

# Ensuring that high ethical standards are applied to clinical audit

## Summary

Participating trusts occasionally enquire about whether the subject and methods of data collection by these networks necessitates research ethics approval. The CCQI collects data for the purpose of audit and occasionally, for the purpose of service evaluation with a view to service improvement; it does not undertake research. Neither clinical audit nor service evaluation, of the type undertaken by the CCQI, require approval from a research ethics committee. However, the Centre is keen to underline its ongoing commitment to conducting its work in a responsible and ethical manner.

## **What is 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. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against each explicit criterion. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery”.*

*Principles for Best Practice in Clinical Audit, National Institute of Clinical Excellence (2002)*

Clinical Audit is directly related to improving services against a standard that has already been set by examining:

1. Whether or not what ought to be happening is happening
2. Whether current practice meets required standards
3. Whether current practice follows published guidelines
4. Whether clinical practice is applying the knowledge that has been gained through research
5. Whether current evidence is being applied in a given situation

*Guidance on developing procedures within NHS organisations for appropriate authorisation and management of research and related projects, Research and Development Forum, 2005*

Table 1 lists the features of research, audit and service evaluation. The table was devised by the Central Office for Research and Ethics Committees. COREC’s position is that *“Audit and Service Evaluation, however defined, were recognised to have no, or less than minimal (risk), and there was broad agreement that such work need not come before an NHS REC, unless specifically requested”*

(COREC: ethics consultation e-group Audit, research or service evaluation, Oct 05)

## Sufficient

**Table 1: A table for researchers and reviewers to use and for the “queries line” to refer to.**

<b>RESEARCH</b>	<b>CLINICAL AUDIT</b>	<b>SERVICE EVALUATION</b>
Designed and conducted to generate new knowledge	Designed and conducted to provide new knowledge to provide best care	Designed and conducted to define current care
Quantitative research – designed to test an hypothesis Qualitative research - 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?”
	Measures current service against a standard	Measures current service without reference to a standard
May involve a new treatment	Doesn’t involve a new treatment	Doesn’t involve a new treatment
May involve additional therapies, samples or investigations	Involves no more than administration of questionnaire or record analysis	Involves no more than administration of simple interview, questionnaire or record analysis
May involve allocation to treatment groups NOT chosen by HCP or patient	Does not involve allocation to treatment groups: the HCP and patients choose treatment	Does not involve allocation to treatment groups: the HCP and patients choose treatment
May involve randomisation	Does NOT involve randomisation	Does NOT involve randomisation
<b>Under current guidance, research REQUIRES R.E.C. REVIEW</b>	<b>Under current guidance, audit DOES NOT REQUIRE R.E.C. REVIEW</b>	<b>Under current guidance, service evaluation DOES NOT REQUIRE R.E.C. REVIEW</b>

*COREC ethics consultation e-group: Audit, research or service evaluation, Oct 05.*

*“The **taxonomy** (Is this work “Research”, “Audit” or “Service Evaluation”?) was clearly of less concern....than the **consequences** for those involved in the project, particularly patients. It is evident therefore that this taxonomy is useful but as a surrogate marker for the **level of risk** in any project. Audit and Service Evaluation, however defined, were recognised to have no, or less than minimal, and there was broad agreement that such work need not come before an NHS REC, unless specifically requested.”*

*COREC ethics consultation e-group: Audit, research or service evaluation, Oct 05.*

## **Discussions between the CCQI and COREC**

On the occasions that the CCQI has consulted ethics committees about its work, their response has confirmed our position. For example, in February 2006, the CCQI submitted a full description of the 'Better Services for People who Self-Harm' Project to COREC, detailing the audit methods used at the CCQI, including staff and patient surveys and consultations, the auditing of case notes and conducting peer-reviews. This included a list of the questions being put to service users and staff. The CCQI also reiterated the safeguards it has put in place to protect the dignity, wellbeing and safety of participants throughout the audit process. The following reply was received from COREC:

*"Thank you for your query. We have read the documents you attached and would deem your work to be audit. We agree entirely that audit should be conducted to accepted ethical standards and your document clearly outlines this".*

(COREC February 2006).

A similar response was received when the CCQI contacted the Welsh MREC about the Electroconvulsive Therapy Accreditation Service (ECTAS) in 2003.

Neither clinical audit nor service evaluation require approval from a research ethics committee.

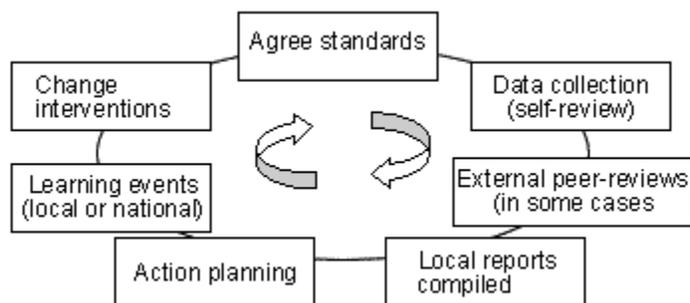
## **The College Centre for Quality Improvement and ethical audit**

The Centre has been running quality improvement programmes since 1999 and now has numerous quality improvement programmes underway. All of the projects managed by the CCQI meet the criteria listed in the 'clinical audit' column above and are therefore defined as audit, not research.

## **Key features of the CCQI programmes**

- They do not manipulate treatment plans, or experiment with new clinical techniques.
- They do explore the extent to which services are complying with nationally agreed standards.
- They all share the same long-term aim: to increase compliance with nationally recognised standards, resulting in an improved quality of care for the patient group in question.
- All of the CCQI projects follow a typical clinical audit process described in figure 1 below.
- Each project has developed its own manual of quality service standards based on the best available evidence, and collects data to help services identify aspects of service provision that require improvement.
- The CCQI supports local teams in action planning and re-audits services periodically, to examine which improvements have been made.
- Services are encouraged to network with each other on a national or international basis to share ideas for best practice, helping all services to improve patient care. This is facilitated by email discussion groups, newsletters, conferences and learning events delivered by the CCQI.

**Figure 1: The Clinical Audit Process**



### **Conducting Audit to Accepted Ethical Standards**

Although neither clinical audit nor service evaluation require approval from a research ethics committee, the CCQI shares the view that “*the dignity, rights, safety and well-being of participants must be the primary consideration*”.

*Research Governance Framework for Health and Social Care, draft second edition, Autumn 2003*  
<http://www.dh.gov.uk/assetRoot/04/02/08/96/04020896.doc>

Below are some examples of the safeguards put in place by the CCQI:

### **Protecting the safety, dignity and rights of participants (service users and clinicians)**

- Clinical audit at the CCQI complies with to the Caldicott principles (1997), the Data Protection Act (1998), the Freedom of Information Act (2000) and the NHS confidentiality code of practice (2003).
- Potential participants are made fully aware that it is entirely their choice whether or not they take part in the any consultation or survey and service users are reassured that choosing not to participate will not affect the care that they receive in any way. This is stated clearly in the information provided and again re-iterated at the beginning of each and every survey. Participants are reminded of their right to withdraw from the audit at any stage, without providing an explanation.
- The information sheets provided by the CCQI are written to the same level of detail as those produced by the Healthcare Research Team at the College Research and Training Unit (who do have to seek ethical approval for such materials), so members and participants can be assured of similarly high quality.
- The audits do not ask for any personal identifiers (e.g. name, date of birth, address).
- The anonymity of service users and staff is protected throughout – views are collated along with those of other participants, meaning that local teams are unable to identify the comments or ratings of individual respondents.
- Confidentiality and its limits are made clear to all participants.
- Our service user advisors have opined that the level of distress associated with this work is no more than a satisfaction survey, and certainly no more than ‘general clinical practice’ – this is something that COREC have defined as an important factor. The staff questionnaires were edited by healthcare professionals.

## Consulting with relevant experts

- All of the CCQI audits have steering groups consisting of healthcare professionals and researchers and many also have extensive service user input. The steering groups play a key role in planning the work of the audit and ethical issues are discussed regularly. Where a question arises that appears to fall outside of the group's knowledge, specialist expert advice is carefully sought.
- Experienced members of the Healthcare Research Team, based at the Royal College of Psychiatrists' Research and Training Unit are available to offer advice about methodology and ethics if required.
- Systematic mechanisms (evaluation forms, discussion groups, AGMs) are in place to ensure that network members can feed back their views on the methods being used and raise concerns at any stage of the process.
- All of the projects consult with service users (for example when writing the service standards) and some employ service users on the central project team to design service user questionnaires, and contribute to information sheets and guidance notes. This helps to ensure that data collection tools do not cause any distress to participants, and that information provided to service users is clear and jargon-free.

## Conclusion

Although it is clear that the CCQI audits do not fall under the remit of local or national research ethic committees, the CCQI takes very seriously its responsibility towards conducting ethical audit. By putting into place the safeguards mentioned above, and continually reviewing its practice, the CCQI is confident that its work would stand up to the scrutiny of any ethical committee.

## Correspondence

Lucy Palmer, Royal College of Psychiatrists' Centre for Quality Improvement  
Email: [lpalmer@cru.rcpsych.ac.uk](mailto:lpalmer@cru.rcpsych.ac.uk)

## References

Caldicott Committee Report (1997)

[www.dh.gov.uk/assesRoot04/06/8404068404.pdf](http://www.dh.gov.uk/assesRoot04/06/8404068404.pdf).

Consultation from the enquiries department at COREC (February 2006)

Data Protection Act (1998)

[www.informationcommissioner.gov.uk/eventual.aspx?id=34](http://www.informationcommissioner.gov.uk/eventual.aspx?id=34)

COREC ethics consultation e-group (2005): Audit, research or service evaluation.

NHS Confidentiality Code of Practice (2003)

NHS Research and Development Forum, (2005)

Principles for Best Practice in Clinical Audit, National Institute of Clinical Excellence (2002).

Research Governance Framework for Health and Social Care, draft second edition, Autumn 2003  
<http://www.dh.gov.uk/assetRoot/04/02/08/96/04020896.doc>