Useful references

Casserat D, et al. Determining when Quality Improvement Initiatives should be considered research. *Journal of the American Medical Association.* 2000; 283: 2275.

National Health and Medical Research Council (NHMRC). 2003. *When Does Quality Assurance in Health Care Require Independent Ethical Review?* Canberra: National Health and Medical Research Council.

Smith R. Audit and Research. *British Medical Journal.* 1992; 305: 905. Available at: www.bmj.com

Wade D. Ethics audit and all shades of grey. *British Medical Journal.* 2005; 330: 468. Available at: www.bmj.com

The National Ethics Advisory Committee (NEAC). 2003. *Ethical Review of Observational Research, Audit and Related Activities.* Available at: www.neac.health.govt.nz/moh.nsf/pagescm/519/$File/EthicalReviewObservationalResearch.pdf

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Defining research

Issue 3

Patients expect healthcare professionals to undertake audit and service evaluation as part of quality assurance. These have no, or less than minimal, risk that can also be regulated in ways other than Research Ethics Committee (REC) review.

Research may carry greater risk to good clinical practice and it may generate conflicts of interest for the healthcare professional.

Hence our different approach to the review. Audit and service evaluation do not warrant mandated REC review. Research does.

The table in this leaflet differentiates research, audit and service evaluation, but we recognise that judgement, on occasions, will be needed.

If required, the National Research Ethics Service (NRES) can provide further help: queries@nationalres.org.uk

To help, key discriminants are:

1 INTENT

The primary aim of research is to derive new knowledge; audit and service evaluation measure level of care. Research is to find out what we should be doing; audit is to find out if we are doing.

Nevertheless, a project may have more than one intent; in such a case, a judgement is needed as to what the primary aim is.

2 TREATMENT

Neither audit nor service evaluation uses a treatment without a firm basis of support in the clinical community.

3 ALLOCATION

Neither audit nor service evaluation allocate treatment by protocol. It is by decision of clinician and patient.

4 RANDOMISATION

If randomisation is used, it is research.

Differentiating audit, service evaluation and research

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**