely with such reductions.[47, 57, 114] Management and policy changes in areas such as hours of operation, staffing patterns, acquisition of new equipment or referral for designated treatments or procedures are not subject to review, even if they have a clear potential to affect patient care.[43] Staff shortages may mean compromises are made that in turn can influence standard setting, in a clinical audit, for example.[98] It is essential to distinguish between genuine QI and financial, organisational or bureaucratic activities in health care that serve interests other than quality, safety and the best interests of patients.[49, 115]
- referring to an expectation of staff participation in clinical audit or QI initiatives in job descriptions and performance appraisals, and following the organisation's ethics policies and systems relating to such projects[44, 83]
- educating staff about the organisation's policies and systems for identifying and handling ethics issues relating to clinical audits or QI activities,[44, 54, 74, 110] including informing them at the time of hiring that QI is viewed as everyone's responsibility and how proposed projects are reviewed and carried out in the organisation.[23, 35]
- tracking clinical audits or QI projects[44]
- monitoring for nonadherence to approved ethical standards[109] or failure to conduct a clinical audit or QI project in accordance with approved ethical standards is reported as an incident[83]
- providing for appropriate review for individuals who wish to publish the results of a clinical audit or QI project.[83, 110]

5.8.4 Informing and involving patients in clinical audits or QI activities

As part of the system of healthcare, patients also have a responsibility to participate in quality improvement.[13, 17, 48, 49] As an ethical matter, the responsibility of patients to cooperate in QI activities is justified by the benefits each patient receives because of the cooperation of the others in the collective enterprise. It is in the best interest of patients to cooperate with QI activities and even to seek out the healthcare organisations that are the most committed to QI.[13]

The patient's responsibility to cooperate is subject to standards of reasonableness, which require that patients have access to general information about QI activities and be kept safe from harms and from violations of their rights. Patients should be given explicit information about the process of clinical audit and quality and safety review and how the work is designed to improve their health and the health and well-being of other patients.[48, 89, 94, 116–117] The information provided to patients should make clear that clinical audits and QI projects are a regular part of how the organisation fulfils its obligation to patients.[89]

While the absence of proper clinical audit is an affront to the rights and interests of patients, patients are entitled to know that the management of their care is subject to audit and to have the reassurance that all reasonable steps are being taken to ensure that their health care is of the highest quality.[81] If a clinical audit or QI project requires patients' direct involvement, patients should be informed that their participation is optional and voluntary. If the project involves significant burdens or risks, written informed consent by patients is needed,[54] although it has been recognised that it can be difficult to obtain individual signed consent for sharing patient identifiable information with an externally located clinical audit database.[118]

6 How ethical principles are applied to clinical audit and QI

An ethical framework for assessing QI activities is the concrete application of the four moral principles of autonomy, beneficence, non-maleficence and justice.[35] To be consistent with the principle of autonomy, patients have the right to information about clinical audit and QI and how a healthcare organisation carries out these processes. Patients also need to know that these activities are part of the normal operation of a healthcare organisation, that their care is assessed routinely as part of the organisation's commitment to provide care that is consistent with best practice, and that the findings of such assessments are analysed and acted on as needed.

Should a clinical audit or QI activity involve more than minimal risk to patients, patients need to be fully informed about the nature of the risk or burden and make the autonomous choice on whether or not to participate.

The beneficence obligation of healthcare professionals supports a moral obligation to carry out clinical audits and QI projects aimed at improving the standard of patient care.[48] QI in general, as part of clinical practice, aims to improve the quality and safety of care by maximising benefits to patients and minimising harms and risk, the non-maleficence obligation. Clinical audits and QI projects should reflect these objectives in their design, conduct and impact. In the end, individual QI projects must have a favourable benefit-to-risk ratio for patients as well as staff.[35]

The principle of justice guides the selection of clinical audits and QI projects as well as participation in the activities by healthcare professional staff. All patients and family members are potentially the beneficiaries of improved systems of care, and therefore, all have an ethical obligation based on justice to participate.[35]

Ethics principles are not always evenly balanced and one principle may take precedence over another in any situation.[38, 64] In research proposals, for example, the principle of autonomy is supreme: the participant in research must be fully informed of all the benefits and risks of participation in the research and make an independent choice about participation. However, individual patients cannot elect to not participate in clinical audit or QI activities that involve no or minimal risk.[38] The ethical principles of beneficence and justice trump the principle of individual patient autonomy when QI initiatives are being established.[38]

In summary, QI programmes are intended to provide the greatest benefit to patients with the least harm, equitable access to participation and protection of individuals' rights.[24]

7 Conclusions

Clinical audit has shifted from a quality assurance to a quality improvement process. In a QI approach to clinical audit, repeated data collection is used to test different change interventions, including redesigning processes and systems, in order to improve the performance of a clinical service in comparison to measures of good practice. QI feeds back measurements rapidly to the care system, leading to further quick modifications in the care process or outcome being measured, with the ultimate goal of achieving an intended improvement.

As clinical audit becomes more sophisticated as a QI tool, it is no longer appropriate to use a distinction between research and clinical audit or QI as the basis for deciding if an ethics review of a proposed study is needed. The distinctions between the activities can be ambiguous and the activities cannot be distinguished in a reliable or valid way. The principle should be that if any clinical audit or QI activity has ethical implications, it requires review. In addition, if there are ethics issues embedded in a clinical audit or QI project, there are a number of reasons why a research ethics committee is not the best way to provide for a proper review and decision about the project.

There are a number of ethics-related issues related to clinical audit or QI programmes including that the following all need to be assured: participation of all healthcare professions in clinical audit and QI activities; coverage of all patient groups and types of conditions; participation in clinical audits or QI activities by all clinical services; a systematic approach to setting priorities for clinical audits or QI activities; and effective management and conduct of clinical audit and QI activities.

There are several stages of a clinical audit that may merit an ethics review. Proposals for clinical audits or QI activities should be screened to ensure that any ethics issues in the design of the activity are recognised and handled properly; the proposed design and measures are valid and that data collected are likely to be reliable; any ethics-related subject of a clinical audit or QI activity is carried out completely consistently with the healthcare organisation's formal policies on the subject. Findings of data collection and effectiveness of actions taken also should be screened for ethics issues.

Healthcare organisations need to have mechanisms in place for ethics oversight of clinical audits and QI activities. Individuals carrying out projects should be required to submit proposals for screening. Healthcare organisations need to designate an accountable person or group for ethical oversight of clinical audit and QI activities and ensure that there are robust

oversight systems in place. Systems should include registration of projects which includes screening of projects at several stages; defined and disseminated policies, procedures and guidance for staff; staff education about the organisation's processes; and monitoring of compliance with defined policies.

Patients have an ethical responsibility to agree to participate in clinical audits or QI activities if requested and the risk or burden for patients is minimal. However, patients need to be informed about the processes and how they are used in a healthcare organisation to make improvements that benefit the quality and safety of patient care.

Clinical audit and QI programmes are intended to provide the greatest benefit to patients with the least harm, equitable access to participation and protection of individuals' rights. Ethical oversight of clinical audit and QI by healthcare organisations assures that these activities protect patients and their rights and contributes to the promise of improved quality and safety of patient care.

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Appendix 1. Differentiating audit, service evaluation and research[5]

Research	Clinical audit	Service evaluation
The attempt to derive generalisable new knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them	Designed and conducted to produce information to inform delivery of best care	Designed and conducted solely to define or judge current care
Quantitative research — designed to test a hypothesis Qualitative research — identifies/ explores themes following established methodology	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
Addresses clearly defined questions, aims and objectives	Measures against a standard	Measures current service without reference to a standard
Quantitative research — may involve evaluating or comparing interventions, particularly new ones Qualitative research — usually involves studying how interventions and relationships are experienced	Involves an intervention in use ONLY (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference)	Involves an intervention in use ONLY (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference)
Usually involves collecting data that are additional to those for routine care, but may include data collected routinely. May involve treatments, samples or investigations additional to routine care	Usually involves analysis of existing data, but may include administration of simple interview or questionnaire	Usually involves analysis of existing data, but may include administration of simple interview or questionnaire
Quantitative research — study design may involve allocating patients to intervention groups Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications	No allocation to intervention groups: the healthcare professional and patient have chosen intervention before clinical audit	No allocation to intervention groups: the healthcare professional and patient have chosen intervention before service evaluation
May involve randomisation	No randomisation	No randomisation
Although any of these three may raise ethical issues, under current guidance:		
Research requires REC review	**Audit does not require REC review**	**Service evaluation does not require REC review**

Appendix 2. Alberta Research Ethics Community Consensus Initiative (ARECCI) Ethics Guidelines for Quality Improvement and Evaluation Projects[99]

1. **How will the knowledge gained from this project be useful?**
   - **Describe what you hope to find out.**
   - **Describe who will benefit from this project.**
   - **Describe how the results will be communicated.**

Points to consider:

What is the specific context of the problem or issue?

Why do you want to obtain the information (eg, for the purpose of evaluation, decision making purposes, information?)

What relevant literature or better/best practices have you consulted?

Who will benefit from this project (eg, patients/clients, providers, families)?

How will you let others know about your results?

2. **How will the described method or approach generate the desired knowledge?**
   - **Describe your approach or method or strategy (eg, focus group, survey, observation, implementation of best practice).**
   - **Explain how it will attain the goal(s) of the project.**

Points to consider:

Why is the approach or method or strategy you have chosen the right one for your particular project?

How will you collect and analyse data?

Is the information individually identifying?

How can you be relatively certain that these methodologies will assist you to obtain reliable information?

How will you know when you have obtained enough information to meet your project goal?

Is there a need for consultation in areas where you don't have the expertise? For example, if your project uses quantitative or qualitative approaches, have you consulted a data analyst or statistician about your sample size if applicable, or have you consulted someone about your data collection and analysis plan?

Are you collecting too much identifiable information (ie, data that is 'nice to know' versus what 'you need to know')?

3. **How will you ensure that the participant (or data) selection process is fair and appropriate?**
   - **Describe how you will select your participants.**
   - **Describe how you will decide how many participants you will need.**
   - **Identify people who may have been appropriate as a participant or subject, but whom you have decided to deliberately exclude. Explain your decision.**
   - **Describe how you will approach people to participate in your project.**

Points to consider:

Is anybody or any group being excluded? If yes, why?

Are you overburdening anybody or any group (eg, marginalised groups, cultural groups, people with a particular disease or disorder, staff, management, community members)?

If you are using a convenience sample (ie, simply whoever is available), what are the risks?

If participants are being compensated, is it fair and equitable?

Are participants going to be provided any sort of honorarium to cover any personal costs they incur as a result of involvement in this project?

Is any specific training needed by those who are going to approach people to participate in your project?

Are you accessing participant data through records or charts?

4. What have you done to identify and minimise risks? Are the remaining risks justified?

- **Describe the potential risks for participants (eg, embarrassment, fear that services will be withdrawn).**
- **Describe the potential benefits to participants.**
- **Describe the potential risks for your organisation.**
- **Describe the potential benefits for your organisation.**
- **Describe what you have done to minimise these risks (ie, decrease the number of them) and mitigate these risks (ie, decrease the severity of the remaining ones) for both the participants and your organisation.**
- **If there are remaining risks, describe how they are justified by the potential benefits.**

Points to consider:

What are the risks of not doing this project?

Have you considered the risks outlined on the ARECCI Risk Filer for Quality and Evaluation Projects in relation to this project?

What strategies have you used to ensure that all reasonable and potential risk has been identified?

If there is risk related to a power relationship in the project (eg, between provider and patient/client, between staff and supervisor), how are you minimising or mitigating this risk?

Have you considered that the level of risk in the project increases if data is individually identifying?

5. How are the rights of individuals, communities and populations respected in this project?

- **Describe how you intend to protect the privacy and confidentiality of participants in your project.**
- **Describe how you will retain, store and secure the data.**

Points to consider:

How are you protecting the privacy of individuals considering their cultural values and norms?

Is personally identifying information being collected? If yes, how are you maintaining the confidentiality of that identifying information?

If personally identifying information is being collected, are you collecting the least amount needed to complete the project?

If personally identifying information is being collected, who will have access to the data and in what form?

How will personally identifying data be recorded and stored, and for how long before it is destroyed? How will it be destroyed?

Is data being transferred across regional, provincial, national or international boundaries?

Have you taken into account your organisation's policy regarding records retention?

Have you considered security measures for any electronic and/or hard copy records(s) (eg, password protection and locked filing cabinet storage; data encryption tools to secure data on laptops or other personal computers)?

How will you maintain the welfare of participants during the course of the project?

How will you inform participants if risks or benefits develop as the project progresses?

What are your plans or mechanisms to inform participants of the results?

How will you ensure that individuals will not be identifiable if the results are shared publicly, or in anything that might be published?

For what other purposes might the data be used?

6. Is informed consent needed in this project?

- **Describe how you will determine whether or not informed consent is needed in this project.**
- **If consent is needed, describe how you will obtain it.**
- **Attach any forms and/or scripts that you will use.**

Points to consider:

Are you or other team members in a position of power or authority over the people who need to be part of the project? If yes, how will you ensure that they do not feel coerced into participating?

Do you or other team members have a conflict of interest with any aspect of this project (eg, potential for financial gain)?

Is the approach to informed consent appropriate for the project and its participants?

How will you let people know that they can withdraw from the project at any time?

Will people likely consent to their information being used, or information about them being used, to carry out your project?

If you could get informed consent, but you are choosing not to obtain consent, why did you make that choice? Will anyone be angry, frustrated or hurt if they find out about your project afterwards and realise they weren't informed of their participation or asked for their consent?

Appendix 3. Alberta Research Ethics Community Consensus Initiative (ARECCI) Ethics Screening Tool[100]

This online tool was developed for ethics decision support with projects involving people or their health information. In the tool, questions are coded as quality improvement or research-focused. As an individual goes through the online tool, prompts appear advising the individual on the probable nature of the project, the level of risk to participants and directions for seeking approval for the project according to the individual's responses.

Preliminary questions

1. Is there an explicit requirement for review of this project by a Research Ethics Board as part of its funding arrangements?
2. Are there any local policies that require this project to undergo review by a Research Ethics Board?
3. Does the project involve use of a pharmaceutical device, drug or natural health product under Health Canada, Food and Drug Act regulations or guidelines?

If Yes to any of the above questions, the project would automatically be considered as research and should therefore be submitted to a research ethics board.

About your project

4. Is the project primarily designed to test a specific hypothesis or answer a specific quantitative or qualitative question?
5. Does the project involve a comparison of multiple sites and/or control groups?
6. Is the project designed to support generalisations that go beyond the particular population the sample is being drawn from?
7. Does the project impose any additional burdens on participants beyond what would be normally expected or normally experienced during the course of care, programme participation or role expectations?
8. Is the primary purpose of the project to produce the kind of results that could be published in a research journal?
9. Will project participants also likely be among those who might potentially benefit from the result of the project as it proceeds?
10. Is the project intended to develop a better practice within your organisation or setting?
11. Would this project still be done at your site even if the results might not be applicable anywhere else?
12. Does the language used in the project description refer explicitly to features of a particular programme, organisation or locale, rather than using more general terminology such as rural vs urban populations?
13. Is the current project part of a continuous process of gathering or monitoring data within an organisation?

Does your project involve ...

14. Non-invasive procedures involving imaging or microwaves not normally required for participant care?
15. Any procedures related to anaesthetics or sedation not normally required for participant care?
16. Evaluation of the safety and effectiveness of a mechanical device, drug or natural health product?
17. Deception or intended incomplete disclosure of the nature of the investigation?
18. Likelihood that a breach of confidentiality could place participants at risk of legal liability, denial of insurance or other damage to financial standing, employability or reputation?
19. Questions or procedures that might cause participants psychological distress, discomfort or anxiety beyond what a reasonable person might expect in day to day interactions?
20. Questions that involve sensitive issues such as sexual orientation or practices, illegal behaviour, stigmatising conditions or diagnoses, religious or cultural beliefs or practices?
21. A power relationship between the investigator and participants (eg, manager/employee, therapist/client, teacher/student?)
22. A real or potential conflict of interest between an investigator and the sponsor of the investigation?
23. Therapeutic and/or non-therapeutic risks or burdens for participants which are beyond what would be experienced in routine care or beyond what a reasonable person might expect in day to day interactions?
24. Any clinically significant departure from the routine care provided to participants or the gathering of information about participants beyond that collected in routine care (eg, blood samples)?

25. A person who does not normally have access to participant records for clinical care, whose use of records is for a secondary purpose?
26. Risks of breaching the confidentiality of any individual's personal information beyond that experienced in the provision of routine care or day-to-day life?
27. Therapeutic procedures that are themselves known to pose considerable risks of harm (eg, surgery, chemotherapy, radiation therapy)?
28. A novel process for which it would be difficult to estimate a balance of risk and benefit in advance?
29. Special populations or any individuals or groups in a socially vulnerable position?
30. Personally identifiable data, documents, records or specimens originally collected solely for purposes not related to the current study?
31. Collection of data from voice, video, digital or image recordings?
32. The use of tests, survey procedures, interview procedures, oral history, focus groups or observation of public behaviour where the participants can be identified directly or indirectly through the information recorded?
33. Collection of data through non-invasive procedures routinely employed in clinical or other settings?
34. Clinical studies on a device, drug or natural health product where Health Canada review and approval is not required?
35. Student projects?

Appendix 4. Advice to Institutions, Human Research Ethics Committees and Health Care Professionals, National Health and Medical Research Council, Australia[74]

The term quality assurance is used to include all of the following terms: peer review, quality assurance, quality improvement, quality activities, quality studies and audit (including all types of audit such as medical, clinical, surgical and record audit). An activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organisation) is a quality assurance study.

Quality assurance activities should utilise valid methodology and tools and must not contravene any relevant State, Territory or Commonwealth legislation, including requirements relating to legal privilege for quality assurance committees. The Australian Health Ethics Committee therefore advises that an appropriately planned activity can proceed without review by a Human Research Ethics Committee (HREC) if:

Both

(a) the activity is undertaken with the consent of the patients, carers, health care providers or institutions involved; or does not use or disclose personal information about an individual for a purpose other than the primary purpose of collection **and**

(b) it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

In deciding whether or not a quality assurance proposal requires ethical review, the following questions should be asked. If all of these questions are answered in the **negative**, the proposal does not need consideration by an HREC. If any questions are answered in the positive, further advice should be obtained from an HREC or its delegate. The delegate may be a member(s) of the HREC, a quality assurance committee, a senior administrator or professional health care worker designated to be responsible for the task.

Question

Consent

1. Is the consent from participants inadequate, or is the activity inconsistent with National Privacy Principle 2.1(a)? Participants may include patients, carers, health care providers and the institution involved.

Risks and burdens

2. Does the proposed quality assurance activity pose any risks for patients beyond those of their routine care? Risks include not only physical risks, but also psychological, spiritual and social harm or distress, eg, stigmatisation or discrimination.
3. Does the proposed quality assurance activity impose a burden on patients beyond that experienced in their routine care? Burdens may include intrusiveness, discomfort, inconvenience or embarrassment, eg, persistent phone calls, additional hospital visits or lengthy questionnaires.

Privacy and confidentiality

4. Is the proposed quality assurance activity to be conducted by a person who does not normally have access to the patient's records for clinical care or a directly related secondary purpose? The involvement of a clinical student who is a member of the team in any clinical setting or involvement of an authorised quality assurance officer would be acceptable. However, the involvement of a student external to the clinical team would need further consideration. Review of medical records by anyone who would not normally have access to information contained therein unavoidably compromises the privacy of individuals. However, authorised audit of records is an extremely valuable quality assurance activity. Provided the individual reviewing the records is bound by legislation or a professional code of ethics, the use is a directly related secondary purpose and is within the expectations of the patient, this question can be answered in the negative.
5. Does the proposed quality assurance activity risk breaching the confidentiality of any individual's personal information, beyond that experienced in the provision of routine care? A quality assurance activity that requires a letter, fax or email to a patient that includes sensitive health information could lead to a breach of confidentiality, if the communication is read by someone other than the proposed recipient.

Overlap with research

6. Does the proposed quality assurance activity involve any clinically significant departure from the routine clinical care provided to the patients? Application and evaluation of a new technology not previously used in the health service may need further consideration.
7. Does the proposed quality assurance activity involve randomisation or the use of a control group or a placebo? Proposals involving comparison with published or prior treatment results with other groups are acceptable if the proposals do not involve randomisation.
8. Does the proposed quality assurance activity seek to gather information about the patient beyond that collected in routine clinical care? Information may include observations, blood samples, additional investigations etc. Genetic studies or others that seek information about family members, relatives or contacts as well as the individual patient require further consideration.

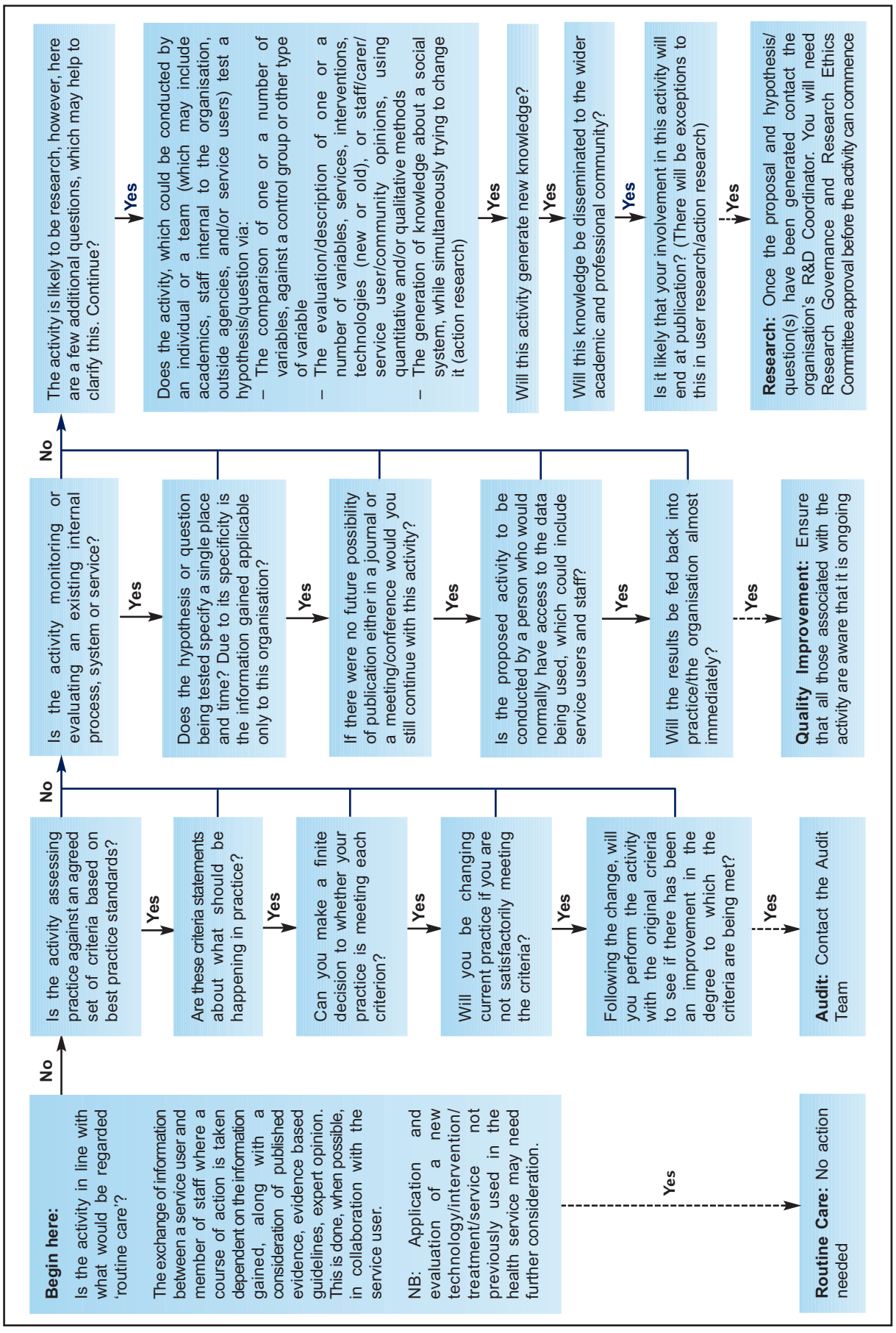
Broader implications

9. Does the proposed quality assurance activity potentially infringe the rights, privacy or professional reputation of carers, health care providers or institutions? These issues should be considered by management and may have legal implications. Consideration may need to be given to the relevant State or Territory legislation with respect to legal privilege for a quality assurance body.

Appendix 5. Quality Improvement and Ethics Review Checklist, Department of Health, New South Wales, Australia[101]

Question	True	False
Issues that may require consent		
1. The project involves direct contact with patients, consumers or members of the public.	❒	❒
2. The project poses additional risks or burdens to the patient beyond their routine care.	❒	❒
3. The data to be collected is of a sensitive nature or application.	❒	❒
4. The purpose of the activity is not 'directly related' to the patient's disease, illness or its management.	❒	❒
5. The data will be used or available in such a way that may identify individuals.	❒	❒
*If the response to **any** of the above statements is **true**, informed consent is usually required and you should contact your nominated HREC delegate to discuss.*		
Privacy and confidentiality		
6. There is no process for de-identification of data.	❒	❒
7. Access to personal information will extend beyond those who are members of the clinical care team, or to others who normally do not have access to the patient's record, or to other data sets.	❒	❒
8. The project involves rare conditions or a small community.	❒	❒
9. Data will be selected or identified by:		
• Aboriginal or Torres Strait Islander status or	❒	❒
• Ethnic, religious or minority group.	❒	❒
10. Data will be collected beyond that which is normally collected in routine care.	❒	❒
*If the response to **any** of the above statements is **true**, you will need to provide more information and you may need full Ethics Committee approval.*		
Other implications		
11. The project uses 'new' interventions, protocols or equipment.	❒	❒
12. The project will involve allocation of patients to groups to enable comparisons.	❒	❒
13. The project will involve genetic tests/testing.	❒	❒
14. The project may potentially infringe the rights, privacy or professional reputation of carers, health professionals or institutions.	❒	❒
15. The project involves use of placebo.	❒	❒
*If the response to **any** of the above statements is **true**, you will need to provide more information and it is highly likely you will need full Ethics Committee approval.*		
16. The project is likely to generate data that may lead to publication.	❒	❒
*If responses to **all** of the above statements in the checklist are **false**, then no ethical risks have been identified with this project and no ethics review is required.*		

Appendix 6. Template to define an activity as routine care, audit, quality improvement or research[29]



Appendix 7. Policy for Review of Audit & Research Projects. The North West London Hospitals NHS Trust, Harrow Research Ethics Committee, Brent Medical Ethics Committee[18]

Question

Audit projects will not cause ethical problems if:

- The audit never involves disturbance to the patient beyond that required for normal clinical management.
- The data are taken from clinical records (provided that confidentiality and data protection rules are followed). The Trust's policy is that consent must be obtained for the purposes of clinical audit, unless the data have been effectively anonymised.
- The data are gathered from routine practice and do not involve patient intervention for the purpose of the audit (eg, morbidity/mortality figures, tests taken as part of normal care).
- There is no approach to patients.
- The data are only seen by members of the clinical team.

Examples of audit studies where ethical review is not required include:

- Interviews or questionnaires performed for the purpose of audit within the clinical area.
- Studies involving responses in electronic form (eg, email, website questionnaires), provided that confidentiality and data protection standards are adhered to.
- Anonymised questionnaires sent to the patient within three months of a clinic visit.

Audit projects may cause ethical problems and require some form of ethical review when:

- The study involves patients in any intervention (eg, test, procedure or questionnaire) which would not be required for standard audit of clinical care (ie, to measure or assess standards of clinical care as part of good clinical practice).
- There is 'cold calling' of patients, or other forms of telephone interview with the patients, outside of the Trust (ie, at the patient's home or place of work).
- The study involves personal interviews with patients outside of the Trust premises.
- The study involves questionnaires that take more than 15 minutes to complete (more than 20 simple questions).
- When the study requires the patient to make extra clinic visits or to change appointments.
- Where a study involves obtaining access to information about the patient or his relations or carers, which would not normally be required for a standard audit.
- When questionnaires or interviews involve sensitive issues or vulnerable groups:
  - HIV, STDs, miscarriage and other distressing/confidential conditions
  - Patients with terminal illness, learning disability or mental health problems
  - Children or the very elderly.
- Members of staff being the subjects of the audit if there is a possibility of duress, eg, one to one interviews, questionnaires that are not confidential/anonymous or there may be fears by the subjects of coercion/distress/job pressure.

Service evaluations, quality improvement initiatives, participatory action research or other health services research projects may not require ethical review if all the following conditions are met:

- There is no additional intervention, eg, an extra blood test.
- The study does not involve use of existing tissue samples or fluids.
- The study does not involve the use of existing clinical data.
- The project does not involve any of the ethical problems outlined above for audit studies, ie, confidentiality, sensitivity, timing, location, length of questionnaires, involvement of vulnerable groups, etc.

Examples of projects which may not require ethical approval include:

- Research gathering data on service performance (ie, not measured against set standards, therefore not audit), eg, focus groups if the discussion is about service provision in general and not about the patient's own health
- Patient and public involvement initiatives aimed at learning from the experiences of patients using services and to improve those services for future patients
- Other types of service evaluation by questionnaire or interview following the criteria above.

Appendix 8. The Simple Rules Toolkit. An Educational Tool Designed to Help Staff Differentiate Between Clinical Audit, Research and Service Review Activities. Sheffield Teaching Hospitals NHS Foundation Trust[102]

Question	Yes	No	DK*
Do you want to: • measure current practice against evidence based clinical standards?	❒	❒	❒
If yes, the project is **clinical audit.** If no, it isn't. If don't know, seek further advice before proceeding.			
Do you want to: • investigate the effects of a new treatment or technique on patients/carers?	❒	❒	❒
• investigate the effects of an existing treatment or technique on a new patient/carer group or pathology?	❒	❒	❒
• investigate the correlation between two treatments/techniques or characteristics?	❒	❒	❒
• test a new technology or new medicine on a patient or carer?	❒	❒	❒
• develop a new technology using NHS staff or facilities?	❒	❒	❒
• develop new knowledge that is generalisable or transferable to other patients or settings?	❒	❒	❒
• investigate a cognitive, physiological, physical/functional, psychological or social phenomenon of staff, patients or carers where current evidence or knowledge is lacking?	❒	❒	❒
• use human tissue from patients/staff in your investigation?	❒	❒	❒
If yes to ***any*** of these questions, the project is **research.** If no, it isn't. If don't know, seek further advice before proceeding.			
Do you want to introduce and evaluate: • a new practice(s) based on evidence published in a peer-reviewed publication?	❒	❒	❒
• a new practice(s) based on evidence of implementation and evaluation in another NHS trust or health/social care setting?	❒	❒	❒
• a new practice(s) for which there is limited evidence but which you have completed an assessment of need and risk?	❒	❒	❒
• a new outcome measure or assessment tool published in a peer reviewed publication?	❒	❒	❒
• a new type of equipment currently licensed in the UK?	❒	❒	❒
If yes to ***any*** of these questions, the project is **practice/service development**. If no, it isn't. If don't know, seek further advice before proceeding.			
*DK means Don't know			

Appendix 9. Recommendations for the Ethical Conduct of Quality Improvement, National Ethics Committee of the Veterans Health Administration, USA[44]

Recommendation
1. Health care organisations should recognise that QI cannot always be meaningfully differentiated from other activities that occur in the clinical area, notably treatment and research.
2. Health care organisations should ensure that the rights and interests of patients involved in all health care activities — including QI — are adequately protected.
3. Health care organisations should take care that efforts designed to protect patients do not unnecessarily encumber the QI process.
4. Health care organisations should clearly define the locus of responsibility for the ethical conduct of QI.
5. Health care organisations should proactively promote the ethical conduct of QI.
6. QI activities should produce benefits that outweigh their potential burdens or risks.
7. QI activities should respect each patient's right to self-determination.
8. QI activities should preserve patients' privacy and confidentiality.
9. QI activities should be fairly distributed across patient groups.
10. Health care organisations should develop specific policies and procedures that fit their unique circumstances and needs.