APPENDIX 1

Ethics and clinical audit

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Key points

- Clinical audit and quality improvement (QI) are ethically driven activities.
- It is a misconception that ethics review is needed for research but not for clinical audit or other QI projects.
- Clinical audits can overlap with quality improvement research, so criteria for making a decision on the nature of the activity are needed.
- Clinical audit and other QI projects can raise ethical issues, and proposals for such projects should be screened in order to flag and handle any ethical issues.
- The findings of clinical audits and quality improvement projects should be screened to ensure that any ethical issues that arise in a project are handled appropriately.
- Healthcare organisations need to have robust structures, policies and processes in place for ethical oversight of clinical audits and QI projects.

The purpose of this appendix

- To set out the ethical issues involved in clinical audit and how these can be managed.

THE ETHICAL OBLIGATION TO UNDERTAKE CLINICAL AUDIT AND QI

The gap between evidence-based practice, actual patient care delivered, and shortcomings in patient safety in healthcare organisations is well documented.[1] Doctors, nurses, allied healthcare professionals and healthcare organisations have an ethical obligation to close the gap in implementation of best known practice, and to overcome patient safety shortcomings.[2–4] Disciplined and focused QI efforts can increase the effectiveness and safety of healthcare.[5] If properly conducted, clinical audits and other QI activities can be seen as an ethical imperative in healthcare, something from

which both professionals and patients benefit and in which they should cooperate.[5] Failure to undertake clinical audits and other QI projects can be harmful if such lack of participation perpetuates unsafe, unnecessary or ineffective clinical practice.[6]

DIFFERENTIATING RESEARCH AND CLINICAL AUDIT OR QI AS A BASIS FOR ETHICS REVIEW

The importance of identifying research properly

Ethics review of proposed research studies is required because clinical research requires participants in the research to take the risk that they will receive a treatment that is not optimal or which may even be harmful.[7] Participation in research is voluntary, and therefore each participant in a research study is entitled to choose whether or not to be a research subject.[8,9] It is very appropriate that people who volunteer to participate in research are safeguarded through effective ethical review of proposed research projects.

It has become important to attempt to distinguish between research and clinical audit and other QI activities in order 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 research project as a clinical audit or QI study, clinicians avoid the time-consuming process of review of research proposals, including requirements for informed consent of the participants.[7,10–17]

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

Studies have demonstrated that research ethics committees, researchers, medical directors, quality improvement or clinical governance practitioners, and journal editors are not consistent in reaching decisions as to whether a proposed project represents research or quality improvement.[15,18–21] Clinicians in different countries have experienced misunderstanding by colleagues as well as by authorities as to what constitutes research as opposed to a quality improvement project.[14,22–31]

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

A number of concepts have been suggested as the basis for differentiating between research and clinical audit or QI, such as purpose, systematic approach, production of generalisable new knowledge, treatment or allocation, intention to publish, and focus on human subjects.[32] These concepts have not been validated as reliably discriminating between research and quality improvement studies. However, as quality improvement studies become increasingly sophisticated, many of these concepts can potentially apply to both research and quality improvement studies.[1,3,4,9,14,24,26,33–40]

No point to differentiating between research and clinical audit or QI as a basis for review

There are three reasons why differentiating between research and clinical audit or QI activities should no longer form the basis for deciding whether an activity requires ethical review.

- Distinctions between the two types of activities are blurred and can be ambiguous, unhelpful and arbitrary.[1,11,12,15,19,24,41–47]
- There are other ethical issues related to clinical audit and QI activities that are beyond consideration of the design of an individual clinical audit or QI initiative as a project. These issues relate to the healthcare organisation's duty to manage and to act on the findings of audits and QI studies.[4]
- Some QI initiatives are truly research on the quality improvement process – that is, 'hybrid' projects.[48–50] Research on the QI process itself or organisational or practice interventions intended to bring about improvements in patient care should be subject to research ethics oversight.

WHAT IS INVOLVED IN ETHICS?

Ethics is the inquiry into situations that have led or which may lead to harms or benefits to others, and into the language that is employed to describe those situations.[51] 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 of these principles[51] and examples of their application to healthcare can be found in Table A1.1.

TABLE A1.1 Ethics principles and examples of their application

Principle	Meaning	Example of application to healthcare
Autonomy	An obligation to respect the rights of people to make choices concerning their own lives (e.g. by disclosing information to enable people to make decisions, to foster their decision making and not to assume a controlling influence on their decisions); also recognising the right of a person to choose to decline 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

(*continued*)

Principle	Meaning	Example of application to healthcare
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 information about patients, and providing privacy for patients Avoiding the intentional or unintentional imposition of a risk of harm to a patient (e.g. by failing to monitor a patient in accordance with the severity of 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

ETHICAL ISSUES WITH REGARD TO A CLINICAL AUDIT OR QI PROGRAMME

Five ethical issues related to a clinical audit or QI programme have been identified. These are:

- the participation of all healthcare professions in clinical audit and QI activities
- assurance that all clinical services are undertaking clinical audits or QI activities
- a systematic approach to setting priorities for clinical audits or QI activities
- coverage of all patient groups and types of conditions
- 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 as meaning that not to be involved in audit or QI is a breach of a professional code of conduct.[52,53] 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.[54,55] The inclusion or exclusion of professionals in the clinical audit or QI process raises important ethical issues, not least in terms of representation and the promotion of fair working practices.[36] It is important for audits or QI studies to be conducted in ways that maximise professionals' obligations towards one another, and in doing so, they may improve the quality of clinical audit.[36]

Secondly, 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 about informing patients of possible harms, 'perhaps providers who do not monitor quality should be required to inform patients that no systematic improvement efforts are under way and they are thus at risk of receiving suboptimal care'[56] because 'the real risk from QI lay in the absence rather than presence of QI.'[57]

Thirdly, priority setting for clinical audits or QI studies may be influenced by a number of factors, including external requirements and expectations, the resources available to carry out the work, pressure from patients and their representatives, or the perceived ease or difficulty with which work on a particular subject is carried out.[58] There is a perception that clinical audits, for example, have tended 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 audits or QI projects respond to the risk–benefit analysis.[11]

Fourthly, 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 that are used to delineate inclusions or exclusions (e.g. 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.[59] In addition, the potential burdens or risks as well as the potential benefits of the activities should be distributed fairly across the population of patients who are served by the healthcare organisation.[11]

Finally, if there is an ethical responsibility to undertake clinical audits and QI activities as an ongoing and integral part of the operations of a healthcare organisation, there is also a responsibility to manage and conduct clinical audits and QI projects effectively and well. Unfortunately, clinical audits and QI activities in many organisations are decentralised, fragmented, under-resourced and ad hoc, with little priority setting,[4] and with priorities driven by poorly researched and politically motivated top-down initiatives by central authorities,[16] inadequate structures to ensure the long-term success of the activities, and lack of a reliable structure of management of and accountability for quality.[4] Arrangements for the management of clinical audits and QI projects should include provision at least for oversight of ethical issues, the quality of the design and implementation of the work, information sharing, and resources allocated to the work.[60]

WHEN SHOULD A PROPOSAL FOR A CLINICAL AUDIT OR QI ACTIVITY HAVE AN ETHICS REVIEW?

Situations in proposals that require ethics review

Some key principles can be used to identify a clinical audit or QI activity that should have an ethics review at the proposal stage. These principles relate directly to the moral principles described earlier not being followed.[12,42] They include the following.

- Each patient's right to self-determination is respected.[3,11,13,61–64]
- There is a benefit to existing or future patients or others that outweighs the potential burdens or risks.[11,13,46,56,57,62–65]
- Each patient's privacy and confidentiality are preserved.[11,13,62–64]
- The activity is fairly distributed across patient groups.[11,13,63]

In addition, specific circumstances have been identified for which a proposal for a clinical audit or QI activity should have an ethics review (*see* Box A1.1). If it is determined that 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, the activity should have an ethics review, and the written permission or informed consent of the participants is needed.[1,11,13,63,66] Risks could include that standards of good practice are not available in the current literature for the project,[67] or that non-compliance with a standard could constitute a 'remediable adverse event.'[67,68]

BOX A1.1 Specific circumstances relating to a clinical audit or QI project proposal that require ethics review

The activity infringes on any patient's rights by:

- limiting or restricting patients' rights to make choices about their healthcare.[11,13,61,64]

The activity places a burden (the additional time and effort required of patients or others for data collection, taking additional tissue samples, or extra clinic or home visits)[46] **on patients or others by:**[1,11,13,15,16,33,42,46,56,61,63,65,69–74]

- posing any risk to or burden on a patient beyond those of their routine care
- involving 'vulnerable' people
- collecting data directly from any patient or carer, except the use of a minimal number of factually based questions that are not of a sensitive nature, with no patient identification details recorded.[67] If data are being collected directly, the activity should not subject a patient or carer to more than a minimal burden or risk (e.g. by requesting sensitive information or requiring time to provide the information).

If data are being obtained directly from patients, and the process may be intrusive for them (e.g. questionnaires or focus groups that involve patients' personal feelings, that take more than 5 to 10 minutes to complete, or that could involve revealing information about an illegal activity), the activity should be reviewed.[11,13,15,16,36,52,57,61,70,75–78]

The activity breaches confidentiality or privacy through:[1,10,11,13,15,16,52,58,61–63,70,72,76,78–81]

- collecting or disclosing any data that could be used to identify any patient or practitioner
- using very small sample sizes that would allow identification of individual patients
- having someone carrying out the activity who does not normally have access to patients' records (e.g. someone who is not part of the clinical care team, who does not have a professional obligation of confidentiality, who is not employed to support QI-related activities, or who is carrying out the work as part of a course of study).

The activity varies from or disrupts established clinical practice by:

- gathering any information about any patient in addition to the data that are normally or routinely collected as part of providing routine care for that patient[70,81]

- providing care that is a clinically significant departure or deviation from current normal (accepted, usual) clinical practice[1,11,16,17,33,46,65,70,81–84]
- causing any disruption to the clinician–patient relationship.[1,11,13,63]

The activity involves a potential conflict of obligation to patients by:

- considering a trade-off between cost and quality to individual patients or to all patients.[4,11,13,16,46,85]

The activity involves any untested intervention, including:

- using any form of selective or untested clinical or systems intervention or testing of a hypothesis[1,2,11,13,15–17,63,76,78,83]
- implementing a new practice that is not already established.[11,13,78]

The activity involves specific allocation or recruitment, including:[1,11,13,17,63,76,78,83]

- allocating treatment or any intervention differently among groups of patients or staff with or without randomisation (e.g. in implementing a change in practice)
- specific recruitment of patients or others to participate.

The activity involves an intention to publish:

- intending at the start of a project to publish or to use any personal health information in the publication.[17,78]

The activity provides no direct benefit to patients, including:

- undertaking an activity for which the patients involved will not directly benefit from the knowledge to be gained.[11,13,33,84]

Ethical issues related to the proposed design and methodology of 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 in care.[86] If a project will be futile, or does not use scientifically valid methods, or will not yield scientifically credible evidence, it should not be undertaken.[2,52,82] What needs to be audited and how a clinical audit is to be conducted may be decided by individual practitioners at a local level, with little consultation with colleagues or other stakeholders. The development of clinical audit activity in this way can raise questions about the validity and ethicality of some studies being undertaken.[78]

Clinical audits and QI projects should be well designed and use measures that are reliable and valid.[11] The activities should be carried out by well-supervised staff who have adequate training in audit or QI methods and access to consultative advice.[11,43] The methods that are used in a clinical audit or QI project need to be as rigorous as those that are used in research if the activity and findings are to be valid, reliable and credible, and clinical audits should be undertaken to the highest professional standard.[61,78,84]

> 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.[46]

Ethics-related subjects of a clinical audit or QI activity

If a clinical audit or QI activity is being undertaken on a clinical subject that itself has ethical implications, the design of the clinical audit or QI activity must 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 the care of women experiencing a miscarriage.[87–90]

WHEN SHOULD THE FINDINGS OF A CLINICAL AUDIT OR QI ACTIVITY HAVE AN ETHICS REVIEW?

Of the principles and circumstances 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 (e.g. if care was not provided consistent with good practice)[1,7,11,13,42,46,56,63,65,69–71,73]
- identify any patients for whom a life-threatening or quality-of-life-threatening shortcoming in care occurred[91]
- disclose any data that could be used to identify any patient or practitioner[11,13,63]
- reveal any clinically significant departure from usual clinical care.[1,11,17,46,65,70,81–84]

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.[67,68]

WHEN SHOULD THE EFFECTIVENESS OF ACTION TAKEN ON A CLINICAL AUDIT OR QI ACTIVITY 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.[92] One contribution of the clinical audit and 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, it helps to identify where and how practice might be improved.[92] Although clinical audits and QI projects aim to improve or maintain the quality of patient care, those in charge cannot be certain that the intervention will be effective. There is a risk that the proposed innovation will be ineffective or even harmful.[73] Therefore risk assessment of changes in patient care or service delivery needs to be undertaken in order to pre-empt what could go wrong during the implementation of a change, and identify what to do if it does.[43]

Clinical audits or QI activities that do not address necessary changes to systems fail to meet the ethical responsibilities of healthcare professionals and organisations to improve quality.[57] 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 or may place an undue burden on patients or others. Major change should always be subjected to ethical scrutiny.[46]

If the audit or QI project is carried out properly, it measures conformance with clinical practices that are known to be effective. Therefore if the audit or project indicates that such effective practice is not being provided to patients, it would be unethical to continue to provide substandard care and to withhold improvements in practice from patients.[57,78] 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?[78] In addition, lessons learned from the clinical impact and outcomes of successful projects should be disseminated within an organisation in order to promote organisational learning and spread the achievement of improvements.[60]

HOW SHOULD A HEALTHCARE ORGANISATION HANDLE ETHICS AND CLINICAL AUDIT OR QI?

Designation of individual responsibility

An individual who takes the lead for a clinical audit or QI project should inform an appropriate manager that the project is being undertaken,[57] 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.[42]

Organisational structure for oversight of clinical audit or QI

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 ensure that

applicable ethical standards are followed.[11,13] Therefore healthcare organisations need to ensure that an individual or group, accountable to senior management and the governance of the organisation, is designated as responsible for the ethical conduct of each clinical audit or QI activity.[4,11,13,59,62,69,93]

Given the ethical issues that can arise during the implementation of a patient safety programme, the ethical oversight structure for clinical audit and QI should also include collaboration with the organisation's patient safety activities.[94] Oversight will protect patients from ad hoc or poorly conceived projects. It will also ensure that the organisation has a vigorous and strategic agenda to improve the quality and safety of patient care.[4] 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.[4]

Management responsibility for all activities that relate to QI and take place within a healthcare organisation is important,[3] because these activities should not be carried out by individuals acting in isolation.[11] Groups or teams carrying out the work should be acting on behalf of the organisation.[11] In order to be effective, the activities must have organisational support, in particular providing authority to act in response to the findings of data collection.[11] 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.[57]

BOX A1.2 Possible healthcare organisational mechanisms for ethical review of clinical audit and QI activities

Department heads assuming responsibility for screening proposals and referring those that require further assessment to a designated individual or group, and also assuming responsibility for the effectiveness of actions taken.[37,57,84]

The director responsible for clinical audit or QI, such as a quality improvement director.[57]

The organisational structure that governs quality management or improvement.[4,11]

A committee or group, accountable to the governance of the healthcare organisation,[37] which could be any of the following:

- quality improvement or quality improvement review committee[11,12,45,57,62]
- clinical audit committee[96]
- ethics (not research ethics) committee[11–13,42,46,70,72–74,97]
- peer review committee[38,78,84]
- joint quality improvement and research ethics committee[1,2,5,47,57,98]
- management ethics committee[60]
- patient safety committee[71]
- clinical policy committee[71]
- special group[12]
- ad hoc group of ethicists.[84]

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.[95] That 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 the findings. Examples of organisational mechanisms are listed in Box A1.2.

The review mechanism needs to ensure that individuals with a knowledge of QI principles and processes and ethical standards for QI processes are involved.[11,13,57,74] The process which is carried out should be designed to determine that clinical audit or QI activity projects:[3,38]

- 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 that 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.[3]

A research ethics committee can be asked to review clinical audit or QI activity proposals routinely or in cases where a possible ethical issue may exist.[1,11,37,66,85,99] It has also been suggested that the chair of a research ethics committee could screen proposals for clinical audits or QI projects, or could expedite projects that involve no more than minimal risk.[6,27] However, there may be several reasons why research ethics committees are not the best solution to overseeing clinical audit and QI.[4,5,8,62,76]

- There are significant differences between research and clinical audit or QI[8,42] with regard to the obligations of a healthcare organisation. Research is an optional activity in a healthcare organisation, whereas QI is ethically intrinsic to the provision of care.[2,8] 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.[2]

  Clinical audit and QI activities, on the other hand, should be part of an overall quality and patient safety improvement strategy that is integrated into the operations of the healthcare organisation.[74] 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.[4]
- Individuals who take the lead for clinical audit or QI activities should take responsibility for leading changes in practice that are needed to achieve improvements, and they should also assume responsibility for ethical 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.[4,8]

- Research ethics committees are often overworked and have lengthy backlogs.[4,8,12,13,63] Given the urgency of improvement in the quality and safety of healthcare, it is counterproductive to contemplate delays in the important business of redesigning the quality and safety of patient care.[4]
- As currently constituted, research ethics committees may lack the knowledge and expertise necessary to evaluate clinical audits or QI activities.[8,12,42,63]
- Many people who are 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.[7,12,13,40] 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.[19]
- In the UK, giving ethical approval for clinical audit or QI projects may put a research ethics committee beyond its indemnity coverage.[84]

Organisational systems for oversight of clinical audit or QI

Healthcare organisations should proactively promote the ethical conduct of clinical audit or QI activities using a systematic approach.[11,72] Systems should provide for screening proposals for clinical audits or QI activities independent of the individual who is leading or carrying out the work, in order to identify any risks or burdens that the project will pose 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.[11,76] Examples of organisational systems for ethical oversight of clinical audit and QI activities are listed in Box A1.3.

BOX A1.3 Healthcare organisational systems to support ethics oversight of clinical audit and QI activities

Registering clinical audits or QI activities electronically with the clinical audit or quality improvement department, where there is one. 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 follow-up of 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.[57,60]

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.[1,9,13,45,52,57] 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.[12,45,71,95]

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[64]
- the screening criteria to be used for ethical issues, and the levels and types of review of any such issues
- the action to be taken if an adverse event experienced by a patient is revealed through a clinical audit or QI project.[67,68]

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.[38,57,100]

For example, patients may need to be protected from initiatives that are primarily intended to reduce length of stay without clinical justification, or to substitute therapies when evidence is lacking that intended outcomes can be achieved safely with such reductions.[1,19,100] 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.[71] Staff shortages may mean that compromises are made which in turn can influence standard setting (e.g. in a clinical audit).[85] It is essential to distinguish between genuine QI and financial, organisational or bureaucratic activities in healthcare that serve interests other than quality, safety and the best interests of patients.[5]

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.[11,57]

Educating staff about the organisation's policies and systems for identifying and handling ethical issues relating to clinical audits or QI activities.[11,13,45,93,101] This includes 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.[43,59]

Tracking clinical audits or QI projects[11] in order to follow their progress in implementation and their effectiveness.

Monitoring for non-adherence to approved ethical standards[93] or ensuring that failure to conduct a clinical audit or QI project in accordance with approved ethical standards is reported as an incident.[57]

Providing for appropriate review for individuals who wish to publish the results of a clinical audit or QI project.[57,93]

ARRANGING FOR ETHICS OVERSIGHT OF CLINICAL AUDIT AND QI IN PRIMARY CARE

Healthcare professionals working in primary care settings, including family or general practitioner centres, should actively participate in clinical audits and QI projects for the same reasons as any other healthcare practitioners. It is important to ensure that ethical issues relating to clinical audits or QI activities are identified and handled properly in these settings. Many primary care organisations are small, with a less formal accountability structure than that which exists in larger healthcare organisations. It is less clear what method of ethics oversight of clinical audits and QI activities might work best in these care settings.[16]

In the UK, financial incentives for general practitioners have had a significant impact on GP motivation to carry out QI on subjects recognised by the UK government as priorities for improving patient care (e.g. asthma, heart disease and diabetes). It may be important to consider whether a QI programme with substantial financial incentives for practitioners poses ethical questions.[16]

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.[3,5,9,48] As an ethical matter, the responsibility of patients to cooperate in QI activities is justified by the benefits that 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 most committed to QI.[48]

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 are 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 both their health and the health and well-being of other patients.[3,76,82,102,103] The information that is provided for patients should make it clear that clinical audits and QI projects are a regular part of how the organisation fulfils its obligation to patients.[76]

Just as 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 healthcare is of the highest quality.[55] If a clinical audit or QI project requires the direct involvement of patients, they should be informed that their participation is optional and voluntary. If the project involves significant burdens or risks, the written informed consent of patients is needed.[13]

CONCLUSIONS

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 other QI as the basis for deciding whether 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 ethical 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 relating to clinical audit or QI programmes, and the following all need to be assured:

- participation by all healthcare professions in clinical audit and QI activities
- coverage of all patient groups and types of conditions
- a systematic approach to setting priorities for clinical audits or QI activities
- participation in clinical audits or QI activities by all clinical services
- 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 ethical issues in the design of the activity are recognised and handled properly. This must ensure that the proposed design and measures are valid and the data collected are likely to be reliable; and that any ethics-related issues in a clinical audit or QI activity are addressed completely consistently with the healthcare organisation's formal policies on that subject. The findings of data collection and the effectiveness of actions taken should also be screened for ethical issues.

Healthcare organisations need to have mechanisms in place for ethics oversight of clinical audits and QI activities. Individuals undertaking projects should be required to submit proposals for screening. Healthcare organisations need to designate an individual or group to be accountable for ethical oversight of clinical audit and QI activities, and to 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, they 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

ensures that these activities protect patients and their rights, and contributes to improved quality and safety of patient care.

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