# Clinical audit: time for a reappraisal?

A recent short article in the *British Medical Journal* stated:

> The audit cycle has become a vicious circle, a noose to strangle any chance of it ever being a practical everyday tool; . . . a whole service industry has mushroomed around this fatal flower, and with every new blossom it becomes more and more remote from real practice and from the people who are actually doing the work.

These are vigorous words from a general practitioner (GP) [1]. A distinguished dean of a medical school has written in similar terms in an article entitled '*Exitus auditus—no fun*' [2]. The failure of clinical audit to win the hearts and minds of health professionals in the UK is a serious setback to improving the quality of clinical care. An important cause is the justifiable perception that the available methods of audit are inadequate. Unless these methods are improved, the academic medical community, which leads opinion on clinical services, will continue to dismiss audit, and an opportunity for improving care will be lost.

## What has led to pressures to develop clinical audit?

One of the working papers accompanying the White Paper before the reforms of the National Health Service (NHS) in the UK stated:

> An effective programme of audit will help to provide the necessary reassurance to doctors, patients and managers that the best possible quality of service is being achieved within the resources available [3,4].

The development of audit was seen as a necessary safeguard to protect the interests of patients in the new market for health care [5]. Well before this, however, there had been increasing concern that the provision of care was driven by availability and accessibility of resources and personal styles of practice rather than by evidence of effectiveness based on research [6,7]. The present emphasis on practising evidence-based medicine, and the more rapid implementation of the findings of clinical research, are responses to these pressures [8–10]. Clinical audit, both by revealing that ineffective interventions continue to be practised and by encouraging their cessation, should also help control the costs of health care.

One stimulus to the development of audit has undoubtedly been the rise of the consumer movement. Through the media, users and potential users of health services have gained a much greater knowledge of different possibilities of treatment. The multiplicity of emerging professions and of types of complementary medicine may also have contributed to some loss of trust between users of health services and health professionals [11]. Yet the most powerful force in the development of better medical care remains the clinicians' desire to do their best for their patients. They are in general proud of their work, and are pleased to show it off. Why then is audit failing?

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## Muddles about audit

### *The meaning of audit*

As in the financial sector where there is cooperation between audit and accounting [12], so too in the health sector there is apparent confusion, as judged by a recent Audit Commission report, *Trusting in the future: towards an audit agenda for NHS providers* [13]. The potential confusion between audit of financial costs and clinical values was foreseen by many physicians, who preferred the more neutral phrase of 'systematic clinical review' [14].

### *Clinical versus medical audit*

Another muddle was the separation of medical audit of care provided by doctors from audit of the care provided by other health professionals. It was unfortunate that from the 1989 White Paper [3,4] until April 1994 there was not only a budgetary but also an intellectual separation between these two aspects of audit. Since then, the concept of clinical as opposed to medical audit has been widely welcomed. However, although all health professionals should have an equal contribution to make to choosing the topics for audit, in virtually all cases such topics are chosen by the medically qualified leaders of the service. We have not yet reached the stage of professional equity that allows the nursing profession, for example, to suggest an audit of some technical aspect of surgical care.

### *Who is being audited?*

It remains unclear who or what is being audited, whether it is:

- health professionals as individuals;
- health professionals as teams;
- teams of health professionals plus health service managers for interhospital comparisons; and/or
- public health physicians, purchasers and planners for interdistrict, regional and even international comparisons.

*For whom is clinical audit undertaken?*

Is clinical audit for:

- government, which needs to ensure a quality health service to improve the health and wealth of the nation;
- purchasers or insurers, who are interested in controlling costs and, as proxies, in buying a service of good quality;
- hospitals, which also wish to control costs in order to get their contracts for the provision of services renewed;
- individuals choosing individual providers;
- individuals choosing fundholding practitioners or, in the USA, health care plans;
- individuals choosing different methods of treatment; or
- health professionals, who wish to know the outcomes of audit in order to improve their service?

*Audit as an educational tool versus a tool for monitoring contract performance*

The government's original concept was that:

> the quality of medical work can only be reviewed by a doctor's peers [3,4].

A number of reports linked medical audit firmly to continuing medical education [15]; in response to this, many hospitals located their audit departments in their postgraduate education centres. The budget for audit in the UK was ring-fenced by a central grant to regional health authorities (RHAs). When there were still large numbers of directly managed units it was easy for hospitals to allocate the money for audit as a tool for education and development. However, with the rising number of trusts, purchasers began to take a greater interest in topics for audit. The concept that audit is an educational tool shifted within a short space of time to the view that it is just one method for monitoring contract performance [16]. Some purchasers have made unrealistic demands about the information they require for monitoring contract performance, without paying sufficient attention to methodological principles.

*Clinical audit and other quality initiatives*

Where does clinical audit stand in relation to other initiatives to ensure quality in the health service? For example, in my trust, it was some years before the quality assurance initiative led for the previous decade by the nursing directorate fused with the clinical audit department. Furthermore, many publications about quality have taken models from the industrial sector, which may well apply to the organisational aspects of the delivery of a service or the work of a directorate [17] but do not readily fit the quality assessment of clinical care.

Patient satisfaction surveys, often breathtakingly trivial in their methodology, are usually run by hospital managers and probably reflect their desire to obtain feedback from patients about clinical topics in relation to other aspects of which they do not feel competent to intervene [18]. The management of complaints by patients is often undertaken by an entirely separate office within a hospital not related to the audit department. Hospital managers also have to collect indicators of administrative efficiency such as Patient's Charter statistics. There are also many health and safety regulations, radiation protection measures, infection control schemes, etc, which do not relate to the primary stream of clinical audit.

Autopsies and clinico-pathological conferences are another and old-established form of audit [19]. External teams, such as those run by the King's Fund Centre, may undertake external appraisal for the purposes of hospital accreditation [20]. A table of some of the identified quality management initiatives in the NHS has recently been published [21].

The diverse nature of these quality assessments makes it difficult to identify whether they are of good quality. Clinical audit, for instance, instead of being integrated into some of the other quality systems within a hospital, has been 'bolted on' as an extra, with a separate audit department staffed by people from different professional backgrounds, with varying and often inappropriate or incoherent lines of accountability.

*Funding*

Funding for medical audit in hospital and community health services (HCHS) was initially from the centre to the RHAs, and thence to district health authorities. Funding for general practice audit was part of the general allocation to Family Health Service Authorities, distributed to Medical Audit Advisory Groups. From 1994 onwards, funding for HCHS was included in RHAs' recurrent funding on a resident population share basis [22] and is now distributed to purchasers.

Funding for HCHS audit was initially ring-fenced to encourage the vigorous early growth of audit. However well intentioned, this encouraged inappropriate methods of developing audit. The only possible outlets for this money were the recruitment of audit-specific staff and the purchase of 'audit information technology (IT) systems'. A number of authorities found ways of circumventing ring-fencing by spending capital on their general requirements for IT systems, or altering offices allegedly to accommodate audit staff [23]. Although the NHS Executive encouraged the development of multiprofessional audit from 1992, separate allocations of funds for medical audit and for nursing and therapy audit continued until April 1994, which probably delayed the development of clinical audit.

Ring-fencing ceased from April 1994. The Clinical Outcomes Group of the NHS Executive considered

eight different ways of directing funds, including funding through educational bodies and various 'slicing' mechanisms, but recommended a specific contract for audit. This has distanced clinical audit from the day-to-day provision of services, and provides no realistic funding for the audit of the care of patients referred extracontractually or for care commissioned in small quantities by distant purchasers.

*Determining a topic for audit*

Some audits, probably many of the most robust in methodological terms, are organised nationally by the Royal Colleges or specialist societies. Examples include the Royal College of Psychiatrists' audit of suicide and homicide [24], and the National Confidential Enquiry into Perioperative Deaths [25]. Because of NHS interest in these two examples, most localities collaborated in collecting data. On the other hand, the Royal Colleges are beginning to find that, although there is enthusiasm for conducting audits on certain topics, they have difficulty in persuading local purchasers that these national endeavours should take priority in terms of resources over topics of local interest, even though the NHS Executive has given relevant guidance [22].

*Undue emphasis on standards*

Many of those writing about clinical audit since the health service reforms (eg Ref 26) have emphasised that the difference between audit and earlier professional attempts at self examination has been the setting of explicit standards. Some processes of care lend themselves to this approach: for example, the need to X-ray patients with head injuries [27]. However, other standards allow gamesmanship and fiddling. For example, the Patient's Charter standard that all patients attending accident and emergency departments should be assessed within five minutes has led to anxieties that a brief inspection by the triage nurse may fulfil this standard, but that the patient may then have to wait several hours before being fully assessed and appropriately treated by a doctor. (There is also some evidence that triage may delay the treatment of urgent cases [28].)

I question also the overall emphasis upon setting standards *before* audit. It is, I believe, an excellent idea to 'explore what is going on here' by observation, by talking to staff and patients, and by looking at a few randomly chosen records in an impressionistic way. Such informal methods may immediately inform a directorate as to how its services might be improved; locally relevant standards will emerge during the course of such an exercise.

The diversity and complexity of the organisational issues make it difficult to ascertain exactly what is going on in any institution when it claims to be undertaking clinical audit. Table 1 is reproduced from the National Audit Office review, *Clinical audit in England* [2]. The aggregation of data in this crude way yields no useful information about the quality or reality of the audit projects reviewed, or about the effectiveness of audit in producing significant improvements in clinical practice. All these organisational muddles and lack of clarity contribute to the poor acceptance of clinical audit.

**Weaknesses in audit based on reviews of medical records**

*Bias due to coding*

The sample of records of patients retrieved for audit may be biased by poor diagnostic coding. The quality of coding has improved considerably since the NHS reforms because of the requirement to fulfil contracts. In the USA, the quality of diagnostic coding and the primacy of different diagnostic codes have a major impact on hospital reimbursement. It is likely that Read coding and its mapping on to International Classification of Diseases (ICD)-10 coding will further improve the quality of discharge coding in the UK.

Another problem is obsessional coding. A hospital with an excellent coding department may well record more complications following procedures and operations than one with sloppy coding—with the curious effect that the latter hospital apparently has better outcomes.

*Bias in record retrieval*

Once a decision has been taken to audit, say, myocardial infarction (MI), a sample of medical records for audit is usually retrieved through the hospital patient administration system using diagnostic codes. Coding is undertaken at discharge from hospital.

**Table 1. Results of clinical audit projects undertaken in 1993–4 in the hospital and community health services at three regional health authorities**

| Regional health authority | Clinical audit projects undertaken | Changes made as a result of clinical audit | Clinical guidelines used or developed | Standards used or resulting from audit | Clinical audits repeated |
|---|---|---|---|---|---|
| Trent | 2,994 | 983 | 845 | 633 | 386 |
| Northern | 2,117 | 699 | 424 | 507 | 425 |
| South East Thames | 1,872 | 698 | 413 | 359 | 412 |
| Total | 6,983 | 2,380 | 1,682 | 1,499 | 1,223 |

Source: Reports of the three regional health authorities visited by the National Audit Office. Reproduced by kind permission.

Retrieval of records with the relevant ICD or Read code for MI will not retrieve the records of a patient who, for example, had a dissecting aneurysm mismanaged as an MI for the first 12 hours of his or her care, or those of a patient with functional chest pain who was overinvestigated with coronary angiography.

There is much to be said for clinical audit of the management of presenting problems. For example, GPs often telephone requesting admission with problems such as 'This old lady has become confused', or 'This old man, who was previously managing quite well at home, has now suddenly gone off his legs'. There is no reason why individual units should not undertake small audits of such clinical problems, but these will necessarily be convenience or consecutive samples. With present information systems, there is no way that a representative sample of patients with such problems could be obtained for the purposes of clinical audit.

Medical records are either with patients or with the directorates responsible for their ongoing care, or in transit between the directorates and the record department, or in the department itself. Although the advent of bar coding allows better methods of record tracking, the expense has meant that few hospitals have so far instituted such systems. Poor records' management [30] often results in failure to retrieve many of the medical records of the sample of patients designated as appropriate for an audit.

There can be no greater bias than failing to retrieve the medical records of deceased patients as, by implication, their care may have been less successful than for those who survived. However, it is often difficult to find their records: they may be with the pathology department, waiting for a delayed discharge summary, with the coroner's officer or mislaid in some way. The relative odds of retrieval of records of patients who had died from bladder cancer was only 0.26 compared to those who had survived [31]. In the same study, retrieval of records from undergraduate teaching hospitals was significantly poorer than from non-teaching hospitals (odds ratio (OR): 0.2) [31]. Such systematic biases can greatly distort the results of audit.

*Bias related to sample size*

The analysis of the course of one case, or one clinico-pathological conference, may make an enormous impact locally upon the organisation of clinical services and the quality of care. For example, a patient admitted with a provisional diagnosis of Lassa fever showed up weaknesses in the organisational arrangement for the management in intensive care of seriously infected patients. With small sample sizes, though, difficulties arise when comparisons are made between hospitals, because of the effect of sample size upon the power of the comparison to detect significant differences. For example, in a national audit of upper gastrointestinal haemorrhage in more than 5,500 patients studied in 74 hospitals in the UK, only six hospitals had crude mortality rates significantly different from the overall figure, even though they varied between 0% and 29% [32]. This was without any adjustment for case-mix (considered further below), yet on the number of hospitals involved it would have been expected by chance alone to find about four hospitals deviating from the mean value. If the scale of such audits is reduced to, say, comparison between surgical teams in one region, the numbers will be insufficiently powerful to detect significant differences between them [33].

*Reliability of audit data*

The reliability of audit is determined by the reliability of the original measurement. For example, in a comparison of post-operative wound infection, one surgeon or nurse may regard some redness or induration around the incision as nothing untoward, and another class this as a clear-cut infection. In research studies, explicit criteria are agreed and followed; all those participating in a multicentre trial use the same methods of measurement, training in which is considered necessary. In *post hoc* observational studies, which are the common base for audit, it is highly improbable that clinicians will use the same criteria when entering data into the patient record.

Another aspect of reliability is whether or not two auditors looking through a medical record will retrieve identical information. In one study, kappa values were 0.3 or less for such important items of information relating to the care of patients with stroke as pulse, whether or not serum glucose had been estimated, whether pre-morbid employment had been recorded, and so on. Inter-rater differences are considerably less when both of the pair of auditors being compared are medically qualified [34]. However, salary costs and professional interest are unlikely to allow such detailed work to be done by medically qualified people.

Auditors will also face difficulties when confronted by a note that reads: 'Full explanation of illness and prognosis given to patient'. Such a one-line sentence may be a fair summary of a detailed 40-minute discussion with the patient about all the complexities that lie in the future–a conversation with empathy and understanding. Equally, it may denote an offhand, brief and unempathic remark by a clinician along the lines of 'You have multiple sclerosis, and I'm sorry but we don't have any useful treatment for it'.

*Missing data*

Clinical audit works on the basis that if an item of care is not recorded, it did not take place. In the USA, reimbursement issues probably lead to more detailed records in this respect, but anybody who has worked in a busy clinical service knows the conflicting pressures to undertake a clinical task, to provide information to patients and relatives, to arrange and administer tests,

to train medical students and junior staff and, finally, record what has been done. If they are pressed, the recording of the task is the item most likely to be dropped.

Many practitioners in the private sector state that the feature of the work they most enjoy compared to the NHS sector is that they have time to talk to patients; in this context, medical records assume lesser importance. There is little need to maintain records for handover to other staff, so the medical records are often of poor quality—a point which should be considered more often by the risk managers of private clinics. Conversely, a common complaint by patients is about obsessional record writers who 'spent all the time writing, and didn't even look at me'.

*Inadequacies of data capture and information technology systems*

Unless an item of information needs to be collected for some clinically relevant aspect of patient management or for billing purposes, it is highly unlikely that it will be routinely recorded, even within one institution. One paper optimistically entitled 'Feasibility of monitoring patient-based health outcomes in a routine hospital setting' lists nine authors, including a research assistant, for 450 patients [35].

If outcome measures from primary care have to be considered alongside the data sets collected within hospitals, there are further concerns about data capture, timeliness and reliability of measurement.

*Case-mix and coexisting morbidity*

Because patients with severe illness or more than one diagnosis (co-morbidity) consume more resources—

> an entire industry has arisen to define and measure the severity of illness of hospitalised patients [36,37].

Probably the best known measure of illness severity remains the APACHE score, based upon a limited number of physiological variables [38,39]. A similar system has been developed for neonatal intensive care [40]. For illustrative purposes, two recent examples will suffice. In the study of gastrointestinal haemorrhage referred to above [32], Rockall and his colleagues identified by analysis of variance certain risk factors which were associated with mortality (age, extent of shock, diagnosis, comorbidity, endoscopic stigmata of recent haemorrhage, and re-bleeding). When the crude hospital mortality rates were adjusted for these risk factors, only two hospitals had standardised mortality ratios significantly different from the reference value. Furthermore, risk standardisation for the three simple variables of age, comorbidity and shock resulted in 21 of the 74 hospitals changing 10 or more places in the outcomes ranking, and one hospital by 30 places.

In another example, the complexity of confounding factors is more striking. Shi Wu Wen and colleagues analysed the short-term outcomes of patients who had an incidental appendicectomy performed during the course of an open primary cholecystectomy [41]. The purpose of incidental appendicectomy is to prevent the risk of future appendicitis. None the less, it is an additional operative procedure and might be expected to carry additional risks. First crude comparisons, using administrative databases on nearly 200,000 patients in Ontario, Canada, showed a striking and unexpected reduction in mortality after cholecystectomy when incidental appendicectomy was performed (OR: 0.37). However, patients who had both procedures were younger, less likely to have other co-morbid conditions or be men, and more likely to be undergoing a total cholecystectomy on an elective basis for cholelithiasis or another benign disorder. When these adjustments and other variables were considered, mortality and lengths of stay were similar in both groups of patients. However, with these adjustments, patients who had the appendicectomy showed a significant increase in non-fatal complications (OR: 1.53). The authors properly point out that their 'analysis was informed by a strong clinical suspicion, *a priori*, of both the direction in which selection biases would operate and the outcome differences that would be reasonable. For comparisons in which the magnitude or direction of differences in outcomes is more controversial, it would be difficult to decide, with confidence, that adequate adjustment has been made for case selection factors' [41]. In plainer terms, these authors recognise the dangers of 'massaging the data' to produce the results required. Their honest paper underlines the pitfalls encountered when attempting to draw conclusions from non-randomised outcome studies. Such studies continue to exacerbate the anxieties that most hospital clinicians have about the creation of league tables [42].

*Other weaknesses in audit based on record review*

The current focus on the effectiveness of care fails to address other important aspects of quality, some of which have been identified by Maxwell [43]. A simple example is *timeliness of care*: a clinician may follow a clinical guideline to the letter, but do it so slowly that a disease process advances to a much more dangerous stage than if care had been provided in a timely fashion.

One of the principal complaints made by patients is about *poor coordination of care*—for example a physiotherapy appointment schedule at the same time as a ward round at which a patient had hoped to get up-to-date information from her consultant. This does not appear in the written record.

Patients also value highly *continuity of care*. There are many informal accounts by patients of the many health professional and other hospital staff they encounter in a short visit without being able to identify

who is primarily responsible for their care. Although the Patient's Charter specifies that patients should have a 'named nurse', the reality is that the hours of duty, days off and movement between wards in the same hospital leave this concept with little relevance to the patient.

Record reviews seldom consider the question of *equity*. A focused research project is needed, rather than an audit, to discover whether a population is receiving care with equity. There are many examples relating to insufficiencies of care provided to older people [44,45]; on the other hand, careful analysis of apparent gender bias in the management of coronary artery disease suggests that men and women are treated equitably once angiography has been performed [46].

The current emphasis upon effectiveness of care devalues the *empathic components of care*. Patients like being treated in a humane, friendly and respectful way, yet these qualities will not emerge from the written record, and patient satisfaction surveys are a relatively crude instrument for determining individual variations in the social manner with which health professionals treat patients.

The concentration on the effectiveness of care has also diverted interest from questions of *appropriateness* [47,48]. Are patients receiving procedures which they do not need, and are they not receiving procedures which they do need [49]?

Clinical audits based on reviews of medical records can be descriptive and informative only at the anecdotal level. If comparisons—either between dates or between firms, hospitals or regions—are to be credible to clinicians, they need to take more account of basic issues relating to measurement. The emphasis upon record review and the effectiveness of medical care has led to neglect of other important aspects of quality of care.

**Failures of accountability and their impact on the acceptance of audit**

Local failures of accountability have weakened the institution of audit [50]. The contracts of many hospital consultants precede the introduction of audit, but the NHS reforms made the undertaking of medical audit a necessary part of clinical work. The Conference of Medical Royal Colleges requires that the names of the attending doctors be recorded [51]—yet, although senior colleagues in a hospital may bemoan the failure of some doctors to attend, I have not heard of any instance of disciplinary action. Even when audits have been successfully completed and poor quality of service discovered, lines of accountability for accomplishing change are confused. Audit is seen as a professional matter so, in general, it is left to the profession to improve matters. Yet a reallocation of resources may be required, and the help of health service managers sought in achieving change [52]. For example, if an audit of the appropriate management of head injuries were to show that good practice was impaired by inadequate radiological facilities at weekends and by delayed transmission of films back to the accident and emergency department, the professional teams would have to improve their own professional liaison, and also seek help from management to improve the availability of trained staff and the portering services. Because of the additional resources required, however, matters may be left as they are, and achieving change considered to be just too difficult. This further undermines the credibility of audit.

What happens when clinical audit turns up persistently poor clinical performance? Although the new General Medical Council performance procedures [53,54] are designed to provide a mechanism for tackling this problem, the consultative paper specifically stated that clinical audit was not to be one of the mechanisms by which persistently poor professional performance was determined [53].

Justifiable concerns about patient confidentiality may have had the effect of decreasing professional accountability. The Conference of Medical Royal Colleges, in their interim guidelines on confidentiality in medical audit stated that:

> . . . the requirements of confidentiality for both patients and clinicians mean that regular reports of audit activities to management must be anonymised. The report should cover the general areas of activity of audit, the overall conclusions and recommendations made, and plans for action . . . [55].

It is comparatively easy to fulfil the letter of these guidelines by providing hospital managers with statements which are so brief that variations in care about which they should be informed are largely concealed.

With the shift of clinical audit from an educational activity to monitoring contract performance, another issue arises. Purchasers will specify in partnership with clinicians the measures which are acceptable to both for monitoring contract performance, but how can they be sure that the data they receive are sound? In short, who will audit audits?

It is noteworthy that in the Department of Health's (DoH) review of the progress of clinical audit, the only comment on accountability refers virtually entirely to financial matters [56]. Clearly public money provided for audit must be accounted for, but regions and health authorities have received no guidance on how to appraise the quality of audit. There have been useful contributions to this topic [57–60], but usually from enthusiasts who have failed to consider many of the difficulties outlined in this article. Furthermore, although numerous national reports have been commissioned on the progress of clinical audit, the conclusions, while worthy, have had little 'bite' [13,61–67]. The professions are largely being left to institute better methods for clinical audit and, as many

health professionals are dubious of its benefit, progress is understandably slow.

### Social structures and their impact upon the acceptability of clinical audit

To resolve some of these problems attention must be paid to the social and anthropological structure of the interactions between patients and doctors, between doctors, between doctors and other health professionals, between health professionals and managers, and between clinical teams and institutions.

Management science is also needed to advance audit because the understanding of how institutions or systems work is essential to improving the quality of care [68]. Good systems result in good care [69–72]. As with aeroplane crashes, most disastrous outcomes are due not to the actions or misjudgements of one individual but to breakdowns in the system.

So far, relatively little work has been done on the social structures within which audit takes place. Potential obstacles to audit include a reluctance to judge peers; the danger of reducing public confidence in doctors; a belief that doctors have already been auditing their work for years; inadequate data and information systems; a lack of time; the fact that the process can be threatening or boring; suspicions about managers' interest in audit; and a view that audit is a mechanism for control of junior doctors [73].

Interviews conducted in 1991 in four district general hospitals revealed that, based on their experience of audit, the consultant and junior staff were not convinced about the value of audit; they questioned the opportunity cost of their time, the resources consumed by audit staff, and the absence of apparent benefit either to patients or to themselves [74]. The interviews also revealed extensive 'medical complacencies', doctors declaring that the principal problems affecting health services are administrative and organisational rather than clinical.

A subsequent enquiry sought the views of junior doctors [74]. The results showed that:

- they were critical of the additional burden imposed by audit;
- there was considerable resentment about the organisation of audit meetings, often held at lunch-time;
- they were concerned that their short periods of contracted employment made it impossible to see the results of their endeavours in audit;
- audit topics were felt to be orientated more towards the interests of consultants than to their own and that audit meetings were boring;
- many were unconvinced that audit led to better care;
- some felt threatened by hostile experiences at audit meetings—a far cry from the idea that audit should be part of professional education; and
- a perception that audit was primarily about monitoring and improving the quality of the juniors' work rather than that of their consultants.

### General conclusions

Audit has failed to win the hearts and minds of the medical profession. The arguments in this article are largely based on hospital practice, but GPs are also suspicious of its value [75].

There is at present a conflict between clinical audit as a tool for education and professional development, and for monitoring contract performance. The medical profession's suspicions about clinical audit reflect concerns that the present methods are not effective. Investment in clinical audit has proceeded ahead of its foundation on a firm academic base. Much could be gained by employing methods commonplace in epidemiology. At present, overambitious projects are undertaken by inadequately trained and supervised audit facilitators, with unclear lines of accountability. Concentration on the effectiveness of care has been at the expense of other dimensions, such as its timeliness, coordination, continuity and appropriateness, and of providing information to patients to allow them to make an informed choice.

Audit of outcomes of care is extremely problematic [76,77], although there is no doubt that meaningful information can be obtained in some restricted areas [78,79]. Audit of the process of care has a rather better chance of contributing to improving care [76,80], but basic aspects of measurement such as validity, inter-rater reliability, sensitivity to change, and the costs of data collection have not yet been adequately addressed. At present, most items of information need to be retrieved by expensive retrospective review of hospital records rather than being collected prospectively during the course of routine patient care.

Clinical audit is seen as a 'bolt-on' extra, an occasion for special 'audit meetings'. It is not integrated into either daily practice or undergraduate education (in most instances being no more than a nominal requirement in training), and does not figure to any extent in the examinations of the Royal Colleges. Achieving change may often be beyond the capacity of health professionals alone. They are now more ready to seek the help of health service managers, whose response to the information provided by clinicians should also be audited. Finally, issues of accountability are usually not addressed, either in relation to achieving change or to poor professional performance.

### The way forward

This depressing review of the present state of clinical audit in the UK should not be taken as suggesting that health professionals should abandon all attempts to monitor the quality of the care they deliver. They have

a moral and professional responsibility to provide the best possible care; unless they regularly inspect the quality of that care and continue to educate themselves throughout their professional life, they will fail their patients. It also seems improbable that there will be any slackening in the demand by users and potential users of health services for reports on the quality of health services, and for greater accountability of those seen to be failing to deliver good care [81]. Whatever the health service system, those who pay for care will be increasingly unwilling to accept variations in practice which are not based upon research evidence of effectiveness and patient choice. However, in the final analysis, clinical audit should be judged by the same standards as any therapeutic intervention is it effective in achieving better outcomes for the health of patients? is it effective in encouraging a more cost-effective use of resources to achieve those outcomes?

The first necessity is to recognise that clinical audit within a directorate or clinical service should be linked to audit within a trust, but uncoupled from the information that purchasers require to monitor contract performance, a suggestion already made by others [82].

*Audit within a directorate*

1. Patients are excellent observers of the health care system, and often have creative, thoughtful and practical suggestions on how a service may be improved [83]. Relatively informal surveys of patient opinion may suggest the need for changes within a directorate which is paying insufficient attention to the individual values, preferences and needs of patients.
2. Complaints related to a directorate's work must initially be handled within the directorate, but should also inform the audit process, rather than being handled—as often at present—as a separate managerial responsibility.
3. The unreliability of comparative reviews of medical records in detecting poor quality care should be recognised for the theoretical reasons advanced in this article and as shown in practice, both in studies addressing this point [34,84], and in re-analysis of published outcomes work [85]. Reviews of single or a few case records in a relatively informal way may, however, provide *illustrative* examples for educational purposes, not only in relation to the natural history of the patient's illness, but also as to how care might have been provided in a more timely or effective way.
4. Clinical guidelines should be considered as an educational tool rather than as part of the contracting process [86]. Many guidelines now finish with a list of audit points [87], and recently there has been a call to make them more explicit [88]. They may provide both topics and standards for directorate audits. In teaching hospitals, medical students and nurses should be encouraged to gather data for the purposes of audit both by surveying the views of patients and other staff and from patient records. Indeed, part of their appraisal during their time on a directorate might be completion of a small, but none the less informative, audit project on some aspect of the directorate's function. Again, these should be seen to be for illustrative and educational purposes. Small-scale, local, but nevertheless important, changes in service delivery may result.
5. Such quality endeavours must involve all staff, ward clerks, nurses, other health professionals, junior doctors, consultants and, where service extends outside the directorate to other hospital functions, similar teams across directorates.
6. Audit meetings should mostly take place within the directorate during normal working hours, so that they are seen to be part of the general work of the firm and not some additional 'lunchtime' meeting.
7. In this type of audit, clinical directors must be responsible for making clear the lines of accountability to them for achieving changes of service within the directorate.
8. Although I stress the informality of this audit process, some order is required to prevent ideas disappearing into a haze of mutual congratulation. It is also needed to satisfy trust managers and representatives both of the local community and of external organisations (such as the King's Fund Organisational Audit Programme) that the clinical directorate is continuing to strive to achieve a service of better quality. In order to have a record of the findings upon which efforts to achieve change may be based, the person responsible for organising quality initiatives within the directorate will need to keep a record of his or her work in a structured way. This will provide a record, not for statistical analysis but simply to 'manage' quality, in exactly the same way as clinicians keep a medical record for the purposes of patient management.

These proposals recognise the continuous small increments in quality that arise from relatively informal professional interchange [72], such as the British Thoracic Society's programme of informal peer review [89].

Directorates will need to respond to another type of clinical audit. An example might be a national audit focusing on a narrow clinical problem, led perhaps by a Royal College or specialist society. For example, the British Cardiac Society might encourage all physicians to undertake a national audit with explicit entry and measurement criteria of all patients admitted with unstable angina in one specific week. Such large-scale and highly focused audits offer possibilities of comparing variations

in practice and outcome between different units, subject as always, of course, to variations of case-mix. Funding arrangements for clinical audit will need to have sufficient slack in the system for individual directorates to be able to respond promptly to the requirements of a national audit.

*Audit within a trust*

1. The money now expended upon trust-wide audit facilitators and coordinators should be used to support audit within directorates, probably by paying part of the salary of the senior health professional who, as described above, manages quality within the directorate.
2. Not all the functions of a hospital take place within individual directorates. Sometimes it will be necessary to have trust-wide audit meetings to consider trust-wide problems such as the management of acute admissions, or quality initiatives relating to outpatient practice. On other occasions, one or two directorates might meet, still relatively informally, to iron out some problems common to them both. An example would be the multidisciplinary management of acute trauma.
3. Clinical directors also need to be responsible, through the clinical advisory machinery, for achieving change through the wider management of the trust which, in turn, must work in partnership with clinicians to change services and, if necessary, acquire further resources.

*Audit for monitoring contract performance*

The foregoing types of audit, which are relatively informal, relatively unstructured, cheap to perform, and based within the daily work of a directorate or trust, are quite different—and must be recognised to be different—from the requirements laid upon purchasers to monitor the successful performance of a contract. One of the principal themes of the NHS reforms was an attempt to use the power of purchasers to reduce practice variation and steer clinical performance towards more effective care. If, therefore, the purchasers do not have some method of monitoring what is going on, they are as powerless as before the reforms.

A clinical director should have no difficulty in explaining that if extensive data collection by a purchaser is required, this must be paid for within a contract. Now that the budget for clinical audit has moved to the purchasers, they must budget for the measures of quality that they demand, and contract for them. Although the NHS Executive recommended a separate trust-wide contract for audit [16], it seems logical to link money for audit more firmly to contracts for care. For example, after costing out the provision of breast cancer services, it might be agreed by purchaser and provider that a 4% supplement be added to the basic price to ensure the collection of certain specified quality measures. However, not all the sum generated by the totality of such contractual surcharges should go to purchaser-led quality initiatives. A proportion (perhaps half) will need to be top-sliced for the support of general quality initiatives within directorates and for hospital-wide initiatives of the sort mentioned above (eg in relation to audit of acute admissions). Research is badly needed into how funding mechanisms of initiatives such as clinical audit determine the structures and quality of the work undertaken.

To monitor contract performance, users of health services, purchasers, clinicians and medical scientists *internationally* need to join together in partnerships which allow the definition of a few measures of outcome for the principal important clinical problems that reflect the concerns and values of patients, which:

- are attributable to the clinical interventions purchased,
- are sensitive to change,
- are reliable in measurement and cheap to collect,
- take into account selective admissions and transfer, and
- can be controlled in respect of variations in case severity and co-morbidity.

In the USA, efforts to compare even a simple outcome measure such as mortality rates between different health care providers suggest that by far the greatest amount of difference is accounted for by chance variation [90]; the problems are likely to be even greater when less clear outcomes are considered. For this reason, the collaborative research partnership should also consider capturing data about processes of care of proven efficacy as proxies for outcome measures. Recognition of this accounts for the emphasis placed by the DoH on immunisation rates in primary care, and on the time interval between onset of MI and administration of thrombolysis [91]. If, however, contracts are to be renegotiated on the basis of such performance indicators, rather than informing practice in a purely anecdotal way, all the measurement issues considered in the earlier part of this article need to be taken into account.

In summary, it is my belief that the simple methods sufficient to improve care in a local and low key way have been confused with the much more rigorous methods required to monitor contract performance and to begin to compare the performance of different hospital teams. A great deal of money has been spent on employing audit assistants with insufficient knowledge of the complexities of clinical measurement, and yet who try to impose this insufficiency of knowledge on the informal methods of directorate audit. No one can criticise the NHS Executive for failing to provide financial resources to help first medical and then clinical audit, but this money was

thrown at the problem without a sufficient research base in clinical audit [92], without sufficient attention to the social structures in hospitals, and medical schools, and without sufficient recognition of the constructively critical faculties of health professionals.

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