Research, audit and quality improvement

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Abstract
Purpose – The purpose of this article is to clarify the distinction between research and audit, and propose appropriate regulatory arrangements for audit and related activities.

Design/methodology/approach – The methods used were literature reviews and conceptual analysis.

Findings – Research and audit overlap in various ways, but differ in terms of their purposes and the risks likely to be encountered and distinguished, along with a third related category of activities called quality improvement.

Practical implications – Appropriate regulatory arrangements are proposed for audit and quality improvement activities. Using these should ensure appropriate ethical standards and risk management, while avoiding the time-consuming over-regulation that occurs when projects are unnecessarily submitted to the ethical scrutiny appropriate for research projects.

Originality/value – Gives suggestions and information that could be of great value in spreading service improvement.

Keywords Research, Auditing, Quality improvement, Specifications

Paper type Conceptual paper

Introduction
Research and audit are similar in several respects: both attempt to answer specific questions through collecting and analysing data, good practice in both involves dissemination of findings, both are intended (at least ultimately) to improve health services, and both are widely regarded as beneficial in terms of staff development and individual practice development. Both also raise particular ethical concerns. There is a tacit covenant between health professional and patient, under which the professional...
acts solely in the interest of the patient. In the case of both research and audit the professionals are concerned with wider benefits for other patients and perhaps society as a whole, rather than any individual patient (Perneger, 2004).

There is both anecdotal and survey evidence that research and audit are often not easily or consistently differentiated (Wilson et al., 1999). Several authors have therefore offered guidance on whether a project should be classed as one or the other (Madden, 1997; Royal Australian College of Surgeons, 2002; Royal College of Physicians of London, 1996). Such clarification is important because of the different mechanisms and processes needed to ensure quality and manage risk in research and audit. With the current British emphasis on research governance and the associated national standards and timetable for implementation the need for a clear distinction is greater than ever. Research projects must be identified and shown to be compliant with research governance standards, whereas audit is not subject to the same stringent external requirements. There are good reasons for this. Research is concerned with acquiring new knowledge, perhaps about new treatments, and so there are likely to be more risks than with audit, which is concerned with assessing current practice against good practice standards. Therefore, for people conducting audit projects the substantial administrative work involved in project registration and ethical approval is not required. There is still an ethical imperative to monitor and regulate audit and perhaps other related activities, but the closeness of the scrutiny and the assessment standards should be in proportion to the likely lower risk.

Because there are fewer registration and monitoring requirements for audit projects there is anecdotal evidence of research projects such as surveys being described as audit. In addition, several authors have argued for further distinctions between different kinds of research so that smaller and less risky research is not subject to the same extensive administrative procedures that apply under current research governance arrangements. Jones and Bamford (2004) described delays and disillusion when their small locally funded study was subject to further ethical scrutiny after what they regarded as a trivial change in their protocol. Parker et al. (2004) proposed a distinction between clinical investigation and research, where only the latter, in their field of genetics, would require full adherence to research governance procedures. Jamrozik (2004) complained that the whole ethics committee submission procedures have become too cumbersome, and all of these writers called for more pragmatism and compromises. Warlow (2004) added a further ethical dimension, suggesting that the impeding or delaying of research by ethics committee review may distort the methods so much that the conclusions are flawed and patients damaged, so producing an unintended unethical consequence.

In this paper we review recent attempts to distinguish these activities, and argue that an adequately clear distinction is possible. We identify other related and valuable activities which are not usefully regarded as either research or audit, and which we call quality improvement. Finally, we outline the different regulatory and management arrangements needed for the different categories.

**Research and audit**
The differences between research and audit have often been summarised thus Smith (1992) “research is concerned with discovering the right thing to do; audit with ensuring that it is done right”. Lists of distinguishing features have been produced by
several authors and Local Research Ethics Committees and other similar bodies. These
differences are summarised in Table I.

These differences involve a number of dimensions: purposes, methods, recruitment,
funding, impact on participants, rigour, breadth of dissemination, external regulation
and involvement. We suggest that the most fundamental difference is purpose; that is
the use to which information generated will be put. The other differences follow from
this. Drawing on the summary above we can then describe and differentiate research
and audit concisely.

Research
Research has as its purpose the acquisition of new knowledge generalisable beyond the
immediate setting. It involves systematic collection and analysis of data to test
particular hypotheses or answer particular questions. Research is normally guided by
a protocol, which has been peer-reviewed, there is an intention to publish, and the
findings are intended to be generalisable (3Ps and a G) (Russell, 1996). Some qualitative
or exploratory research may not be intended to produce generalisable findings (and so
might satisfy 3Ps but not the G). In this case it is likely that the subject matter is of
widespread interest and the methods are innovative. So in general research informs. Of
course, some research is applied, resulting in practice changes, but the overall purpose
of research itself is to inform.

<table>
<thead>
<tr>
<th>Research</th>
<th>Clinical audit</th>
</tr>
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<tbody>
<tr>
<td>A systematic investigation which aims to generate new knowledge</td>
<td>A systematic peer review of health care in order to monitor or improve services</td>
</tr>
<tr>
<td>Defines best practice or standards</td>
<td>Monitors current practice against best practice or known standards</td>
</tr>
<tr>
<td>Is based on a hypothesis</td>
<td>Measures against standards</td>
</tr>
<tr>
<td>May involve a new treatment</td>
<td>Never involves new treatment</td>
</tr>
<tr>
<td>May involve extra disturbance to patients over and above normal clinical management</td>
<td>Never involves disturbance of patients over and above normal clinical management</td>
</tr>
<tr>
<td>Usually involves well-defined selection criteria for recruiting participants</td>
<td>Recruitment criteria not usually as well defined or strict</td>
</tr>
<tr>
<td>Generalisable: aims to inform care across the NHS and beyond</td>
<td>Not generalisable: aims to influence local services</td>
</tr>
<tr>
<td>Intention to publish or widely disseminate outputs</td>
<td>Primarily local dissemination</td>
</tr>
<tr>
<td>Often commissioned and/or funded externally</td>
<td>Funded by local health services</td>
</tr>
<tr>
<td>Often conducted by people outside of the local service</td>
<td>Usually conducted by people providing the service locally</td>
</tr>
<tr>
<td>May involve patients being allocated to different treatment groups</td>
<td>Never involves allocation to different treatment groups</td>
</tr>
<tr>
<td>Is usually carried out on a large scale over a prolonged period</td>
<td>Is usually carried out on a relatively small population over a short time span</td>
</tr>
<tr>
<td>Extensive statistical analysis of data is routine</td>
<td>Some statistical analysis may be useful</td>
</tr>
<tr>
<td>Responsibility to act on findings is unclear</td>
<td>Responsibility to act on findings rests with clinical directorates</td>
</tr>
<tr>
<td>Always requires ethical approval</td>
<td>Does not require ethical approval</td>
</tr>
</tbody>
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Source: Choo, 1998; Thomson et al., 2000

Table I.
Differences between research and clinical audit
Audit
Audit is the cyclical process of assessing current services against set standards, acting to bring practice in line with the standards, reviewing again, and so on. Its primary purpose is improving the quality of a service or intervention by promoting adherence to standards. Good practice and innovative work on audit, like research, should be disseminated, including publication in appropriate journals, but the main use of audit data, and the clear reason for carrying out audit is to improve or maintain practice in line with set standards.

Other related activities?
Having summarised and drawn from previous attempts at clarification, it is clear that there are other activities that share features with research or audit but which are strictly and most usefully best regarded as neither. For instance, consider as an example a project to conduct a client satisfaction survey within a particular service. It is like research in that it is intended to produce new knowledge about the service, it involves systematic data collection and analysis to answer particular questions, it is guided by a protocol, and there is an intention to disseminate findings, at least locally. It is unlike research in not having been peer-reviewed, there not being an intention to publish findings in a journal, and because the findings are unlikely to be generalisable to other services. This project shares with audit the primary purpose of improving quality, using systematic data collection and analysis, and providing feedback to the local service. However, it is not audit because it is investigating a service rather than comparing practice in the service against previously set standards.

Consider as a second example a psychological therapist setting out to investigate her own effectiveness with different client problems by administering a consistent set of clinical assessments at initial contact, and set points subsequently. This project shares with research most of the same features as the client satisfaction survey. Only the dissemination and feedback arrangements are likely to be different, with the information generated available only to the psychotherapist and her clinical supervisor. The relationship of this project to audit is the same as that of the client satisfaction survey.

As a third example consider a project to investigate factors associated with sick leave within an organisation, through comparing sick leave rates between departments, and aggregating and comparing anonymised information obtained from interviews with managers after staff returned to work. This shares with both research and audit all the same features as the client satisfaction survey.

Many similar examples could easily be generated, but is it true that they represent neither research nor audit? It is clear that they are not audit, because none involves comparisons against set standards, but should they be regarded as research? All share most of the defining features of research, and certainly share the overall purpose of systematic knowledge acquisition. However, the knowledge they all seek is local rather than general, and their underlying aim is to improve local services rather than to add to the sum of generalisable knowledge. All might be regarded as examples of data-driven reflective practice on the part of a service manager, psychological therapist and Human Resources Director respectively. Widespread adoption of reflective practice of this kind by clinical staff and managers should surely be encouraged as a major component of quality improvement and clinical effectiveness efforts. Should all such projects be
expected to comply with current research governance requirements, with project registration, external peer review, ethical committee approval and so on? This would firstly be costly and secondly counterproductive, through stifling innovation and improvement. Thirdly, it is unnecessary because of the low risks they present.

**Quality improvement**

We propose that it is useful to identify a third class of activities – quality improvement – within which the above examples fit. These activities share features with both research and audit, but are different from both in important respects, although it might be argued that audit is one class of quality improvement activities. Research, and quality improvement should all be similarly valued but appropriately regulated.

Casarett *et al.* (2000) described a category of activities which they labelled quality improvement (QI) that are diverse but share the goal of generating knowledge that will guide improvements in health care. QI includes research, and a range of other activities. These authors noted the value of avoiding unnecessary documentation and regulation through identifying QI activities that are not research. They proposed two stepwise criteria to identify QI initiatives that require review as research under US Federal regulations. The first criterion is that a QI initiative should be reviewed and regulated as research if the majority of participants in the work are not expected to benefit directly from the knowledge gained. If most participants in the initiative are likely to benefit a second criterion applies. The initiative should be accepted as research if participants would be subjected to additional risks or burdens beyond usual clinical practice in order to make its results generalisable.

These criteria are attractive in centring on protecting the rights of patients. However, looking again at our examples, they do not seem consistently helpful. The client satisfaction survey outlined above would be unlikely to yield direct benefits for the participants, the same might well apply to the psychotherapist’s project, and no patients would benefit immediately from the sick leave project. So should these projects all be classed as research, with all the regulatory consequences that follow? This seems counterintuitive, for the reasons above. We believe that a category of activities that are neither research nor audit, but whose purpose is quality or service improvement, may be adequately described and consistently identified without recourse to Casarett’s criteria, as follows (Casarett *et al.*, 2000).

We propose using the term quality improvement (QI) for projects that do not involve set standards, but which aim to acquire knowledge about local services in order to improve those services rather than to acquire generalisable knowledge. The findings are not intended to be generalisable (although they and the methods may be). Nevertheless, good practice and innovations in QI should be disseminated, including publication in appropriate journals. Crucially, QI projects generally involve low risk. This feature of QI was emphasised by Lo and Groman (2003) in a paper arguing for systematic but appropriate ethical oversight arrangements. Projects of this kind might be similar to phase I and II studies (modelling and exploratory trials) in the MRC framework for trials of complex interventions (Medical Research Council, 2000). They might lead on to more definitive studies but they might not. As they stand they raise fewer risks and require less regulation. We believe also that the QI category would cover many of the projects, and deal with the concerns raised by Jones and Bamford (2004), Parker *et al.* (2004), Jamrozik (2004) and Warlow (2004).
Conclusions

It is useful to distinguish research from audit because, although both require ethical review, the associated risks differ and therefore the regulatory requirements for them should differ. An intermediate class of activities intended to improve service quality can be identified, and we have labelled it quality improvement. We believe these activities can be similarly adequately described.

There remains a need to promote the appropriate development of all of these activities and to provide information that will reveal which projects fall into which category. There is a similar need to establish systems to monitor these decisions and the projects flowing from them. Clear and rigorous arrangements to monitor and assure the quality of research exist through the NHS research governance arrangements, and similar but appropriately less stringent requirements are needed to scrutinise and assure the quality of audit and service improvement work. We suggest that these arrangements should cover the same domains that are within the research governance framework: ethics, science, information sharing, health and safety, finance. Such arrangements must not be inordinately burdensome, and their rigour and time requirements should be in proportion to the likely small scale and low risk of the work involved. These arrangements should also underpin dissemination of audit and service improvement projects and their results so as to promote organisational learning and the spreading of good practice. Brief project registration and record systems are needed, along with monitoring arrangements and systems for sharing good practice. Responsibilities need to be clear between R&D departments, clinical governance departments, managers and clinical directors. Perneger (2004) argued that new bodies are required to achieve this clarity and to ensure appropriate ethical standards in the conduct of improvement projects. These could be called management ethics committees, and they would assess the merits of all proposed quality or service improvement projects. Their work would focus on the expected effectiveness of interventions under consideration, their associated risks and burdens, and fairness in the distribution of benefits and risks. Perneger argued that these bodies should also, by extension, assess the merits of any management decisions that may impact on the quality of care. They should have the authority to decide whether any such project or management initiative could proceed.

There should also be manageable systems to follow up improvement projects to collect and share information on their outcomes and the clinical impact of these. Information of this kind could be of great value in spreading service improvement. We need to move away from the current all or nothing arrangements in which small and generally safe quality improvement projects are subject to the same regulation as much larger and potentially risky research projects.

References


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