

HQIP

Robin Burgess
Chief Executive, HQIP

About HQIP

- Established April 2008
- Led by Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices
- Non-profit making and non-regulatory
- Partnership forming and collaborative working



Our aims

- To re-invigorate clinical audit
- To be a leading player in quality improvement



Priorities

Key business areas within **clinical audit**

- Improving national clinical audit
- Supporting and enabling local clinical audit
- Developing the professional status of audit
- Promoting clinical audit within commissioning, performance management and regulation
- Developing audit as part of re-validation





Support for audit

- Local quality improvement team
- Creation of audit practitioner and best practice database
- Guidance to NHS Trusts about managing audit
- Support established networks and create new local/regional networks in audit
- Created a library of resources/tools for local audit use



Review of Ethics and Clinical Audit and Quality Improvement Literature

Nancy Dixon

clinical audit

- • • • Overview
- • • • Ethics issues related to clinical audit
- • • • Organizational oversight approaches
- • • • Implications

clinical audit

clinical audit

- • • • Overview
- • • • Ethics issues related to clinical audit
- • • • Organizational oversight approaches
- • • • Implications

clinical audit

clinical audit

Literature review

Purposes	<p>Identify:</p> <ul style="list-style-type: none"> • Ethics issues related to clinical audit or QI • Circumstances relating to clinical audit or QI that need ethics review • Organizational oversight structures and systems
Method	<ul style="list-style-type: none"> • Publication databases and web sites for 'ethics and clinical audit' and 'ethics and quality improvement' with health care • HQQ library • Abstract form completed for publications deemed to be relevant (~105 publications)

clinical audit

clinical audit

Why is ethics and clinical audit or QI important

- Clinical audit and related activities can pose burdens on or risks to patients
- Findings of clinical audits or QI projects need to be acted on to benefit patients
- Clinical audits or QI projects may be poorly designed and unlikely to benefit patients, which is ethically unjustifiable
- Clinicians can designate a research project as a clinical audit or QI project to avoid the research ethics review process
- True research on the quality improvement process may not be recognized as research

clinical audit

clinical audit

Ethics is the inquiry into certain situations and into the language employed to describe them; the kind of situations referred to are those which have led or may lead to harms or benefits to others

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

clinical audit

clinical audit

Clinical audit is 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

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

clinical audit

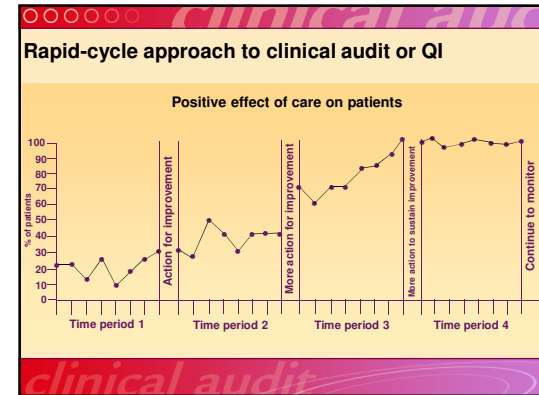
The *quality improvement process* is a systematic, data-guided activity designed to bring about immediate, positive changes in the delivery of health care in particular settings. For quality improvement to occur, the information produced by quality assessment must be translated into systematic improvements in healthcare practices

Baily MA, Bottrell M, Lynn J, Jennings B. *The Ethics of Using QI Methods to Improve Health Care Quality and Safety*. Garrison NY: The Hastings Center; July–August 2006 and Fox E, Tully JA. Recommendations for the ethical conduct of quality improvement. *J Clin Ethics* 2005;16(1):61–71

Characteristics of quality improvement

Aim	Improve patient care through measurement of the effects of change
Defining element	Repeated data collection used to test different change interventions
Pace	Feeds back measurements <i>rapidly</i> to the care system, leading to further <i>quick</i> changes in the care process or outcome being measured

QI is a sequential, dynamic process involving ongoing cycles of change–measurement–change–measurement



Differentiating between research and clinical audit

Ethics is not just about research versus clinical audit

- Research and clinical audit cannot be distinguished in a reliable and valid way
- There are ethics issues related to the clinical audit or QI process, not just about individual clinical audits or QI projects
- Research projects on quality improvement need research ethics oversight

clinical audit

- ● ● Overview
 - ● ● Ethics issues related to clinical audit
 - ● ● Organizational oversight approaches
 - ● ● Implications
- clinical audit

Ethics issues related to clinical audit and QI

Clinical audit or quality improvement programmes need to —

Meet ethical principles	<ul style="list-style-type: none"> Respect patients' rights Benefit patients Avoid risks to patients Be fair
--------------------------------	--

clinical audit

Providing benefit and avoiding risk

Clinical audits or QI projects need to be managed effectively to ensure that patients

- actually benefit from clinical audits or QI projects
- are not put at any risk through any clinical audit or QI project

clinical audit

“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”

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

clinical audit

Providing benefit and avoiding risk

Clinical audits or QI projects need to be managed effectively to ensure that patients

- actually benefit from clinical audits or QI projects
- are not put at any risk through any clinical audit or QI project

Priorities for clinical audits or QI projects need to reflect a benefit–risk analysis from a patient perspective — those that can achieve the most benefit for patients or minimize the risk of harm to patients

clinical audit

Being fair

All clinical services need to carry out clinical audits or QI projects

All healthcare professions need to carry out clinical audits or QI projects

All patient groups and types of conditions need to be covered in the programme over time

clinical audit

Individual clinical audits or QI projects need to be screened —

At proposal stage	Any reason(s) for ethics review? Proposed design valid and likely to produce reliable data? Subject have any ethical implications?
--------------------------	--

clinical audit

Ethics screening questions for clinical audit or QI proposals

Will the proposed clinical audit or QI project —

- Infringe on any patient's rights or risk breaching any patient's confidentiality or privacy?
- Pose any risk for or burden on a patient beyond those of his or her routine care?
- Involve any clinically significant departure from usual clinical care?
- Gather any information about any patient other than information that is ordinarily collected as part of providing routine care for the patient?

○ ○ ○ ○ ○ ○

- Collect data directly from any patient or carer, and if so, could the activity subject a patient or carer to more than a minimal burden or risk?
- Collect or disclose any data that could be used to identify any patient or any practitioner?
- Have someone carrying out the activity who does not normally have access to patients' records?
- Involve a potential conflict of obligation to individual patients or to all patients such as if the activity involves a trade-off between cost and quality?
- Involve the use of any untested clinical or systems intervention or testing an hypothesis?
- Allocate any interventions differently among groups of patients or staff?

clinical audit

○ ○ ○ ○ ○ ○

Individual clinical audits or QI projects need to be screened —

Following analysis of data	<ul style="list-style-type: none"> • Any risk to patients in findings? • Any patient with serious shortcoming in care? • Disclose any identity data? • Reveal any clinically significant departure from good practice?
Following action	<ul style="list-style-type: none"> • Improvements achieved? • Any patients at risk?

clinical audit

○ ○ ○ ○ ○ ○

- • • • Overview
- • • • Ethics issues related to clinical audit
- • • • **Organizational oversight approaches**
- • • • Implications

clinical audit

○ ○ ○ ○ ○ ○

Options for ethical oversight

- Clinical directors and/or clinical service managers
- Governance director
- Clinical audit or quality improvement committee

Oversight of —

- Clinical audit and QI programmes
- Individual clinical audits or QI projects at proposal, following data analysis and following repeat measurement stages

clinical audit

○ ○ ○ ○ ○ ○

Research ethics committees — not the best solution

Clinical audit and quality improvement is an organizational responsibility — should not be delegated to a research ethics committee

Research ethics committees:

- Were not created to review projects on improvement
- Often overworked and backlogged
- Don't necessarily have expertise in clinical audit and QI

Staff can be discouraged by paperwork

clinical audit

○ ○ ○ ○ ○ ○

Summary

Shift from the rule —

If it's research, it requires ethical review

To the principle —

If it has ethical implications, it requires review

clinical audit

clinical audit

- • • • Overview
- • • • Ethics issues related to clinical audit
- • • • Organizational oversight approaches
- • • • **Implications**

clinical audit

- clinical audit
- ### Implications — ethics and clinical audit and QI policy and process
- Responsibility and accountability
 - How clinical audit programme is reviewed
 - How individual clinical audits are reviewed
 - Ethics screening questions
 - Who decides on clinical audits with ethics implications and how
 - How patient consent is handled when needed
 - How patients are followed up if serious shortcomings in care are identified
 - How staff are informed about ethical oversight
 - How the clinical audit programme is monitored
 - How submissions for publication of clinical audits are to be handled

Review of Ethics and Clinical Audit and Quality Improvement Literature

www.hqip.org.uk www.hqq.co.uk