BRI INQUIRY PAPER ON MEDICAL AND CLINICAL AUDIT IN THE NHS

BRI Inquiry Secretariat
September 1999

CONTENTS

EXECUTIVE SUMMARY

The purpose of this paper is to provide information on the wider context of medical and clinical audit in NHS hospitals during the period 1984-95, looking particularly at how attitudes, policy and practice changed over this period and at what is known about the impact of audit on quality of care.

The paper does not look specifically at the development of audit in nursing practice or in the therapy professions. Information about developments in these areas can be found in the chapters by Kitson et al and Packwood in *Evaluating clinical audit: past lessons, future directions*.[38]

The paper is based on analysis of:

* government publications and policy documents
* commentaries and research/evaluation papers in academic journals
* relevant "grey literature"

Section 1 clarifies the position of medical and clinical audit within the wider framework of quality assurance in the NHS.

Para 1.1 begins with an explanation of the concept of quality assurance and outlines the differences between the traditional "scientific" approach to quality assurance and the more recently developed approach defined as "total quality management". The development of managerial concerns about "quality" in the NHS during the 1980s is then described and attention is drawn to the exclusion of medical and clinical activity from the quality initiatives developed during that period.

Para 1.2 begins by explaining the absence of extra-professional involvement with the quality of clinical practice before 1989. Factors involved in the growing pressure during the 1980s for some formal process of medical quality assurance are then outlined. These include evidence of variation in medical practice and outcomes, public concern about clinical competence and quality of care and changing attitudes within the medical profession itself. Following these developments, the introduction of medical audit in the 1989 NHS reforms was both expected and regarded as inevitable.

Para 2.3 begins by defining the concept of audit, clarifying the differences between different types of audit (medical, clinical and organisational) and explaining the distinction between audit and other quality assurance activities such surveillance and monitoring. The various potential benefits of audit are briefly discussed and attention is drawn to the lack of rigorous evidence as to whether audit actually does result in beneficial change. It is clear that, for every successful audit project undertaken, there are many others that do not work so well. A summary is given of factors that have been found to influence whether audit is successfully completed.

Section 2 identifies significant developments in national policy on clinical and medical audit after 1989 and outlines the response within and beyond the medical profession to the medical audit policy.

Para 2.1 looks at how medical audit was defined in the 1989 white paper *Working for Patients,*

outlines the arrangements introduced to support the participation of all doctors in "regular, systematic medical audit" and describes the benefits which the government hoped the introduction of this policy would produce. Key developments in audit policy in the five years after 1989 are summarised. These include the introduction of a separately funded Nursing & Therapy audit programme in 1991, a shift in emphasis from medical to clinical audit and a greater emphasis on the role of management in the audit process.

Para 2.2 describes the reaction of the medical profession to the proposals on audit and shows that while the various representative bodies welcomed the new policy, greater scepticism and uncertainty was expressed among practitioners on the ground. While the need for some form of audit was generally accepted, there was widespread concern about the practical difficulties of undertaking it and about the ultimate value of the efforts it would involve. Reactions from outside medicine are then considered and attention is drawn to concerns that were voiced about the relative weakness of the policy in terms of transparency and external accountability, the inappropriate separation of medical audit from other clinical professions and of clinical quality assurance from the rest of the NHS.

Section 3 provides a brief assessment of the extent and effectiveness of audit activity in NHS hospitals after 1989.

Para 3.1 identifies the various evaluation studies that were undertaken of medical/clinical audit in hospitals after 1989.

Para 3.2 describes research findings concerning the process of audit in four hospitals studied in 1991/92 which show that audit activities on the ground (at least in these hospitals at this early stage) were relatively disorganised. The findings of a larger study undertaken by CASPE Research to look at the quality of hospital audit activity are then presented. The researchers concluded that only a very few provider units had successful audit programmes in place. A range of factors whose presence or absence appear to determine whether audit programmes successfully achieve their aims are then outlined. These include issues of staffing and leadership, structures and planning, training and education, and the overall organisational environment. This section ends with a reiteration of the continuing lack of good information about the impact of the audit policy on the quality of patient care. The paper then concludes with a summary of the main points raised.

INTRODUCTION

A new customer-oriented approach to quality was developed in the USA between the wars and initially adopted by major Japanese manufacturers (notably Toyota). Subsequently, American and European firms increasingly followed their lead. It appears that in Britain widespread adoption was slower, with the new approach being confined to isolated pockets of industry and innovative retailers (eg Sainsbury's and Marks & Spencer) until the 1980s. It has been suggested that a key event in generating more general interest in the new ideas was the 1982 publication of a best selling book *In search of Excellence: lessons from America's best run companies* (Peters & Waterman, New York, Harpers & Row 1982).

The new thinking about quality then spread across both private and public sectors during the course of the 1980s. Dissemination of the new approaches in the NHS was facilitated early on because of the introduction of general management which led to the appointment of managers from areas of industry outside the public sector, where quality assurance was already in vogue. Sir Roy Griffiths, whose 1983 Report[1] brought these changes about, was the deputy Chairman and Managing Director of Sainsbury's and a champion of customer-oriented quality assurance.

1. AUDIT AND QUALITY ASSURANCE IN THE NHS

. This section:

* outlines the concept of quality assurance and summarises the evolution of general quality assurance activities in the NHS in the 1980s
* explains how concerns about the quality of medical care developed along a separate route
* outlines the concept of audit and its purpose

1.1 Concerns about quality

1.1.1 The concept of quality assurance

i. The "quality" of a service can be defined as the totality of features and characteristics of the service that bear on its ability to satisfy the stated or implied needs of the users of that service. A wide range of different activities contribute to ensuring and enhancing service quality. These include:

* **needs assessment** (finding out what users' needs are)
* **research** (finding out how those needs may be met effectively)
* **dissemination and guidelines** (making research findings available in an appropriate and accessible form
* **education** (ensuring that service providers have the skills, knowledge and commitment to enable them to meet users' needs) and
* **service planning** (ensuring that structures/systems are appropriate and adequately

resourced)

ii. In addition to these there is the activity of **quality assurance**. This term is usually used to refer specifically to methods of maintaining or enhancing service quality which use systematic assessment of performance against predetermined standards as a means of identifying problems in the service and of introducing and monitoring improvements.

iii. Quality assurance is a separate activity in its own right, but it is also intimately linked with all the other activities listed above. For example, knowledge gained from needs assessment may be used to define the aspects of the service to be subject to the process of quality assurance and research findings provide the standards against which the service is assessed. In turn, quality assurance may show up problems in relation to service organisation, resource provision or education or identify the need for improved guidelines or further questions for research.

1.1.2 Approaches to quality assurance

i. The objectives and practice of quality assurance programmes vary depending on how quality is thought about and this is an area where attitudes and assumptions have changed considerably in the past few decades.

ii. Until relatively recently, quality assurance programmes both in industry and public services were based on principles of "scientific" management developed in the era of mass production and assembly-line working methods and predicated on the pre-eminence of "expert" knowledge. In this "traditional" approach:

* the aim is to avoid substandard practice
* experts decide which aspects of the service are important and what standards are appropriate
* quality control is an external activity undertaken by people with specific responsibility for identifying faults
* problems are seen as arising from the failure of individual people or components and are dealt with by removal or sanctions

iii. In the 1950s a new philosophy which became known as "total quality management" (TQM) was developed in the USA and subsequently widely taken up by industry in other countries including Britain. TQM differs from the more traditional approach in several ways:

* the aim is not simply to maintain standards but to increase organisational success through continually seeking out ways to do things better
* expert criteria for quality are eschewed in favour of customers' definitions of their own needs
* quality assurance is seen as a generic internal activity whereby all participants in the organisation take responsibility for their own area of work
* problems are assumed to derive from weaknesses in the system rather than individual failings and are dealt with by reviewing the system rather than punishing or removing the offender

1.1.3 Quality assurance in the NHS

i. Before the 1980's explicit concerns about "quality" appear to have been absent from NHS thinking and policy documents. In the second half of the 1980s, however, the introduction of general management (on the recommendation of the *Griffith's Report*) (led to an influx of managerial ideas from areas of industry where the TQM approach had already been adopted, and the pursuit of quality became an increasing managerial preoccupation. Insofar as the absence of quality in processes of work had been repeatedly identified as a major cause of high costs and attention to quality was seen as a way to improve services without increasing costs, TQM was seen as a powerful way of addressing continuing concerns about value for money in the NHS.

ii. The new focus on quality was reflected in a burgeoning of "total quality management" schemes, "quality circles", "quality standards" and "quality charters". These involved an enormous range of diverse activities from training in "customer awareness" to improving the physical environment by planting bulbs. The common feature of all such schemes was an emphasis on listening to patients and acting on their requirements and on involving staff at all levels in identifying problems and developing solutions. In 1989, a survey of quality assurance initiatives in the NHS produced details of 1,478 initiatives in 116 districts and the growth of such initiatives was said to have reached "epidemic proportions".[2]

iii. In one important respect, however, the developing managerial focus on quality in the NHS differed from the industrial model on which it was based. Far from involving all parts of the organisation, quality as an issue in the NHS was quickly divided along "tribal" lines. Notably, concern with the quality of medical work was consistently excluded from health authority remits for quality management. The NHS Management Executive's *The Quality Journey*, which reported on progress in the 23 pilot TQM schemes funded by the government in 1989, made it quite clear that these projects were not intended to address quality within professional boundaries nor to impinge on the exercise of clinical judgment.[3]

1.2 Events leading to the development of quality assurance for medicine

1.2.1 Absence of formal structures before 1989

i. The origins of the different approach to medical quality assurance may be traced back to the 1858 Medical Act which, in establishing the General Medical Council (GMC) to regulate the medical profession on behalf of the state, legitimated the profession's claims to autonomy and its right to self regulation. When the NHS was created in the 1940s, the rights of the medical profession to collective autonomy and individual clinical freedom were taken for granted and explicitly acknowledged and regulation of the medical profession was left entirely in the hands of the GMC and the Royal Colleges. Up until 1989, therefore, management opportunities to influence the quality of medical activity were very limited, being confined to disciplinary procedures for dealing with cases of serious incompetence. The only government attempts to influence clinical practice directly were in the area of prescribing, through the introduction in 1984 of the "limited list".

1.2.2 Developments encouraging the introduction of medical audit

i. During the 1980s, a variety of developments combined to make it likely that some mechanism of quality assurance for doctors would soon be introduced. These included:

* growing evidence of unexplained variations in medical work (eg hospital admissions rates, length of stay in hospital, annual operation rates of individual surgeons)

* evidence of variations in outcomes of health care (eg variations between health authorities in standardised mortality ratios associated with a range of different hospital interventions, variation between districts in rates of potentially avoidable deaths)

* a number of well-publicised arguments about individual clinical competence (eg the investigation into the work of the obstetrician Wendy Savage and the debate about the fallibility of medical diagnosis at the time of the judicial enquiry into child abuse in Cleveland)

* increasing willingness on the part of self-help groups, pressure groups and consumer organisations to take more proactive approaches to informing health service users about quality of care and to publicise information about sub-standard services

* changing attitudes within medicine itself with increased recognition of the need for the profession to make a demonstrable commitment to maintaining and improving clinical quality. A survey of 33 national specialist medical bodies published in 1986 showed a general acceptance of professional responsibility for, and numerous initiatives towards, quality assurance.[4] By the late 1980s some parts of the medical profession already had extensive experience of formal quality assurance exercises set up mainly by the Royal Colleges. (Notably in anaesthetics and obstetrics, confidential enquiries had been established on a national basis to study maternal, infant and perioperative deaths.[5,6,7]) In general, however, involvement remained patchy and unsystematic and there was no coherent strategy of quality assurance for the medical profession as a whole.

ii. While doctors' clinical activity had so far been left out of NHS initiatives concerning service quality, pressure was increasing, for example from the National Audit Office[8], to make good this omission. If the logic of keeping costs down and increasing efficiency by addressing issues of quality in the NHS was correct, there was no rational reason why clinical activity should remain exempt from this process. The government's interest in developing an internal market for health care also increased the political need to establish effective quality control mechanisms throughout the system to deflect charges of creating a two class system.

iii. Perceptions that the time was ripe in terms of public and professional expectations and government strategy for taking some initiative in this area were reinforced both by the government's own recent experience and by international developments. In Britain, with the 1988 Education Act, the government had already demonstrated its capacity to tackle other professions on issues of quality by introducing teacher appraisal in schools. From the USA there was evidence from almost 15 years of experience that state-led systems of medical audit could be run successfully. In Europe in 1985 the World Health Organisation had exhorted all member states to introduce effective mechanisms for ensuring the quality of patient care within their health systems by 1990.[9]

iv. When all these factors are taken together it can be seen why one commentator, writing in anticipation of the outcome of the Prime Ministerial Review of the NHS concluded that "an inexorable and unstoppable move towards some form of medical audit" was already underway.[10] With the publication of the white paper *Working for Patients*[11] in 1989, in which the participation of all doctors in regular and systematic audit was defined as "a fundamental principle of the review" that conclusion was shown to be correct.

1.3 The concept of audit

1.3.1 What is audit?

i. To health professionals, audit offers a systematic framework for investigating and assessing their work and for introducing and monitoring improvements. The process of carrying out an audit involves a characteristic sequence of events which include:

* defining standards, criteria, targets or protocols for good practice against which performance can be compared;

* gathering systematic and objective evidence about performance;

* comparing results against standards and/or among peers;

* identifying deficiencies and taking action to remedy them; and

* monitoring the effects of this action i.e. "closing the audit loop".

Audit is regarded as a cyclical activity, on the assumption that reviews of this sort should be carried out continuously.

1.3.2 Different types of audit

i. Distinctions have been drawn between different types of audit in terms of the focus of the activity and the personnel involved. Thus:

* **medical audit** involves the review of activities initiated directly by doctors

* **clinical audit** covers all aspects of clinical care including that provided by nursing and paramedical staff

* **organisational audit** refers to investigation of aspects of practice such as appointments systems which are regarded as primarily administrative

1.3.3 Distinction between audit and other quality assurance activities

i. Audit is one of a range of activities (including review, evaluation, surveillance, appraisal and monitoring) which collectively comprise the intelligence gathering arm of quality assurance. Stone[12] devised a taxonomy which differentiates these activities according to the professional

perspective they reflect (clinical, epidemiological or managerial) and the extent to which they are ad hoc or routinely carried out. Thus:

* **review** is the process of critical reflection used by clinicians wishing to assess their own (or their peers') performance

* **audit** is the activity of review when conducted on a continuous and routine basis.

* **evaluation** is one-off assessment of the impact of a service on indices of health

* **surveillance** is routinely repeated evaluation

* **appraisal** is ad hoc data collection and analysis by management in relation to health care delivery

* **monitoring** is ongoing appraisal

Stone summarises audit, surveillance and monitoring as routine processes which share a common objective of continuous quality assessment but are distinguished by the nature of their feedback loops to clinical, public health and administrative action respectively.

1.3.4 The benefits of audit

i. It is widely assumed that, if undertaken properly, audit has the potential to deliver substantial benefits to patients in terms of more appropriate and higher quality care, better educated and more highly skilled carers and better organised services. These benefits may follow directly from changes introduced following audit of a specific area of care or aspect of service organisation. Alternatively, they may arise as an indirect consequence of the activities involved in doing audit. For example, part of an audit cycle might involve agreement of a protocol for managing a particular condition. Meetings convened for this purpose also provide opportunities for discussion and information sharing related areas. The result may be better teamwork, generally improved communication between staff and consequently better organised care for patients in a variety of respects over and above those specifically addressed in the audit. In addition, the development of a more general "audit culture" involving regular review of policy and practice may produce beneficial changes in participants' attitudes, including a greater degree of consciousness about their activities and a more critical approach to their work.

1.3.5 Does audit work in practice?

i. Most attempts to assess the effectiveness of audit have concentrated on looking at the improvement achieved as a direct result of changes introduced. Sometimes changes in outcomes for patients are directly measurable, but more often benefits are imputed from changes in the structure or process of care. The more indirect or unanticipated side effects of audit are harder to take account of and have been largely overlooked in considerations of effectiveness, as have the more loosely defined consequences of introducing an "audit culture".

ii. There is a shortage of sound evidence about the effectiveness of audit because relatively few rigorous evaluations of its impact have been carried out and the findings of these have been mixed. What does seem to be clear is that for every project which successfully completes the

audit loop and results in beneficial change, there are many others that do not reach that stage.

iii. A number of factors have been identified as significant in determining whether audit leads to change. These include:

* issues of perception, attitude and motivation;
* organisational and environmental factors;
* interpersonal and managerial skills;
* choice of audit topic, adequacy of audit method and understanding of the reasons for deficiencies identified; and
* the extent to which audit is systematically integrated into the routine management of care.

iv. Identification of the obstacles to carrying out effective audit has led to much improved understanding of the skills, circumstances and resources required to make it work. But knowing what is needed does not, in itself, solve the difficulties presented by audit. As Buxton[13] observed in a key review:

"Scientific audit is a complex and not easily replicable technology. It is not a technology embodied in hardware or software or purchaseable "off the shelf" but instead has to be created locally. Audit needs to follow a relatively complex sequence of procedures to be effective, and it entails a dificult set of organisational processes...The limited evidence available [suggests] very clearly that the process necessary for good audit is difficult and not easily replicated and maintained over time without appropriate skills or enthusiasm."

2. NHS AUDIT POLICY AFTER 1989

This section:

* summarises the arrangements for medical audit in *Working for Patients* and outlines the main modifications to audit policy after 1989

* describes the reactions of the medical profession and others to medical audit policy and practice after 1989

2.1 Policy on medical audit

2.1.1 Definition of audit in Working for Patients

Medical audit was defined in the 1989 white paper[11] as "a systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome for the patient". It was emphasised that the practice of medical audit was essentially a professional matter which required both specialised knowledge of current medical practice and access to adequate medical records. Audit was presented as an educational activity based on peer review, and one that should be professionally led. However, management involvement was seen as necessary to ensure that an effective system of medical audit was set up.

2.1.2 Arrangements for audit support

Medical audit in hospitals was to be supported by newly created medical audit committees, led by clinicians but funded through and accountable to their local health authorities. Central funds for medical audit were distributed to provider units through regions on a capitation basis (whole time equivalent consultant numbers). £28 million was allocated for this purpose in the first two years, rising to £48.8 million in 1991-92 (the year in which the committees began to function fully). The monies were intended to finance and resource the new organisational structures, but not to fund individual doctors to do audit. Audit was to be included in all consultants' job descriptions and time for audit reflected in locally agreed job plans. No indication was given as to how much time consultants should spend on audit, but estimates from the Royal Colleges ranged from one hour (Royal College of Physicians) to half a session (Royal College of Surgeons) per week.

2.1.3 Anticipated benefits of audit

The expected benefits of the medical audit programme, as described for example in an internal Department of Health discussion paper[14], were both profound and wide- ranging:

"Medical audit should trigger changes in practice within specialties, across specialties, across provider units and across boundaries including those between primary, secondary and tertiary care. The findings of medical audit should encourage comparison and challenge working practices throughout the NHS...This should result in optimal delivery of effective and appropriate care by the right professionals, in the right combination, in the right setting and at the right time."

2.1.4 Policy developments after 1989

A number of significant modifications to the policy on audit took place in the five years after 1989. These included:

1991 introduction of a separately funded Nursing & Therapy audit programme (which received £2.3 in 1991-92)

1993 a shift in emphasis from uni-disciplinary medical audit to multi-disciplinary clinical audit and a greater emphasis on the role of management in the audit process, although audit was to remain professionally led. Stress was also put on purchasers' rights to know their providers' arrangements for clinical audit, the level of participation by professional staff, the topics examined and improvements generated[15]

1995 top sliced monies for audit were transferred into the NHS general allocation thereby devolving responsibility for development of clinical audit to local level

1995 the focus of advice shifted away from organisation and monitoring of audit to considerations of effectiveness. An effective clinical audit programme defined as one which: involves balanced topic selection; employs adequate audit processes; secures implementation of audit results; and is comprehensive (involving all aspects of health care)[16]

1996 audit programme no longer regarded as the central mechanism for improving clinical care in the way it was in 1989, but rather seen as "a part of the broader work" on improving clinical effectiveness

2.2 Reactions to the audit policy

2.2.1 Reactions from the medical profession

i. Medical reactions to the 1989 proposals for audit must be seen in the context of reactions to the white paper proposals as a whole, which were generally very negative. There was concern that the proposals failed to address the chronic underfunding of the NHS, doubts about the need for such a major reorganisation of the system and scepticism as to whether patients would benefit from the changes. Against this background, the reaction to the ideas for audit from the Royal Colleges and others speaking on behalf of the medical profession was strikingly positive.[17,18,19,20] However the Colleges took care in their publications to reiterate the principles of medical audit as educational, confidential and non-judgmental.

ii. A combination of reasons may account for the acceptability to the medical leadership of the government's audit policy. First, it was generally accepted that some strategy to ensure the quality of clinical care was needed and would soon be introduced. It had been feared that this would involve inspectorates or other forms of external review. In the event the proposals were far more moderate and the Department of Health took care to emphasise the positive aspects of medical audit as against other existing quality control mechanisms such as the GMC's disciplinary procedures and the law. Second, the various documents relating to medical audit were extremely circumspect about the wording of the proposals, avoiding provocative terms such as "mandatory" or "compulsory" in relation to participation in audit and making no

mention of penalties for those who resisted.

iii. Not all clinicians, however, were reassured. In a series of *Lancet* articles by various specialists invited to comment on the audit policy, all had positive things to say about the benefits of audit in principle, but there were many doubts about how the policy would work in practice - was the committee structure too bureaucratic? would there be adequate time for audit? could confidentiality really be maintained? - and some suspicion about the possible covert use of the policy as a diversionary device to deflect attention from insufficient resources. Among hospital doctors on the ground, attitudes were also very mixed. In an interview study carried out in four English district general hospitals in 1991, most doctors accepted the need for audit but there was suspicion about the government's motives and anxiety about what might be done with audit findings. Most of the respondents saw practical difficulties in doing audit (lack of time, lack of skills, lack of interest, lack of adequate data and information systems, lack of willingness to focus on key issues such as appropriateness of treatment, reluctance among consultants to judge their peers and risk of unfair attribution of blame to junior staff) and there was some scepticism about its effectiveness.[21,22]

2.2.2 Reactions outside medicine

i. Outside medicine, the concessions to medical sensitivities that helped achieve the profession's endorsement were seen by some commentators as significantly undermining the policy's potential value. Pollitt[23] has described the prevailing view of audit in the medical literature with its emphasis on local standards, local and absolute confidentiality and anonymity, voluntary participation and no external sanctions for poor performance as the "medical model" of medical audit. He argues that informal, internal methods of quality assurance of this sort, where management plays no significant role and the results are not made publicly available, are disadvantageous from the perspective of public accountability because they fail the "transparency test" - the nature of the attention given to quality is not monitored and justice is not seen to be done. While acknowledging that the white paper did significantly challenge the "medical model" of audit, insofar as it made medical audit a matter of public policy, put pressure on clinicians to participate and involved management (albeit in a very limited way), Pollitt commented that NHS medical audit was still "a rather pale affair" in comparison with the American model of mandatory external peer review backed up by sanctions.[24] And, to the extent that audit remained a private activity internal to the medical profession, the need for greater public accountability would remain unmet.

ii. There was also concern that the emphasis on medical leadership and peer review had led to an overly narrow focus on medicine in the policy as a whole. The new organisational arrangements and new money were introduced specifically to facilitate the development of medical audit by doctors. (The Nursing & Therapy audit programme was not set up until 1991 and the shift of emphasis towards clinical audit did not occur until 1993.) At a time of increasing recognition of the importance of a team approach in clinical work, the emphasis on uni-professional audit was criticised, by the Director of the Royal College of Nursing among others, as inappropriate and potentially divisive.[25,26]

iii. Similar anxieties were voiced by commentators looking at the implications of audit from a management perspective, but their concerns went one stage further in that they challenged the appropriateness of segregating professional audit (whether uni- or multi-disciplinary, medical or clinical) from other quality management initiatives such as resource management and total quality management.[27,28] Observing that "the briefest consideration of how treatment and care is

delivered to patients emphasises the interdependence of the individuals and departments that provide it", the Director of the Institute of Health Service Managers argued for the integration of professional audit into a much wider model of co-operative working.[27]

iv. There were also more fundamental doubts about the wisdom of a policy focusing on the methodology, rather than the purposes, of clinical quality assurance, and concentrating so heavily on one particular approach. There was a danger that:

* doing audit might become and end in itself, rather than merely a means to an end

* topics would be chosen for audit because they were easy and interesting to study, rather than because they were necessarily important to patients

* aspects of care for which data already existed would be early candidates for audit, whether or not they were causing concern

* important aspects of practice might be neglected entirely because they were not susceptible to audit

* because of the emphasis on audit over other approaches, important problems might be tackled ineffectually through audit, when they could be dealt with more satisfactorily in some other way

v. These concerns were the more important because of the weakness of the evidence that audit could be beneficial to patients and the known difficulties of completing the audit cycle effectively. In a vigorous challenge to the policy on audit, Maynard accused the government of profligate expenditure on an unproven methodology, based on an expedient alliance with the medical profession rather than on any real evidence, and argued for urgent evaluation of the costs and benefits of the audit programme.[29]

3. ASSESSMENT OF AUDIT ACTIVITY IN NHS HOSPITALS AFTER 1989

This section:

* outlines the studies undertaken to evaluate the audit programme

* summarises the evidence available on the extent and effectiveness of audit activity in NHS hospitals

3.1 Evaluation of audit

3.1.1 Studies undertaken

i. At the time of the 1989 NHS reforms, there was widespread concern about the absence of plans for testing out or evaluating the effects of the major changes set in train. The proposals for audit were no exception to the general rule and there was no built in programme of evaluation. Nevertheless, a number of evaluation studies subsequently took place and a large amount of information was generated about activities occurring under the auspices of the various audit programmes. Data regarding audit projects undertaken during the first three years of the policy were summarised in four separate reports published by the NHS Management Executive.[30,31,32,33]

ii. A review published in 1993 of evaluation initiatives relating to the medical and clinical audit programme in secondary care found a total of 20 studies carried out for the Department of Health. Most of these focused on medical rather than clinical audit and were dominated by the provider/clinician perspective. There was little formal evaluation of audit programmes above provider level.[34] In addition, in 1993 the Department of Health commissioned CASPE to undertake a multi-stranded evaluation of the medical audit programme in the hospital and community health services in England. The project involved a series of separate but interlinked sub-projects, each directed at a different area of the programme and using a variety of data collection methods.[35] Medical audit in secondary care was also one of the topics studied in the evaluation programme set up by the King's Fund to evaluate the NHS reforms.[36]

3.2 Audit in NHS hospitals

3.2.1 The practice of audit

i. Some of the most revealing insights into the practice of audit after 1989 come from a detailed case study of the implementation of audit in general medicine in four hospitals undertaken in 1991/92 on behalf of the King's Fund.[37] Key findings included:

* audit programmes were formulated by local clinicians on an ad hoc basis and managers had little role in shaping the audit process

* overall attendance at audit meetings averaged two-thirds to three-quarters of all those designated as part of the general medicine audit group

* in audit meetings, doctors did not act as peers but rather as consultants and juniors in a hierarchical relationship

* there was very little planning and the entire audit cycle was usually collapsed in a single meeting

* there was often uncertainty about what should happen as a result of audit or who was responsible for taking any action

* audit activities concentrated on the technical aspects of inpatient care

* there was very little use of hospital wide information technology systems and, in almost all cases, the sample sizes used were small

* most criteria were developed locally with little reference to external guidelines

3.2.2 Quality of audit activity

i. The best information about the quality of hospital audit activity comes from a detailed review of the progress and impact of audit at a sample of 29 health care providers undertaken by CASPE Research in 1994.[38] The audit programmes in these organisations were assessed against four benchmarks of success defined by the researchers. A successful audit programme was defined as one which:

* is directed at quality improvement
* is valued and respected by stakeholders
* covers the full range of provider services, departments and professions
* produces documented, demonstrable improvement in the quality of care

ii. The study found "a very few" providers whose audit programme could genuinely said to be achieving most or all of these benchmarks. They were still capable of doing better, but were already doing very well indeed. Most of the providers studied had made fair progress in achieving two or three of the benchmarks, and a substantial minority had audit programmes which could not be said to have achieved any of them. The researchers suggest that:

"if one expected that, after three or four years of experience, providers should have largely established effective clinical audit programme which were demonstrably good value for money, then our findings are disappointing, because very few had achieved anything like that level of success. On the other hand, if one's expectations were somewhat lower, and one hoped to see some form of audit in every provider, involving most or all doctors in audit activities, raising the profile and priority towards clinical audit, and improving general levels of understanding and attitudes towards audit, then our findings might seem more encouraging."

iii. The CASPE study identified seven "critical success factors" for clinical audit programmes, whose presence or absence appeared to be a critical determinant of whether the benchmarks of success defined above were achieved. These are:

* **Clinical leadership** This seemed to be the most important single determinant of an audit programme's success.
* **Vision, strategy, objectives and planning** At providers with successful audit programmes there was an explicit vision of what the audit programme was there to do, which had been communicated to everyone and was kept to consistently.

* **Audit staff and support** Successful audit programmes had good audit staff who were recognised as an expert resource for advice and support and valued as important members of the team.
* **Structures and systems** Many audit programmes faltered because they lacked basic structures and systems, eg for managing the workload, prioritising, timetabling, monitoring and reporting.
* **Training and education** Few providers had recognised the need for training in audit skills which, despite their professional background, many clinicians did not already possess.
* **Understanding and involvement** As well as good communication, training and leadership, successful participation in audit programmes also depended on resources, time and appropriate incentives and sanctions
* **Organisational environment** Well-managed providers with good personal and professional relationships among staff and with purchasers were able to establish better audit programmes. Dysfunctional organisations with a history of internal and external conflict and dissent found establishing audit more difficult. Thus the organisations likely to be most in need of audit and quality improvement were probably the least able to make it happen.

3.2.3 Impact of audit on patient care

i. The most serious criticism of the audit policy at the time of its introduction was that it was based on assumptions about the value of audit for which there was not sufficient evidence. Despite the enormous amount of audit activity generated by the policy, the evidence about the benefits remains almost as shaky as it was before 1989.

ii In its submission to the National Audit Office enquiry on clinical audit[39], the NHS Executive acknowledged both that information about the impact of audit was incomplete and that there were major difficulties in interpreting the evidence available. Despite these problems, the Executive concluded that clinical audit was having a significant impact on clinical practice and organisation. But it presented no evidence on the effect of audit on quality of patient care or outcomes. The NAO's own investigation of progress was based on visits to three regional health authorities. It was claimed that about one third of audit projects undertaken locally during 1993-94 had led to changes in clinical care and that "some of these had led - and others may lead - to improved quality of patient care and outcomes". However, there was no independent verification of the regional reports on which these claims were based.

iii The CASPE evaluation reports concluded that clinical audit had been established as part of clinical practice and health care provision and had caused or facilitated change in a wide range of areas. But they also acknowledged that monitoring of progress was difficult due to a general lack of well-focused objectives for audit programmes and low quality data, and that relatively few of the changes reported directly affected the quality of health care delivered to patients.

3.2.4 Conclusion

* As far as the public sector was concerned, the changing ideas about quality in the NHS in the 1980s were very much of their time and comparable with what was going on in other areas. For a variety of reasons, however, the transfer of the new thinking on quality assurance from the commercial to the public sector was not entirely

straightforward, and therefore in general the adoption of the new ideas was slower/less complete than in industry as a whole.

* There were some doubts about whether a model of quality assurance developed in a commercial setting either could or should be applied without modification in a complex service sector like the health service. The Department of Health appears not to have seen this as a problem (see for example the NHSME 1993 report *The Quality Journey*[3]), but in practice it made the implementation of total quality management considerably less straightforward and probably more controversial.

* The traditional, hierarchical and bureaucratic organisational structures characteristic of the public sector in the UK were not initially well-suited to the new approaches to quality, which are predicated on a relatively close, contractual relationship between producer/provider and customer. Changes in this direction were central to the widespread restructuring of a whole range of public sector organisations during the course of the 1980s. The NHS reforms of 1989 which introduced the purchaser/provider split were part of this wider change.

* The NHS was a special case in the implementation of quality assurance because of the central role of the medical profession with its unusually strong tradition of professional autonomy. In this important sense (that the key occupational group working within it remains self-regulating) the NHS was - and to a large extent remains - in a very different position from other organisations.

* Quality assurance of clinical care was left in the hands of the professions until the late 1980s when, as part of the 1989 NHS reforms, the government introduced a policy intended to ensure the participation of every doctor in regular, systematic, medical audit.

* Prior to this time, some parts of the medical profession already had extensive experience of formal quality assurance exercises set up mainly by the Royal Colleges, but involvement remained patchy and unsystematic and there was no coherent strategy of quality assurance for the medical profession as a whole.

* Responses to the 1989 policy were mixed. In policy documents, audit was seen as a key aspect of the reforms, with the potential to produced considerable benefits for patient care. The policy was broadly welcomed by the Colleges and other representatives of the medical profession. Medical practitioners on the ground were more sceptical about the benefits and concerned about the practical problems of undertaking effective audit. External commentators were concerned about the medical focus of the audit policy, lack of input from or links with other parts of the health service and, most of all, about the lack of sound evidence of the effectiveness of audit in improving patient care.

* Policy on audit was subsequently modified in the direction of increased emphasis on clinical audit, greater management involvement and achieving beneficial change.

* Evaluation of the implementation of audit in NHS hospitals showed extensive audit activity, with most doctors involved to some extent. However, the quality, coherence and effectiveness of the audit programmes was very variable. There continued to be a shortage of good evidence of the impact of audit on patient care.

REFERENCES

1. Griffiths Report. *NHS Management Enquiry* London: Department of Health & Social Security, 1983.

2. Carr-Hill R, Dalley G. Assessing the effectiveness of quality assurance. *Journal of Management in Medicine* 1992;6:10-18.

3. NHS Management Executive. *The Quality Journey. A Guide to Total Quality Management in the NHS* Leeds: Department of Health NHS Management Executive, 1993.

4. Shaw CD. *Quality Assurance - What the Colleges are Doing* London: King's Fund, 1986.

5. UK Departments of Health *Report on Confidential Enquiries into Maternal Deaths in the UK 1985-7* London: HMSO, 1991.

6. Department of Health *Confidential Enquiry into Stillbirths and Deaths in Infancy: Report of a Working Group* London: Department of Health, 1990.

7. Campling EA, Devlin HB, Lunn JN. *The Report of the National Confidential Enquiry into Perioperative Deaths* (NCEPOD report) London: National Confidential Enquiry into Perioperative Deaths, 1990.

8. National Audit Office *Quality of Clinical Care in NHS Hospitals* House of Commons Paper 736. London: National Audit Office, 1988.

9. World Health Organisation *The Principles of Quality Assurance* Report on working group meeting convened by Regional Office for Europe (Copenhagen) in Barcelona, 1983. European Reports and Studies, 94. Copenhagen: WHO, 1985.

10. Moores B. The need for medical audit. *Journal of Management in Medicine* 1989;3:323-339.

11. Secretaries of State for Social Services, Wales, Northern Ireland and Scotland. *Working for Patients* (Cm 555) London: HMSO, 1989.

12. Stone DH. Proposed taxonomy of audit and related activities *Journal of the Royal College of Physicians of London* 1990;24:30-1.

13. Buxton MJ. Achievements of audit in the NHS. *Quality in Health Care* 1994;3:Supplement:S31-S34.

14. NHS Management Executive *Steering the Audit Programme* (Internal Discussion Paper) London: Department of Health NHS Management Executive, 1991.

15. NHS Management Executive Clinical Audit. *Meeting and Improving Standards in Health Care* Leeds: Department of Health NHS Management Executive, 1993.

16. NHS Executive *The New Health Authorities and the Clinical Audit Initiative: Outline of*

Planned Monitoring Arrangements (EL(95)103) Leeds: Department of Health NHS Executive, 1995.

17. Standing Committee on Postgraduate Medical Education. Response to the White Paper. *British Medical Journal* 1989;299:509.

18. Standing Committee on Postgraduate Medical Education. *Medical Audit: the Educational Implications* London: SCOPME, 1989.

19. Royal College of Physicians of London. *Medical Audit: A First Report: What, Why and How?* London: Royal College of Physicians of London, 1989.

20. Royal College of Surgeons of England. *Guidelines to Clinical Audit in Surgical Practice* London: Royal College of Surgeons of England, 1989.

21. Black N, Thompson E. Obstacles to medical audit: British doctors speak. *Social Science & Medicine* 1993;36:849-56.

22. Black N, Thompson E. Medical audit: the views of junior doctors. *Journal of Management in Medicine* 1993,7:33-42.

23. Pollitt C. The struggle for quality: The case of the National Health Service. *Policy and Politics* 1993;21:161-170.

24. Pollitt C. The politics of medical quality: Auditing doctors in the UK and the USA. *Health Services Management Research* 1993;6:24-34.

25. Hancock C. Can it work for patients? *Senior Nurse* 1990;10(7):8-10.

26. Frater A, Spiby J. *Measured Progress: Audit for Physicians. A Manual of Theory and Practice* London: North West Thames RHA Public Health Directorate, 1990.

27. Charlwood P. Audit and Accountability. *Medical Audit News* 1991;1:34-6.

28. Harman D, Martin G. Managers and medical audit. *Health Services Management* April 1992:27-9.

29. Maynard A. Case for auditing audit. *The Health Service Journal* 18 July 1991:26.

30. NHS Management Executive. *Medical Audit in the Hospital and Community Health Services* Leeds: Department of Health NHS Management Executive, 1994.

31. NHS Management Executive. *Clinical Audit in the Nursing and Therapy Professions* Leeds: Department of Health NHS Management Executive, 1994.

32. Humphrey C, Berrow D. *Medical Audit in Primary Care: A Collation of Evaluative Projects* Leeds: Department of Health NHS Management Executive, 1994.

33. Hopkins A. *Medical Audit Activities of the Royal Colleges and their Faculties in the UK* Leeds: Department of Health NHS Management Executive, 1994.

34. Walshe K, Coles J. *Evaluating Audit in the NHS. A Review of Initiatives* London: CASPE Research, 1993.

35. Walshe K, Coles J. *Evaluating Audit in the NHS. Developing a Framework* London: CASPE Research, 1993.

36. Robinson R, LeGrand J. (eds) *Evaluating the NHS Reforms* London:King's Fund Institute, 1994.

37. Kerrison S, Packwood T, Buxton M. *Medical Audit: Taking Stock* London: King's Fund Centre, 1993.

38. Walshe K. (ed) *Evaluating Clinical Audit: Past Lessons, Future Directions* London: Royal Society of Medicine Press, 1995.

39. National Audit Office. *Clinical Audit in England. Report of the Comptroller and Auditor General* London: National Audit Office, 1995.

GLOSSARY OF TERMS

Audit	A systematic framework used by health professional for investigating and assessing their work and for introducing and monitoring improvements. The process of audit is a cyclical activity involving a characteristic sequence of events which include: defining standards against which performance can be compared; gathering systematic evidence about performance; comparing results against standards; taking action to remedy any deficiencies identified; and monitoring the effects of this action.
Clinical audit	refers to audit covering all aspects of clinical care including that provided by nursing and paramedical staff.
Medical audit	refers to audit of activities initiated directly by doctors.
Organisational audit	refers to investigation of aspects of practice such as appointments systems which are regarded as primarily administrative
Quality assurance	Methods of maintaining or enhancing service quality which use systematic assessment of performance against predetermined standards as a means of identifying problems in the service and of introducing and monitoring improvements.
Total quality management	An approach to quality assurance first developed in industry and subsequently widely adopted by management in the public sector. Main components of TQM approach are that: the aim is not simply to maintain standards but to increase organisational success through continuously seeking out ways to do things better; expert criteria for quality are eschewed in favour of customers' definitions of their own needs; quality assurance is seen as a generic internal activity whereby all participants in the organisation take responsibility for their own areas of work; problems are assumed to derive from weaknesses in the system rather than individual failings

3