

***Review of Ethics and Clinical  
Audit and Quality Improvement  
Literature and  
Guide on Ethics and Clinical Audit***



# Workshop and marketplace etiquette

- Authors will discuss openly the details of their products
- Authors will listen carefully to ideas and comments
- Delegates will consider the details of products privileged information until publication
- Delegates will be honest, open and constructive in their contributions
- Delegates are invited to complete feedback cards to submit comments and ideas about the content of the products



- ● ● ● **Overview**
- ● ● ● **Ethics issues related to clinical audit**
- ● ● ● **Organizational oversight approaches**
- ● ● ● **Next steps**



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# Literature review

## Purposes

### Identify:

- 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

- 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)

# Why is ethics and clinical audit important

Clinical audit and related activities can pose **burdens** on or **risks** to patients

Findings of clinical audits need to be acted on to **benefit** patients

Clinical audits may be poorly designed and unlikely to benefit patients, which is **ethically unjustifiable**

Clinicians can designate a research project as a clinical audit to avoid the **research ethics review** process

**True research** on the quality improvement process may not be recognized as research

***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 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

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

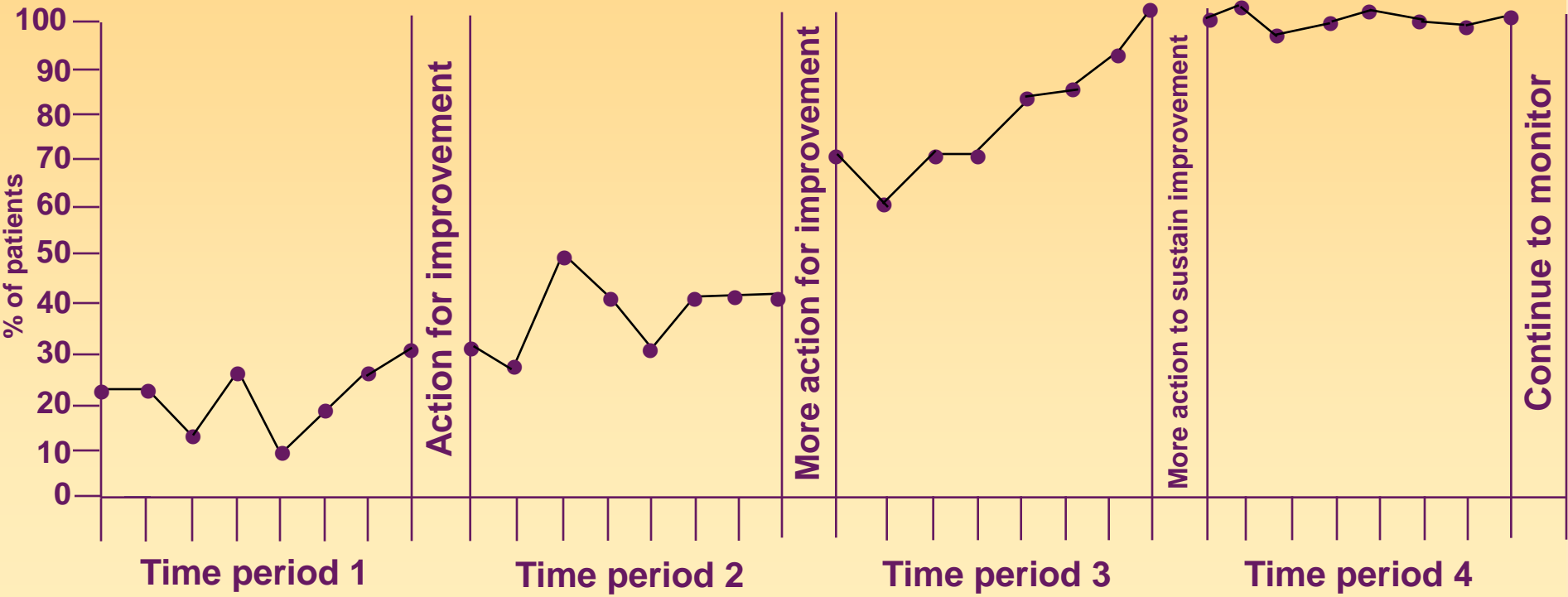
# Characteristics of quality improvement

<b>Aim</b>	Improve patient care through measurement of the effects of change
<b>Defining element</b>	Repeated data collection used to test different change interventions
<b>Pace</b>	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*

# Rapid-cycle approach to clinical audit

## Positive effect of care on patients



# 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 process, not just about individual clinical audits
- Research projects on quality improvement need research ethics oversight



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# Ethics issues related to clinical audit

Clinical audit programmes **need to** —

**Meet ethical principles**

**Respect patients' rights**

**Benefit patients**

**Avoid risks to patients**

**Be fair**

# ***Providing benefit and avoiding risk***

**Clinical audits need to be managed effectively to ensure that patients**

- actually benefit from clinical audits**
- are not put at any risk through any 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

# ***Providing benefit and avoiding risk***

**Clinical audits need to be managed effectively to ensure that patients**

- actually benefit from clinical audits**
- are not put at any risk through any clinical audit**

**Priorities for clinical audits 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**

## ***Being fair***

**All clinical services need to carry out clinical audits**

**All healthcare professions need to carry out clinical audits**

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


# Individual clinical audits 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?**



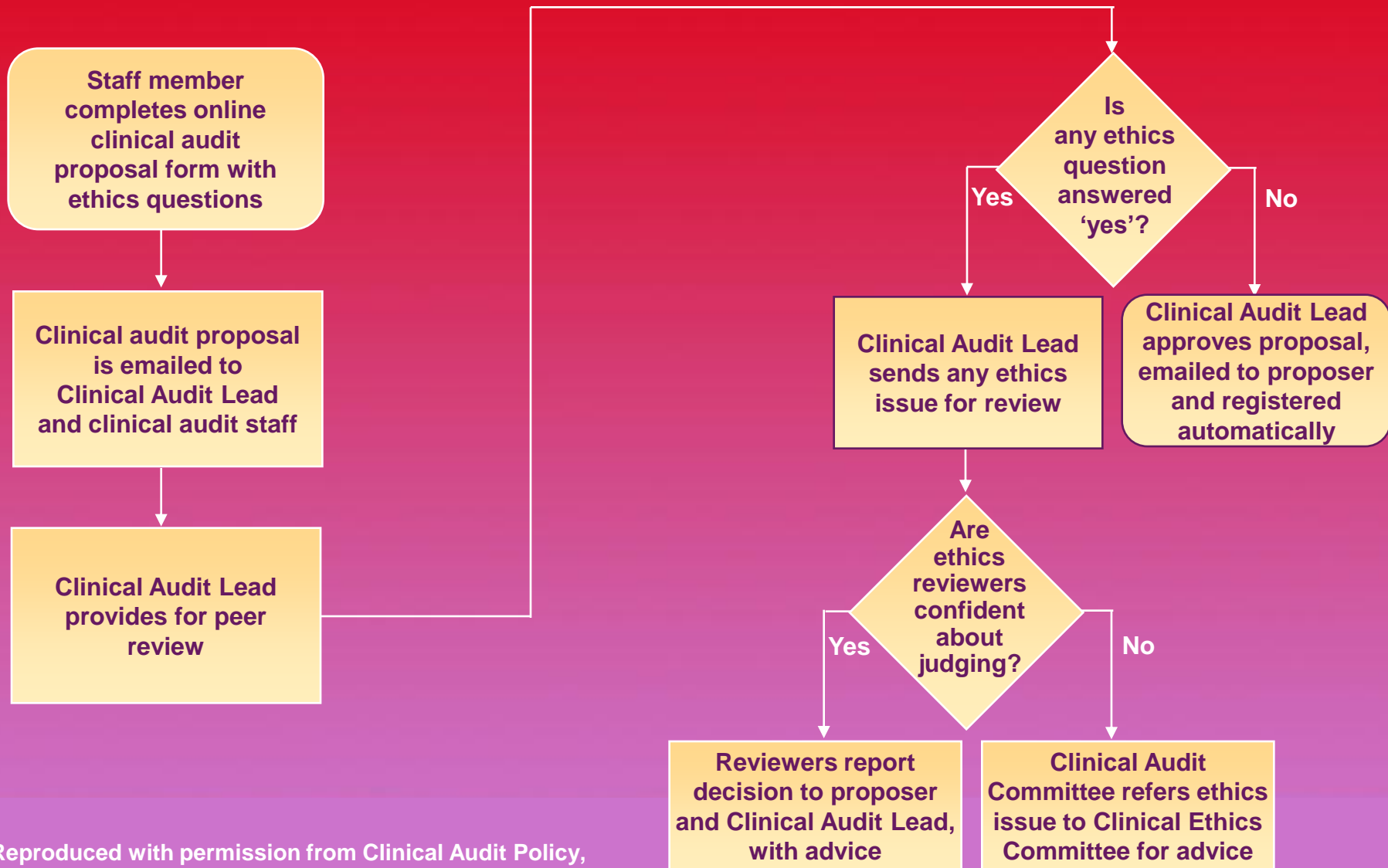
# Ethics screening questions for clinical audit proposals

**Will the proposed clinical audit —**

- **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?**

# Possible ethics screening and handling process for clinical audits



# Individual clinical audits need to be screened —

## Following analysis of data

- Any risk to patients in audit findings?
- Any patient with serious shortcoming in care?
- Disclose any identity data?
- Reveal any clinically significant departure from good practice?

## Following action

- Improvements achieved?
- Any patients at risk?



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# Options for ethical oversight

- Clinical directors and/or clinical service managers
- Clinical governance director
- Clinical audit or clinical effectiveness committee

## *Oversight of —*

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

# Research ethics committees — not the best solution

**Clinical audit 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**

**Staff can be discouraged by paperwork**

# Template ethics and clinical audit policy

- 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

# Summary

*Shift from the rule —*

*If it's research, it requires ethical review*

*To the principle —*

*If it has ethical implications, it requires review*



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# Next steps

- Comments raised will inform final draft
- Final drafts prepared for mid May
- Editorial Board in June
- Publication on HQIP website in July

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