Editorial

Clinical audit: more research is required

The widespread introduction of audit \(^1\) was based upon frequently quoted examples of good practice, \(^2\) support within the professions, \(^3\) and faith in the potential of audit to be widely effective when introduced routinely. Five years on, however, it is our experience that the support for audit displayed by the government and professional bodies may not be reflected in the attitudes of many clinicians. \(^4\) Audit has joined an already long list of responsibilities beyond direct patient care – responsibilities such as management, training of junior staff, advisory committee work, contracting, service development, and research. It is still regarded by some as an independent and burdensome addition to clinical practice, by others as repetitive and boring, \(^5\) and even those who support audit may regard it as too time consuming to be practical. \(^6\) Questions about the value of audit are being asked: \(^7\) the National Audit Office report is keenly awaited.

We, and others, have argued that fundamental research questions about audit require answers if it is to gain and retain credibility across the professions. \(^8\) It is not that audit is ineffective, but that the enormous financial and opportunity costs of routine audit have not yet been justified. \(^9\) Research is one of the key requirements to help maintain enthusiasm for audit, as well as enhancing its effectiveness. \(^10\) It is not easy to assess the direct costs of audit, let alone the opportunity costs, and it is still more difficult to disaggregate these costs of audit at different levels of organisation – for example the costs to a clinical department, a trust, a general practice, or a health authority. Without evidence that the benefits of audit exceed its costs, commitment will wane. As with research, \(^11\) audit needs a clear analysis of purpose, costs, funding and anticipated benefits to the NHS. So what should be included in the potential research agenda?

Potential research questions

Table 1 details some of the broad research questions (column 1), the settings in which research is needed (column 2), and the research methods required (column 3).

The government’s and professional bodies’ support for audit is backed up by some research that shows a relationship between audit and improved patient care, or clear direction on how to achieve improvement, as well as several examples of effective audit practice. \(^12\) To our first question “Can audit work?” we are able to answer unequivocally, “Yes”. These studies and case reports do not, however, constitute evidence that audit will be effective as a widespread part of routine clinical practice: evidence to date has come largely from work conducted by, or on, unrepresentative groups of clinicians. In other words, the question “Does audit work?” has not yet been answered (analogous to the effectiveness of an intervention as opposed to its efficacy).

Our third research question (table 1) seeks to explore the dynamics of the audit process. What is it about some programmes or projects that makes them successful? Evidence here is largely anecdotal. There has been no systematic attempt to characterise successful audit projects or programmes, although there is a growing literature on features of audit likely to support change. \(^13\) Such research would make it possible to influence audit training, education, and practice to greatest effect and ensure that audit resources are efficiently targeted. The CASPE research unit has conducted large surveys of providers and purchasers of audit activity throughout the UK. \(^14\) Kerrison et al have shown some of the problems and difficulties of implementing medical audit in the early stages of the national programme. \(^15\) Similar methods have addressed the role and function of medical audit advisory groups in general practice. \(^16\) Variation in clinical involvement, and the processes and impact of clinical audit have been described, but, to date, little hard evidence has emerged about the cause of these variations.

Grimshaw and Russell and others have recently developed ground rules for the effective implementation of referral guidelines based on scientifically sound research findings. \(^17\) Similar ground rules for successful audit based upon research evidence should also be devised, but the evidence upon which to base such guidance is at present

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**Table 1: Research into audit: questions, settings and methods**

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<thead>
<tr>
<th>Research questions</th>
<th>Settings</th>
<th>Methods</th>
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<tbody>
<tr>
<td>Can audit work?</td>
<td>Individual audit projects</td>
<td>Systematic literature reviews</td>
</tr>
<tr>
<td>Does audit work?</td>
<td>Audit programmes: Provider Purchaser Primary care Secondary care</td>
<td>Surveillance of audit activities</td>
</tr>
<tr>
<td>How can audit be facilitated?</td>
<td></td>
<td>Qualitative methods: Unstructured and semi-structured interviews Participant and non-participant observation</td>
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<tr>
<td>Is audit the most effective means of achieving quality improvement?</td>
<td>Cross sectional surveys</td>
<td></td>
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<tr>
<td>How much does audit cost?</td>
<td></td>
<td>Cohort and case control studies</td>
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<tr>
<td>Is audit cost-effective?</td>
<td></td>
<td>Intervention trials</td>
</tr>
<tr>
<td>Is another quality mechanism likely to be more cost-effective</td>
<td></td>
<td>Economic analysis: Costs Cost effectiveness Cost benefit analysis Cost effectiveness of audit compared with alternative activities</td>
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patch. Furthermore, evidence of the factors that influence the effectiveness of audit or quality assurance activity in other countries or settings may not be directly applicable in the different culture and organisation of the NHS, thus emphasising the need for UK based research into such policy implementation issues.

Other fundamental research questions include: Is audit the most effective way of achieving quality improvement in clinical practice? and Is it the most cost effective? Audit in its classic form should be seen as only one tool for quality improvement and needs to be compared with alternative approaches including contracting, continuing education, and total quality management. Although the value of audit has been questioned, to our knowledge only one research project in Britain has addressed its cost effectiveness. Establishing the cost of audit at each organisational level is clearly a necessary component of cost effectiveness research.

There is obviously a huge agenda for research into audit and the methods employed will need to be correspondingly diverse, as indicated in table 1, and illustrated below. The range of methods in health services research is broad and often underutilised.

The diversity of audit research: an illustration of methods
We now illustrate the difficulties and the potential for research into audit with reference to questions which can be asked about the function of audit support staff. A series of questions could be posed ranging from “What do audit support staff do?” to “Are audit support staff cost effective?”, and the questions can be addressed by a variety of methods. A register of audit support staff can allow routine surveillance of trends and activity and provide a sampling frame for cross sectional surveys. A self completion, postal questionnaire has been used to obtain data on audit support staff’s knowledge, attitudes, and behaviour and to inform us about the difficulties and the challenges facing these staff.

Methods such as direct observation, self completion diary records, or focus groups could supplement and complement such data.

To examine whether and how audit support staff contribute to the success of audit would be much more complex. Initially there is a need to define “success” in audit. Having done so, the association between employment of audit support staff and the success of audit projects could be measured and adjusted with reference to confounding variables. Initial studies could use the case control or cohort design. A research literature on audit support staff is developing, and includes a trial, but much more is needed. A study design similar to that used by Fowkes could help to define what types of intervention are more effective in creating change within the audit setting. For example, it might be possible to compare the effects of the application of written guidelines in a specialty with or without audit support staff.

Economic studies of the role, potential, and effects of audit support staff are needed. For instance, what are the true costs and benefits of support staff to a project or programme? Are audit support staff the most cost effective means of supporting successful audit?

The assessment of clinical audit is not dissimilar in concept to that of patient care, as shown in table 2, which compares the evaluation of cardiothoracic units and of audit. The success of a cardiothoracic unit or audit programme will depend upon the effective dissemination and application of sound research into routine practice such as is promoted by the movement for evidence based medicine. For example, the appropriate investigation and treatment of symptomatic coronary heart disease can be defined with reference to clinical trials and other research results, and incorporated into evidence based guidelines. At present, the research base for audit is insufficient to do the same. All clinicians are being expected to undertake audit, because audit has been shown to have value in certain settings (predominantly in case studies), while all cardiothoracic surgeons would not be expected to undertake coronary artery bypass grafts on the basis of similar evidence!

Conclusions
There is both a need and considerable opportunity for further rigorous research into audit. While there is a growing and useful body of work in this area, it is still limited to a small number of research teams, using an understandably limited range of methods.

A programme of research should consider the organisational context, available support, the methods employed, and the application and impact of audit, including how change was achieved; the objective being to tease out the factors that are associated with success. Furthermore, there is a need to demonstrate the effectiveness of audit in creating quality improvement in patient care, including research into its cost effectiveness or cost utility compared with other strategies for quality improvement. Such research and evaluation studies are essential, both to answer questions concerning the present value of audit and to support the design and development of audit projects and programmes.

Much effort and money has already been expended in the introduction of audit within the NHS. In proportion, research and evaluation of audit has been limited. One and a half per cent of the NHS budget now supports a coordinated, strategic regional and national programme of research and development. Given the importance of audit, both financially and strategically, we believe there should be further major investment into its evaluation. Ideally, such work should be guided by a strategy and coordinated. The audit budget in the last year of explicit funding was £62.3 M. Some 1.5% of this budget (£940 000) would pump prime a strategic research programme on the evaluation of audit.

Table 2
<table>
<thead>
<tr>
<th>Variables</th>
<th>CTU</th>
<th>Audit</th>
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<tbody>
<tr>
<td>Structural variables</td>
<td>No and grade of staff employed</td>
<td>No and grade of staff employed</td>
</tr>
<tr>
<td>Activity measures</td>
<td>No and types of cases treated</td>
<td>No and types of projects undertaken</td>
</tr>
<tr>
<td>Process measures</td>
<td>Proportion of patients appropriately operated upon</td>
<td>Proportion of projects using standards or guidelines</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>No/proportion of coronary artery bypass graft patients dying peripheratively</td>
<td>No/proportion of projects leading to improvement in the quality of care</td>
</tr>
<tr>
<td>Comparative outcomes</td>
<td>Intervention specific mortality rate compared with other units</td>
<td>Proportion of projects leading to improvement in the quality of care compared to other units/programmes</td>
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</table>
There are new opportunities to coordinate and enhance a programme of research into audit. The Department of Health funded National Clinical Audit Information and Dissemination Centre will have a key role in identifying priority research questions and perhaps in supporting or commissioning research. The Cochrane Collaboration Review Group on Effective Professional Practice and the NHS Centre for Reviews and Dissemination could both have an important role. Furthermore, the developing lead role of purchasers, both in commissioning audit and funding NHS R & D, offers potential for promoting research into audit.

Progress made since our previous call for research action is encouraging, but the pace and breadth of research on audit needs to be increased. Research into audit is both essential and urgent.

We thank Dr Bill Ennis and Dr Chris Holland for their important contributions to early thinking on this topic. Their views were invaluable in shaping our thoughts.

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