Medical audit and total quality management in health care: a sociological assessment

Kinchin-White, James

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Changes in the organization, funding and delivery of health care are affecting health systems in all societies in the search for greater economy, efficiency and effectiveness. The issue of quality is at the forefront of these changes and has been largely addressed by the implementation of the Medical Audit initiative. Medical Audit is the review of clinical practice, a process largely designed by doctors, led by doctors and, described as an issue that is essentially a matter for the medical profession. Nevertheless, since its formal introduction, the initiative has largely failed to meet expectations. Some argue that the problem is technical in character, that audit methods are inadequately researched. Others believe that the philosophy of Total Quality Management, designed to effect continuous improvement in all aspects of health service delivery, is more appropriate.

However, this study, conducted through participation and observation of both the audit process and implementation of Total Quality Management in health care, will argue that, in their current form, neither is adequate for fulfilling its stated objectives. It will suggest that Medical Audit is conceptually rather than technically inadequate, because little account is taken of the complex social and technical systems that exist within hospital settings. Similarly, the industrial model of 'total quality' presupposes conditions that do not exist within provider organizations. Nevertheless, this is not to say that Medical Audit and Total Quality Management are inappropriate for health care. Audit has demonstrated only limited success and, though many of aspects of the 'total quality' approach are clearly relevant, it will require modification and further testing prior to full implementation. Both audit and 'total quality' require fundamental changes in behaviour, and if they fail, they may not get a second chance - health care quality is much to important for that to be allowed to happen.
Medical Audit and Total Quality Management in Health Care:
A Sociological Assessment

JAMES KINCHIN-WHITE

MA

UNIVERSITY of DURHAM
DEPARTMENT OF SOCIOLOGY

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1994

20 JUN 1995
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DECLARATION

I confirm that no part of the material offered has previously been submitted by me for a degree in this or any other University.

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CHAPTER ONE

INTRODUCTION

Following the publication of the White Paper *Working for Patients* (DoH, 1989a), the British National Health Service (NHS) was subject to radical reforms designed to change its system of management and organizational structure in pursuit of greater efficiency, accountability and effectiveness. These issues are addressed in three key features of the reforms, namely: the introduction of a competitive *internal market* which was established by separating the roles of purchasing and providing health care; the creation of independently accountable NHS Trust hospitals; and the introduction of formal mechanisms aimed at improving service standards, optimizing the use of resources and enhancing the quality of care.

The reforms were considered necessary for three main reasons. First, although general management had been introduced to the NHS in 1983, and government continued to have primary control over NHS funding, neither government nor the NHS management have control over the demand for health care or over the technical capacity of the health care system to provide an increasingly wide range of diagnostic and therapeutic services. Hence, the associated costs of providing modern health care together with the pervasive value-for-money ethos in contemporary economic thought, combined to provide powerful stimuli for focusing (or re-focusing) political attention on the issue of efficiency within the NHS.

Second, as a result of what Moran and Wood (1993) term the 'state sanctioned self-regulation' of medicine, and the continuity of a decentralized system of health service administration, government remained largely unable to exercise operational control over the NHS. Moreover, the relative autonomy enjoyed by the medical profession at national level was effectively replicated at local level where "...formal organisational arrangements [had] been so designed as to leave doctors...free from day to day management" (Harrison *et al.*, 1992, p. 23). Thus, in spite of repeated attempts to reform the health care system during the 1970s and 1980s, the NHS remained largely unaccountable because "...real power at the periphery lay not with the appointed members [of health authorities] but with varying combinations of doctors and managers." (Harrison *et al.*, *Op. cit.*, pp. 132-3) Recent proposals to re-organize Regional Health Authorities may significantly alter central-peripheral relationships and while these changes are not yet fully implemented their implications will be discussed.
Third, government were concerned about inter-regional variation in both the financial and operational performance of health care providers. Although a more equitable distribution of resources was achieved following the report of the Resource Allocation Working Party (DHSS, 1976), standardized performance indicators, introduced following recommendations in the Körner Committee report (DHSS, 1983), revealed that there were significant differences in terms of the cost and length of stay for similar types of in-patient episode. Widespread concern was also expressed about variation in waiting times for out-patient appointments and elective surgery, inadequate information systems, the lack of explicit standards for patient care, and the general absence of a systematic review of the quality of clinical practice (Institute of Health Service Management, 1988). These views were partly endorsed by the medical profession who recognized that "...a more systematic evaluation of the quality and effectiveness of doctors' work...can now be regarded as an important professional obligation." (Royal College of Physicians, 1989, p. 1).

The focus in the health care system had therefore changed from an emphasis on science and technology, through cost containment, to a central concern with assessment and accountability. However, the limitations posed by the NHS organization and its internal management structure effectively constrained attempts to improve accountability or increase effectiveness and efficiency. Consequently, a principal objective of the 1991 reforms was to alter the balance of power between doctors and managers in order to change the cultural orientation of the health service from reactive administration to proactive managerialism (Harrison et al., Op. cit.; Klein, 1989).

Three specific but interrelated NHS policy initiatives have the potential to alter the balance of power between managers and clinicians and, ipso facto, change the organizational culture. These are Medical Audit, Total Quality Management and the Resource Management Initiative (RMI) - the latter being a modified version of Management Budgeting implemented following the 1983 Griffiths Report (DHSS, 1983; DHSS, 1986, HN(86)34). The explicit aim of the RMI is to improve patient care by providing doctors and managers with an improved information base upon which to make better judgements about their use of resources. By the time the major new reforms were introduced however, it had become clear, despite increased participation by clinicians, that the RMI had made little impact on facilitating the desired cultural transformation towards managerialism (Harrison et al., 1992; Packwood et al., 1991; Buxton et al., 1991).
The Medical Audit initiative is, on the other hand, intended to ensure that the review of clinical practice against professionally determined standards becomes a formal, systematic and obligatory activity, and Unit General Managers have been empowered to include participation in Medical Audit as a feature of job descriptions for consultant medical staff (DoH, 1989b; DoH, 1990; DoH, 1989c). Nevertheless, at the outset, the precise meaning of Medical Audit was elusive since it was variously described as: a powerful mechanism for improving the quality of care; an information system to be integrated with Resource Management (RM); an educational process primarily a matter for the medical profession and one that should therefore be led by doctors (Dixon, 1990; DHSS Executive Letter, 1989, EL(89)MB/224; Scottish Home & Health Dept, 1989 HC(Gen) 29; Standing Committee on Postgraduate Medical Education, 1989).

Finally, Total Quality Management (TQM) is an American derivative of the concept of Total Quality Control developed by Japanese industry and was applied within the NHS in 1989 when the NHS Management Executive established seventeen pilot demonstration projects. TQM is a management philosophy which entails commitment to the development of internal structures that will ensure Continuous Quality Improvement (CQI) throughout an organization. In effect, implementing CQI in health care presupposes the creation of an organizational culture that includes a high level of employee empowerment, but which may result in the organizational structure being turned upside down (Wilson, 1992).

In short, together with the major structural reforms of the health service, the three policy initiatives outlined above represent 'unprecedented opportunities' for managers to change the culture of NHS and shape the behaviour of its employees (Harrison et al., Op. cit.). However, these authors argue that the new structural context within which the service must function will combine with financial issues to dominate the managerial agenda, and they question whether senior managers will be prepared, or be able, to immerse themselves in the "...deep and sensitive waters [of Medical Audit and other quality initiatives] when there are so many other issues demanding urgent attention" (Harrison et al., Ibid., pp. 131-2). This question provides a rationale for research and it is partly the purpose of this study to investigate the extent to which the Medical Audit, Total Quality Management and Resource Management initiatives are conceptually adequate for effecting cultural change within health care provider units. In addition, an examination of the Medical Audit and TQM initiatives, including their interaction with RM, allows for a technical evaluation of their adequacy for improving the quality of patient care.
At the level of technical adequacy, there are three major factors that may constrain the impact of Medical Audit. First, the focus on solely medical issues excludes the potential for adverse patient outcomes to result from a failure in some other part of the health care system and thus, the integration of audit with other quality initiatives may be crucial. Second, there is a risk that unproven methods may be widely adopted and practiced before they can be shown to have a causal relationship with improvements in patient care (Crombie et al., 1993). Third, the systematic review of clinical data will not, in itself, result in changes in clinical practice (Fowkes et al., 1985). Such change will require the development of standards and the implementation of clinical guidelines which, though implicit in the Medical Audit process, will depend on education, and subsequent behavioural change within the medical profession.

Similarly, at the level of conceptual adequacy, several factors may inhibit the Medical Audit initiative from effecting cultural change either in professional or organizational terms. Medical ethics, for example, especially the principles of autonomy and confidentiality, are not conducive to improvements in the quality of care through formal review (Garrett et al., 1993). Yet, Crombie et al. (Op. cit., p. 7) argue that "...complete confidentiality is a cornerstone of modern [medical] audit". What then of accountability, and to whom? If Medical Audit really is a matter 'primarily for the medical profession', then doctors will remain clinically accountable solely through the established medical hierarchy. What then of cultural change? Doctors may, as Harrison et al. (Op. cit.) have suggested, become obliged to assume greater managerial responsibility, but this could be resisted by managers, nurses and other healthcare professionals if perceived as a threat to their relative autonomy. In contrast, the Resource Management Initiative implies a partnership between clinicians and managers and joint access to pertinent clinical and administrative information, yet, given the current definitive characteristics of Medical Audit, it is difficult to perceive how audit activities will feed into the RM process. Finally, effective TQM demands an unprecedented level of devolution and delegation to other staff groups, but is an issue that may lead to dysfunctional competition for authority and responsibility.

The significance of the above issues was largely identified during the research process, however they raise two distinct questions which provide the central focus for this study. First, are the Medical Audit and TQM initiatives technically adequate for improving the quality of patient care? Second, how will medical-management relations develop in response to Medical Audit, TQM and structural change; will the result represent a genuine cultural shift, or will the status quo be maintained?
The research methodology was partly determined by the subject matter and partly by the occupational status of the author. On the one hand, the focus on policy implementation created a need for empirical evidence about formal and informal structures within the NHS - evidence that does not lend itself readily to the type of quantitative research favoured by policy makers or planners (Booth, 1988; Bryman, 1989; Pollitt, et al., 1990). On the other hand, the author enjoyed total participant proximity to the topics under investigation and to health care provider units within which they were being implemented. An ethnographic approach was thus considered the most appropriate research tool.

The relevant level of analysis and locus for the study were less easily determined. Traditionally, medical sociology has tended to be studied at one of two extremes, viz, wide ranging macro level studies such as the Black Report into health inequalities (DHSS, 1980), or micro level studies into doctor-patient relationships for example. There has been little qualitative research on the impact of policy implementation at the meso or intermediate level "...where policy and organizational and managerial processes tend to be concentrated" (Hunter, 1990, p. 215). However, at the outset of the study, Working for Patients had been under considerable debate for little over one year and the major interest groups had identified their particular areas of concern. Consequently, there was a broad national consensus within though not necessarily between these groups about issues relating to the new policy initiatives (RCP, 1989; BMA, 1989; Healthcare Independent, 1990; Shaw, 1990). Moreover, strategies for the implementation of Medical Audit, TQM and RM were largely directed from the centre, accommodating or avoiding identified areas of concern, and were supported by 'ring-fenced' central funding. It was considered feasible therefore, to conduct a meso level analysis of the impact of central policy within the relative confines of a Regional (Northern) Health Authority area. In addition, an unexpected opportunity to develop US quality improvement systems in hospitals in the Middle East enabled the author to gain experience of the advanced application of TQM and CQI in health care settings. It should be noted however, that materials gained during this latter part of the research were limited for use in conducting an assessment of the adaptability of US designs to the NHS environment. A direct comparison of the implementation process was not considered feasible due to the distinct administrative and environmental contexts of health care provision in the Middle East. It has been argued however, that because of the relative infancy of health care quality improvement in the UK, and since we have not yet developed our own terminology, we must adopt the US vernacular (Samuel, 1991). A technical assessment was thus considered feasible, timely and relevant.
Finally, it should be clear from the central questions that the research seeks to answer, that the research aims to provide elements of description, interpretation, analysis and explanation. The first of these is largely a technical issue facilitated partly by a comprehensive review of secondary literature and through participation in local, national and international seminars and training courses. The interpretation and analysis of findings are necessarily conducted within, and limited by, the chosen methodology. The final element is however, constrained by the author's theoretical position and conceptual framework from which the NHS organization is examined and both are outlined below.

Organizational culture is a vague concept which is difficult to define, but is often explained from one of four perspectives broadly classified as Classical, Human Relations, Systems and Contingency approaches (Mullins, 1993; Huczynski and Buchanan, 1991). The classical approach has sought to locate definitions and explanations in terms of management hierarchies and formal organizations in which reality is to be found in "...an inert amalgam of facts waiting to be unravelled by an investigator" (Bryman, Op. cit., p. 141). Indeed, it is difficult to perceive how the NHS could function without exhibiting some classical bureaucratic characteristics since the various health care professions function in a continuous state of flux as they absorb the impact of new policy initiatives, science and technology within an environment that readily admits change, but demands a measure of regularity and uniformity to ensure continuity. The classical approach accommodates these features of organizations, but fails to account for the concepts of power and status and has been described as "...an outmoded, narrowly Weberian, and apolitical rational-legal-institutional model of organization." (Hunter, Op. cit., p. 220)

The human relations approach on the other hand, gained much impetus following the Hawthorne experiments conducted in the USA during the 1920s. Here, the organization is regarded as a predominantly social system within which behaviour and group membership are key concepts. Emphasis is placed on the importance of informal structures in determining the construction and maintenance of organizational culture and the approach has demonstrated that organizations do not merely fulfil an economic function, but provide their members but with a variety of social needs (Maslow, 1943). The approach can nevertheless, be criticised for failing to account for the impact of environmental factors. In contrast, a systems approach accounts for the impact of some environmental influences by focusing on interrelationships between the various systems found within an organization (Huczynski and Buchanan, Op. cit.).
From a systems perspective the manner in which an organization functions can best be understood by examining the interaction between its social and technical systems (Trist and Bamforth, 1951). The technical system includes equipment, physical location and supply of materials while the social system is designed to meet the socio-psychological needs of employees, establish the boundaries of work relationships, develop communications systems and staff training programmes for example. Advocates of the approach argue that organizational design is open to choice and depends on decisions about the way in which technology will be used to achieve corporate and employee goals. Hence, an analysis of the resultant socio-technical system is said to provide an explanation of how and why an organization functions in a particular way. Nevertheless, there are two major objections to adopting a basic systems approach when considering the NHS. First, the approach presupposes that decision makers identify and act in accord with the significant constituent parts of each system - a scenario that is not consistent with the frequent difficulties encountered in the NHS when attempts are made to achieve central policy objectives at local level. Second, central policy is external to the technical system that exists at the intermediate level of the health service and is, by definition, part of a third 'political' system within which the service must function. A systems approach would thus divorce the NHS from its environment and pay "...scant regard...to the actual setting in which managers have to operate." (Hunter, Op. cit., p. 230)

Alternatively, the contingency approach, developed from systems theory, considers the design of an organization to be dependent on the complexity and variability of its environment (Burns and Stalker, 1961). These authors argue that, in unstable or changing circumstances, the 'mechanistic' structure becomes untenable, and that a flexible 'organismic' structure is appropriate. Characteristics of the organismic organization contrast sharply with those found in a rational bureaucracy and include multidisciplinary participation, shared responsibility and lateral communication (Burns, 1963). In brief, a contingency approach attempts to understand relationships by examining the interaction between the mechanical and organic components of an organization, though in doing so it tends to raise more questions than it provides answers for. Nevertheless, it is considered an appropriate conceptual approach because a major issue for NHS managers in the post-1989 era "...is to decide which organizational components might best be organized along bureaucratic, mechanistic lines and which might best be organized in...more flexible, organic lines." (Hunter, Op. cit., p. 231) This does not entail a complete rejection of the alternative approaches, but is to regard them as too narrow to accommodate the complexities of the reformed NHS.
The focus on specific policy issues, together with the central concept of organizational culture and the recognition of the importance of external environmental influences on the NHS, all value-influenced choices or judgements made by the author, were the major factors in establishing the theoretical orientation of the research. A review of the literature reveals that political theory predominates in the study of policy issues whether considered at the level of initiation, formulation or implementation where organizational culture is a key concept (Klein, 1989; Harrison et al., 1990; Harrison et al., 1992; Ham, 1992). Similarly, though perhaps inevitably, discussions about the environmental context of the NHS have given significant attention to the political and economic objectives of many recent changes (Levitt and Wall, 1992; Ham, 1991). Finally, where specific health care sub-cultures or the social context of health care have been examined, a political dimension, though perhaps not central, is nevertheless acknowledged (Freidson, 1988; Jones, R. 1994).

In addition, during the initial phases of the research process, although the concept of power was rarely explicitly acknowledged by NHS members, it was clearly exercised in a variety of guises. Furthermore, the concept of authority was similarly evident in all three of its Weberian forms (see Albrow, 1970). Finally, many observations signified the importance of status as a key concept in explaining behaviour within NHS health care organizations. Hence, at the outset there were sufficient grounds, reinforced by observation and by subsequent literature, for accepting the theory that the NHS was essentially a political organization in which the concepts of power, status and authority, though not particularly original, were important facets of an organizational culture that was perceived by organizational members to be in the process of radical transformation. The structure of the remainder of the thesis is as follows:

Chapter Two provides an overview of the development of Medical Audit in the UK, including a general historical summary and a discussion about its theoretical and methodological bases.

Chapter Three contains a conceptual framework for understanding the philosophy of Total Quality Management, but also discusses the issues and techniques employed in Continuous Quality Improvement programmes.
Chapter Four considers the macro-level environmental context of the NHS and discusses its implications for the meso-level organization of health care provider units.

Chapter Five outlines the research methodology.

Chapter Six describes the meso-level environment of hospital provider units as it has developed in response to some of the issues identified in Chapter Four.

Chapter Seven focuses on social relations within health care provider units and is centrally concerned with the question of the conceptual adequacy of new quality initiatives. Based almost entirely on observed behaviour within provider units, it nevertheless includes elements of analysis in an attempt to derive meaning from this complex social environment.

Chapter Eight provides an evaluation of the potential for applying the industrial model of Total Quality Management (TQM) to the health care environment based on experience of attempts to implement TQM in health care settings.

Chapter Nine completes the thesis by providing a brief summary of the main findings.
Although formal medical audit was introduced to the NHS as recently as April 1991, concern about the quality of medical care is not new. The earliest recorded attempt to specify standards in medicine was introduced by Hammurabi, king of Babylon (1948-05 BC), who constructed a legal code which specified maximum medical fees and defined the penalties to be suffered by unsuccessful surgeons (Devlin, 1988). If, for example, a patient lost an eye due to an error during surgery, the surgeon also lost an eye! Modern medical audit on the other hand, has been defined in less punitive terms as:

...a systematic, critical analysis of the quality of medical care, including procedures used for diagnosis and treatment, the use of resources and the resulting outcome for the patient. (DoH, 1989a, Chapter 5, p. 39)

Rudimentary ideas about audit were however, developed in the United States where three major studies into medical education, surgical outcomes and standards of care were conducted between 1910 and 1916. The first, by Abraham Flexner resulted in major reforms in US medical education; the second, conducted by Dr Ernest Codeman in 1912, was a major factor in establishing the American College of Surgeons; and the third, a survey of 692 hospitals by J.G. Bowman, a founder director of the college, resulted in the development of minimum standards for hospital-based surgery (Devlin, 1988; Crombie et al., 1993). Subsequently, the development of professional standards spread amongst other medical specialties and led, in 1951, to the formation of the Joint Commission on the Accreditation of Hospitals (currently known as the Joint Commission on the Accreditation of Health Care Organizations - JCAHO).

Indeed, external scrutiny of clinical practice, either by government or private sector agencies, is a significant characteristic of medical audit, sometimes called Medical Quality Assurance or Utilization Review, in the United States. In Europe (Belgium, Germany, Netherlands, UK and Sweden), Canada and Australia on the other hand, medical audit activities, both internal (local) and external (regional and national) have remained the preserve of the medical profession. Nevertheless, governments in all of these countries are increasingly becoming involved in facilitating, or legislating for, improvements in medical accountability (Moran and Wood, 1993; Jost, 1992; Wilson, 1992; Grol et al., 1988; Australian Council on Hospital Standards, 1981).
In the UK the earliest systematic attempt to assess the quality of medical care began in 1952 when the Confidential Enquiry into Maternal Mortality was established. In its first report, the enquiry revealed that, in home deliveries, almost 90% of deaths associated with retained placenta (afterbirth) were potentially avoidable. Clinical guidelines were established and, during the next three year period, deaths from this cause were almost halved. Other significant and ongoing audits include the National External Quality Assessment Scheme (NEQAS) for Pathology established in 1969, and the National Confidential Enquiry into Perioperative Deaths which evolved from an earlier study by Buck et al. (1988).

Despite these successes the development of audit in the UK has been relatively sporadic even though governmental and professional interest in the expansion of audit pre-dated Working for Patients. The Committee of Enquiry into Competence to Practice (Almen Committee, 1975) reported that it considered doctors' professionally responsible for improving their own knowledge by regularly and collectively assessing patient care, a view endorsed by the wide-ranging Merrison report (Royal Commission, HMSO, 1979). Nevertheless, it was the medical profession, through the Royal Colleges, that largely took the lead in developing audit in the UK. The Royal College of General Practitioners has been involved in quality improvement issues almost since its inception in 1952, the Royal College of Radiologists established a working party into the use of diagnostic radiology in 1975, and between 1977 and 1990, the colleges of Physicians, Surgeons and other disciplines have conducted studies and issued guidelines for the conduct and confidentiality of the medical audit process (Royal College of Physicians, 1989; DoH, 1990a; Royal College of Surgeons, 1990; Crombie et al., Op. cit.).

This historical development of audit in the UK had significant impact on policy formulation and implementation for several reasons. Perhaps mindful of the argument, best expressed by Devlin (1988, p. 320), that the "...price of clinical freedom is eternal professional vigilance", it is clear that the medical establishment had effectively taken control of audit before it featured prominently in public policy. Second, the profession's control over the audit process was explicitly though perhaps pragmatically acknowledged in government policy, and the sole threat of sanction, making participation in audit a condition of funding for training posts, was devolved to the Royal Colleges (DoH, 1989a, pp. 39-40). Third, the technical design, and thus, the basic characteristics of the audit process, were left largely to the discretion of the medical profession.
Although these developments did much to overcome the initial inertia displayed by many practitioners, they indicate that the introduction of formal medical audit, rather than being representative of a radical change in policy, was little more than "...the natural progression of a movement which has been gathering momentum [within the medical profession] over the last 20 years." (Crombie et al., Op. cit., p. 17) However, in spite of the evolutionary nature of audit development in the UK, there were important external demands for changes in medical practice. Improved access to education for example, and increased life expectancy have resulted in social demands from a more knowledgeable population for improvements in the quality of all goods and services provided by both the public and private sectors. Within the public sector, this social pressure has been reinforced by monetarist economic arguments that underpin the dominant political ideology which demands reductions in state intervention through increases in the quantity and quality of services provided from existing resources and, as indicated above, there was a recognition within the medical profession that clinical practice could not function in a vacuum divorced from the socio-economic and political bases of its authority.

In response to these demands, and to the empirical and epistemological evidence resulting from early audit studies, the profession designed a base model of the audit process (Figure I, overleaf), but mindful of the intense intra-professional debate about issues of authority, control, and confidentiality, they also defined the key characteristics of audit (Table 1) that were said to be hidden in the government definition (Batstone, 1990):

<table>
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<th>Table 1: Characteristics of Medical Audit defined by the Medical Profession</th>
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<td>Audit is an activity that is led by doctors.</td>
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<td>It is primarily an educational process.</td>
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<td>The process should lead to improvements in the quality of patient care.</td>
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<tr>
<td>It is a system of peer review involving voluntary participation.</td>
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<td>Standards should be set locally by participating clinicians.</td>
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<td>Confidentiality for both patients and doctors is a primary consideration.</td>
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Sources: RCP, 1989; Batstone, 1990; Crombie et al., 1993

In effect, these characteristics represented the fundamental criteria upon which the profession would consider the audit process acceptable given that its authority was perceived to have been already challenged by general management, academics and, increasingly, by patients. Moreover, concomitant objectives of audit were also identified as being: the assessment and improvement of the quality of care; the enhancement of medical education; and the attainment of greater efficiency (RCP, 1989).
However, it was recognized that in order to achieve its objectives the audit process would need to accommodate setting standards, the observation of practice, comparison between practice and standards, and the implementation of change where necessary. Further observation and assessment would also be required to ensure that change was effective (RCP, *Op. cit.*; Batstone, 1990).

**FIGURE 1**

![THE CYCLE OF MEDICAL AUDIT](Adapted from: RCP, 1989; Batstone, 1990)

Although this model has gained general acceptance, it has been challenged by those who emphasize education as the primary function of audit. An alternative four stage cyclical model has been developed and adapted by Coles (1990) and Batstone (1992) in an attempt to reconcile quality improvement and education in a single framework (see Figure 2).

**FIGURE 2**

![THE INTEGRATED EDUCATIONAL AND QUALITY IMPROVEMENT CYCLE](Adapted from: Coles, 1990; Batstone, 1992)
The illustrations at Figures 1 and 2 represent the extent of the debate over a framework for the conduct of audit during the first three years of its formal introduction to the NHS. Coles and Batstone argue that the integrated model not only facilitates the learning process, but also minimizes the risk of inappropriate or untested standards being applied to medical practice. On the other hand, standards based on the prior observation of practice may be lower than what is either desirable or possible. In addition, others have argued that medical audit is not research and though it may feed the research agenda, it need not extend the epistemological base of medicine (Bhopal and Thomson, 1992; Crombie et al., Op. cit.).

Confusion between medical audit and medical research is compounded by their use of similar methods and techniques; each requires that studies are adequately designed to reduce sampling error or other sources of bias, both use statistical techniques and may involve the use of qualitative and/or quantitative methods - significantly, the tools of the social rather than the medical sciences. However, while research is concerned with global advances in knowledge, audit is concerned with an assessment of the extent to which existing knowledge and resources are being correctly utilized in a given locality. In short, the debate over an appropriate framework for the audit process reflects in part, clinicians' unfamiliarity in the use and applicability of social science methods, and partly uncertainty about the implied precision of 'standards' within the somewhat imprecise world of medical practice. Although the audit cycle will, undoubtedly, continue to be adapted and refined as clinicians gain experience in the audit process, all models produced thus far are essentially variations of the design illustrated at Figure 1.

In its basic form, the audit cycle can be associated with distinct methodological tasks which provide an insight into a potential, task-based, division of labour within the audit process (see Figure 3, overleaf). Setting standards for clinical practice is clearly a task solely for the medical profession, but involves the identification of measurement criteria. The measurement phase on the other hand, involves data collection, statistical analyses and interpretation, of which the first two are time consuming and essentially technical tasks that do not require clinical skills. Conversely, the interpretation of such data must be conducted by medically qualified staff. At stage three of the audit process the range of actors involved will depend on the resource implications of desired change and may therefore involve managers. Finally, the success or otherwise of an audit project will depend crucially upon the assessment of change. Thus, the final phase will require the combination of technical and medical skills employed during phase two and possibly the involvement of management when further action is considered necessary.
METHODOLOGICAL IMPLICATIONS FOR THE DIVISION OF LABOUR WITHIN THE AUDIT PROCESS

Figure 3:

Adapted from: Royal College of Physicians, 1989; Scottish Home and Health Department, 1988
The task-based division of labour identified within the audit cycle (Figure 3.) is not a mere sociological abstraction derived from the base model of the audit cycle, but represents a practical framework which was established for the conduct of audit at a time when few practitioners fully understood the audit process and existing NHS information systems were designed for other purposes. The most common of these, the patient administration system (PAS), routinely captures demographic and basic in-patient data such as discharge diagnosis, follow-up arrangements and lengths of stay. Although such data can be utilized in audit programmes, PAS does not contain detailed information of the kind required to conduct an audit of specific aspects of clinical management. Similarly, though other common information systems do contain clinical data, for example, in pathology, radiology and pharmacy, these are designed primarily to automate the production of the results of diagnostic tests and reports, or to record drug prescription information, but they reveal little about why a particular course of action was chosen in the first place, or whether it was effective. Consequently, the patient record provided the primary source of medical audit information, but had the major disadvantage of being a time consuming source for aggregate data due to the individuality of their focus, and also because of illegibility, inaccuracy or incompleteness. Indeed, many early audit studies focused specifically on improving the accuracy and completeness of the medical record in accordance with guidelines produced by the Royal Colleges, (see, for example, Royal College of Surgeons of England, 1990).

Thus, in response to technical needs associated with the methodological implications of the audit cycle (Figure 3.), and to the shortcomings of existing data systems, central 'ring-fenced' funding was made available for distribution among provider units by Regional Health Authorities to ensure the provision of administrative staff and better information systems in support of medical audit programmes. However, partly because of a general acceptance of the defined characteristics of the audit process (Table 1, p. 16, above), and possibly because of managerial unease about the success of the initiative, fueled by murmurs of resistance to audit by some doctors, control over these additional human and financial resources was largely transferred to the medical profession - (though management consent is usually a necessary condition for capital or revenue expenditure which had recurrent cost implications). These developments, though intended to facilitate the implementation process, may prove to limit or undermine the concept of increasing medical accountability through audit since, at the outset, audit was effectively re-defined by doctors, and was designed and controlled, at local level, by the medical profession.
By definition and design, medical audit is largely, though not exclusively, a local activity and medical control over the audit process is clearly illustrated in the local organization of audit which, in the hospital sector, revolves around and is directed by a Local Medical Audit Committee (LMAC), usually a formally constituted body established by and accountable to the Medical Staff Committee. Audit support staff generally report directly to the chair of the LMAC and are bound by a formal confidentiality statement which is usually integral to the LMAC constitution. Moreover, LMAC chairmen may also perform a liaison function with General Practitioners (GPs) through membership of the local Medical Audit Advisory Group (MAAG) which coordinates audit in primary care and, though accountable to the Family Health Service Authority (FHSA), is largely medical in membership. Furthermore, while medical audit in the primary sector addresses distinct clinical issues, it is conducted within the same cyclical framework that has been applied in the acute sector (Figure 1). Hence, there is, in medical audit terms, a certain affinity between GPs, as purchasers, and hospital based practitioners, as providers, with regard to the issues and tensions posed by the audit initiative and it is unlikely therefore, that GP purchasers will, at least in the short term, be prepared to specify explicit clinical criteria within their contracts with hospital based provider units. As a result, clinical accountability through medical audit will not only continue to be pursued through local professional hierarchies, but, established mechanisms apart, will remain effectively closed to external scrutiny. In short, with one major exception, the concept of medical audit in the UK is, in all relevant respects, fundamentally different to the model of audit through external governmental or business (insurance) controlled review adopted in the USA (Jost, 1992). The exception on the other hand, concerns a common acceptance of some theories about quality in health care.

UK practitioners turned to the American experience and adopted a theoretical construct devised by Dr. Avedis Donabedian. Donabedian's theoretical division of a health care delivery system was devised in order to introduce logical and systematic methods into the review of hospital practice, and although it is somewhat limited, it remains the bedrock upon which all subsequent health care quality improvement techniques are based. Donabedian recognizes the importance of technical and interpersonal (social) systems in health care organizations, but argues that their complex interaction may render them inseparable (Donabedian, 1980). Health care settings are unique in that the production and consumption of services often occurs simultaneously within a relatively small spatial area and thus, the distinction between technical and socio-psychological processes is often blurred.
Donabedian devised a model that allowed for the totality of hospital activity to be distinguished within three dimensions, namely, *structure*, *process* and *outcome* (Donabedian, 1969). Examples of *structure* include the provision of equipment, the suitability of the estate, the availability of suitably trained and qualified staff, the organization of service delivery, and the production of policies, procedures and protocols. *Structure* is essentially concerned with *inputs* into the health care system and is thus, the least difficult dimension to measure and improve through the application of the audit cycle. However, for Donabedian, *process* is the 'primary object' upon which quality improvement audit should focus since it represents the sum of all activities involving patients' interaction with the health care provider. Management and administration, admission, consultation, diagnosis, prescription, therapy, cross-specialty and inter-unit referral, and discharge are but some examples of *process*. Yet, patient episodes never coincide with a single process, and it is acknowledged within the medical profession that single disciplinary or sub-specialty audit can only have a limited impact on the overall quality of service experienced by patients.

At its most simple, *outcome* represents the change in a patient's health status that results from medical intervention, but it is clear that all activities described as either *structure* or *process* may influence *outcome*. Moreover, all issues of *structure* are part of the *process* of administration. In short, the original Donabedian construct exhibits a static, almost linear progression from *structure*, through *process*, to *outcome*, whereas the actual delivery of care results from multi-dimensional and multi-disciplinary interaction. Furthermore, the availability of meaningful *outcome* indicators is scarce and is the subject of much contemporary social and medical research. In spite of these limitations, the fusion of Donabedian's theoretical model with the framework provided by the audit cycle promises closer integration between the planning and execution of medical quality improvement activities. However, this is not, by itself, sufficient for effecting substantial change. What criteria for example, should be used for evaluating the quality of clinical practice or an aspect of the health care service? An influential paper by R.J. Maxwell (1984) contains six criteria which provide a basis for the evaluation of health care quality in terms of either *structure*, *process* or *outcome*. Maxwell's six *dimensions of quality* which can be measured and assessed are, *accessibility*, *relevance*, *effectiveness*, *equity*, *social acceptability* and *efficiency*. In the UK, *economy* can be considered an further dimension given current government policy, but, in the USA, because of the different organization and funding of health care, equity and economy are less central to the definition of health care quality held by external assessors (Jost, Op. cit.).
The above mentioned dimensions of quality may however, have varying levels of significance for different professional groups within the health delivery system. Accessibility, equity and social acceptability for example, are sensitive issues which have gained their fullest political expression in the form of the Patients Charter and the retention of Community Health Councils and are thus, broad concerns of executive management. Though, where speed of access can be shown to influence clinical outcome, in patients suffering from a cerebral vascular accident (stroke) for example, doctors, explicitly committed to equity via the Hippocratic Oath, will also, albeit more narrowly, be concerned with accessibility.

The dimension of relevance, or appropriateness may, on the other hand, promote much debate within the medical profession since the mere raising of the issue carries an implicit suggestion of inappropriate treatments or resource usage which might be attributable to individual practitioners. Yet, given the extent of medical control over the audit process, managers are unlikely to peer too deeply into this question other than through the Resource Management initiative. Nevertheless, in the USA, clinical relevance is addressed through the medical aspects of distinct Risk Management programmes (see Chapter Three) which, because of actual or potential increases of health related litigation in the UK, will undoubtedly appear on the NHS management agenda in the near future. In contrast, the dimensions of economy, efficiency and effectiveness are at the forefront of the issues currently facing the NHS professions. Yet, while the new contractual processes necessarily constrain financial and operational managers to focus on economy and efficiency, clinicians have ethical reasons for focusing primarily on the effectiveness of their actions even though, at a certain level of interpretation, the individual or collective effect of medical interventions may be limited because of the opportunity costs of uneconomical or inefficient practices.

Nevertheless, the convergence of the Donabedian model with the technical framework of the audit cycle and Maxwell's evaluative criteria illustrates the emergence of a potentially powerful tool for improving the quality of medical care in the NHS. Much will depend however, on doctor participation in the audit process, and on the extent to which the results of medical audit can be transformed into meaningful action. In short, for medical audit to have a significant impact, the crucial challenge facing managers and clinicians is to recognize the interdependence of the various dimensions of quality.
CHAPTER THREE

TOTAL QUALITY MANAGEMENT

In the early 1980s, Total Quality Management (TQM) became the most popular business management philosophy in the industrialized world. Yet, despite its widespread appeal, the precise meaning of TQM remains ambiguous and its successful implementation correspondingly sporadic (Oakland, 1989; Flood, 1993). These issues thus provide a justification for examining the roots, principles, objectives and technical practices associated with TQM, a concept that Koch (1991) argues, is not optional, but must become an integral aspect of modern health care systems.

The TQM concept originated in post-war Japan which, having been reduced to the status of a non-combatant in military terms, turned to economic development to secure its place in the new world order. In the early 1950s, when the West was preoccupied with social reconstruction, the Cold War and other conflicts, the Japanese, conscious of the poor quality of their products, enlisted the help of American pioneers in quality management, notably W. Edwards Deming and Joseph M. Juran. Deming established a basis for the development of Statistical Process Control (SPC), a method applied to processes that are repetitive and where outcomes are quantifiable. A process is said to be under control when variations in measured outcomes are random. On the other hand, when specific causes of deviation emerge, the process is no longer said to be under control.

Influenced by Deming, a number of Japanese students took interest in quality improvement, including Kaoru Ishikawa who developed 'cause and effect' diagrams and Genichi Taguchi who championed the introduction of pre-production quality controls as an aid to minimizing both the organizational and societal costs of poor quality (Flood, *Op. cit.*, pp. 30-32). However, the main contribution made by Deming's early work, and that of his students, was to establish the TQM principle of managing product or service delivery through the systematic use of data as opposed to 'gut feeling' based on past experience of process performance. Nonetheless, quality control procedures are largely designed to prevent process changes that result from adverse events, and as such, they are directed at *sporadic* quality problems rather than underlying or *chronic* issues which require fundamental changes in order to improve process design or methods of execution (Juran and Gryna, 1993, pp. 40-41 and 98-99).
Sporadic quality problems cause unexpected and unplanned changes in process inputs and operations and demand immediate action to restore the process to a state of control; sporadic quality problems are thus tackled by the people who do the work and quality control (QC) programmes are designed to resist unplanned change - (where a process is consistently shown to be under control, then quality is assured). Chronic quality problems on the other hand, refer to underlying and sustained impediments to better process performance and must, therefore, be tackled by an improvement programme which is designed to promote change (Juran and Gryna, *Ibid.*). This is not to say that quality control procedures and quality improvement programmes are incompatible, but rather that they have distinct aims and may employ different methods and techniques. Hence, before discussing other sources of ambiguity within the TQM concept, it may prove fruitful to re-examine the Audit Cycle (Chapter Two, p. 17) within the framework provided above in order to illustrate whether, and in what sense, it may be described as a quality control mechanism, a quality assurance procedure, or a quality improvement programme.

In Figure 4a (below, p. 27), the audit cycle represents a QC mechanism, a description that is crucially dependent on taking *corrective action* in order to restore a process or procedure to what is regarded as acceptable. Conversely, where practice is monitored and is considered acceptable, then no action is required, but both patients and staff gain reassurance, hence the QA label is more appropriate (Figure 4b). Alternatively, in order to be described as a quality improvement programme, a professionally determined characteristic of the audit process (see Chapter Two, p. 16, Table 1), the audit cycle would need to be redesigned to include some of the features identified by Coles and Batstone (see Chapter Two, p. 17, Figure 2). However, as Rakich *et al.* (1992, p. 407) note, in health care organizations, there is a "...potential conflict between CQI [Continuous Quality Improvement] and professional autonomy". On one hand, there is a need for a formal and competent body to determine priorities for improvement, the creation of which might create conflict within professions. On the other hand, many processes that contribute to the outcome of medical intervention are not 'owned' by the medical profession and thus, meaningful improvement would need multidisciplinary inputs into an activity that is 'primarily a matter for the medical profession' (see p. 7). Moreover, as Figure 4c illustrates, both the QC and QA functions are integral to the improvement process which may be described as an extension of the basic audit cycle. In short, if there is general acceptance of the characteristics of audit determined by the medical profession (p. 16, Table 1), then the basic audit cycle is both conceptually and technically inadequate to achieve at least one of its stated objectives.
A brief analysis of the TQM conceptual statement may reveal other ambiguities associated with the meaning of total quality. There is on the one hand, a common assumption that total quality simply means setting and consistently meeting standards throughout an organization in order to assure consumers that a quality product or service is being provided (Ellis and Whittington, 1993). Indeed, accreditation agencies such as the British Standards Institute, the International Standards Organization and, in UK health care, the King's Fund Centre, provide programmes that enable accredited organizations to qualify for the 'quality assured' (QA) attribute. However, as Conti (1993) notes, quality based solely on external accreditation is limited to attaining the 'standard' requirements for entry into a competitive market and does little to distinguish between commodities or their suppliers. Interestingly, this view is shared by the King's Fund Centre which states that:

Organisational audit [accreditation] alone cannot provide an assurance of quality, but must form part of a managed approach to the provision of healthcare....While organisational audit cannot guarantee the quality of healthcare offered, it is a good measure of the hospital's ability to sustain a quality clinical service. This will have considerable significance in the proposed purchaser/provider system of healthcare planned for this country. (King's Fund Centre, October, 1990, p. 25)

Moreover, mere conformance with standards, though necessary, is not sufficient since it implies a static upper limit of attainment which may conceal any potential for improvement. In short, assurances about quality that are achieved solely through retrospective inspection are severely flawed since they allow for the retention of poor quality in production or service delivery processes.

On the other hand, when the 'total quality' statement is suffixed with the term management the TQM concept has tended to be subject to fundamental "...misconceptions about [the nature of] quality, management and organizations." (Flood, Op. cit., pp. xii). Flood argues that the substantial failure of TQM at the implementation stage reflects insufficient attention by the quality gurus to mainstream management and organization theories. Conversely, some quality specialists ascribe to the view that a major cause of failure in quality management stems from a lack of training in the quality disciplines amongst conventional managers. Quality planning, argues Juran (1992, p. 3) "...has been done by amateurs". TQM however, contains two distinct elements with which these apparently competing positions are concerned, that is, there is a need for a conceptual fit with the actual or desired structure and culture, and for a technical design which is consistent with the aims of the organization. In short, compatibility between structure and function is a prerequisite for effective TQM implementation.
Figure 4. Medical Audit within the context of TQM

4a: Audit as QC

4b: Audit as QA

4c: Audit as CQI
Juran's major contribution to the development of a TQM philosophy was to identify continuous quality improvement (CQI) as a primary objective of 'total quality'. The CQI principle has become central to contemporary interpretations of TQM since it represents the primary technique through which chronic quality problems are systematically removed or minimized. However, CQI involves the provision of skills and the delegation of authority to front line employees to enable them to focus upon, define, analyze and, where desirable, change processes that are within their sphere of competence. In healthcare, effective CQI has four key characteristics (Rakich et al., Op. cit., p. 409). First, outputs must meet the expectations of both internal and external consumers. Second, both prospective and retrospective monitoring are essential to prevent poor quality. Third, quality is the concern of all employees. Fourth, quality improvement programmes must focus on processes as well as outcomes. In short, TQM demands that employees are empowered to effect CQI, but this poses profound challenges to mainstream management theories and often provokes a 'rejection crisis' amongst the established hierarchy (Conti, Op. cit., p. 9).

Following his early statistical work, W. Edwards Deming introduced a framework for quality standardization based on quality control studies conducted by W.A. Shewhart at the AT&T Bell Laboratories in the USA (Shewhart, 1931). Shewhart's work was essentially an extension of F.W. Taylor's principles of scientific management (Taylor, 1947) since planning was still considered an administrative function separate from execution. Nonetheless, the PCDA wheel (Figure 5) became the basis for all future cyclical improvement models. However, by the 1980s, Deming had changed his focus from technical issues to human relations concepts such as leadership, motivation, training and morale. He identified five major issues that constrained quality, viz, a lack of consistency, an absence of long-term vision, inadequate review mechanisms, high levels of mobility amongst managers and over-dependence on quantitative measures (Flood, Op. cit.). Deming's prescription takes the form of a fourteen step programme that has been widely adopted as a basis for quality improvement in the USA and that recognizes that TQM contains both technical and conceptual elements.
First, it requires a conceptual shift on the part of senior management in order to facilitate the transformation of organizational structures and values to reflect a genuine quality ethos, including the integration of quality improvement activities as part of the working practices of all employees. This latter point is crucial to understanding the meaning of TQM since it represents the small 'm' management of quality throughout the totality of an organization (Flood, *Op. Cit.*, p. 47). Second, the technical design of the quality system must include mechanisms for quality control, assurance and improvement that are supported by data systems which reveal information about operational performance.

Although these substantive distinctions may help to clarify the meaning of TQM, to be conceptually adequate, the precise detail of any new organizational paradigm must take account of internal social and external environmental circumstances in order to identify current and desired characteristics of the organization. As Flood (*Ibid*, pp. 86-7) further argues, perceptions that consider an organization to be either mechanistic, organic, culturally specific, political, or a combination of all these features, will demand different or variable treatments to effect desired change. Moreover, though purchaser or consumer interests may provide inputs into product or service specifications, because of the non-profit nature of most healthcare organizations, the dynamics of change must come from within the provider organization (Övretveit, 1992). However, to be technically adequate on the other hand, any new quality management paradigm must accommodate or improve upon existing quality functions that are considered necessary in support of the organizations specific aims.

Within the context of healthcare organizations, maintaining and improving the quality of care has always been a central concern of practitioners. In the NHS for example, the medical, nursing and allied professions function in an almost continuous state of flux as they absorb the impact of new technology, the application of medical science and changes in social policy or administrative procedure that are designed to improve care or service delivery. Indeed, healthcare systems are open to constant change, yet require functional continuity. Within this operational paradox, the issue of quality is commonly addressed by conducting problem-oriented exercises which find popular expression in retrospective QA monitoring systems or periodic analyses of patient complaints. However, as argued above, conformance to QA standards is a static process which, by definition, cannot effect improvement and does little, therefore, to assure either patients, purchasers or staff that a quality service is being provided.
The development of a total approach to health care quality may, therefore, have much to offer NHS provider units. In the USA, the Joint Commission are currently promoting the transition from QA to CQI in healthcare quality and have re-defined the term QA to mean Quality Assessment and Improvement (JCAHO, 1991). The Commission continue however, to place significant importance on conformance with professional and technical standards and thus, existing quality control and quality assurance monitoring mechanisms are retained (JCAHO, 1993). A similar situation exists in Canada where QC, QA and CQI co-exist in what Wilson (1992) describes as a complimentary model that reflects the special need of healthcare organizations to retain a measure of technical control over some functions while empowering employees to improve the way in which tasks are executed. In both Canada and the USA there is nevertheless, much emphasis on the changing the quality focus from individual performance to organizational-wide quality issues in an attempt to "...give rise to a new paradigm for defining expected organizational behaviors in the assessment and improvement of patient care." (JCAHO, 1993, p. iii; Wilson, Op. cit., p. 358) Consequently, multidisciplinary teamwork and other TQM techniques represent the principle mechanisms through which change is to be effected. In the UK there is also an awareness that, since the delivery of care is inter-professional, quality assessment, evaluation and improvement must also cut across established boundaries and, ipso facto, depends as much on the people within the organization as it does on technical systems (Krebs, 1992; Townsend, 1992; Ellis and Whittington, 1993). In short, an acceptance of TQM does not necessarily imply a rejection of older methods, for though they may be inadequate, they may not be entirely obsolete - a distinction that may further serve to clarify some of the ambiguity within the total quality concept. However, TQM does require cultural change, the nature and scale of which may be illustrated by examining a key component of CQI programmes.

Process management is a central feature of CQI and may be defined, in the context of healthcare, as a method for enhancing patient and purchaser satisfaction on a continual basis by systematically focusing on, defining, analyzing and improving processes. A distinguishing characteristic of a significant process is that its outputs represent the sum of activities conducted by one or more permanent teams who are concerned with the organization of human and material resources which, through working practices, are combined to achieve a specific outcome (Juran and Gryna, Op. cit., p. 541). Hence, a process, since it is concerned with more than the sum of its constituent parts, is a concept based on general systems theory Bertalanffy (1968).
In order to avoid further ambiguity, and because most hospital provider units are organized along functional lines, Figure 6 (overleaf) illustrates the nature of differences between process and functional management. The primary concern of functional management is to ensure that operational activities are directed towards the achievement of departmental and corporate objectives and thus, responsibility, authority and control are key organizing concepts in functional management. However, even if the technical execution of activities is consistent with established departmental policies or standards, it does not follow that optimal process performance is achieved in terms of either economy, efficiency or effectiveness. On the other hand, process management is predominantly consumer oriented and is designed to focus on the sum of cross-functional activities, both within and between departments (only inter-departmental process are illustrated in Figure 6), that combine to meet patient needs.

Processes can, therefore, be regarded as major determinants of patient satisfaction, and coordination is a key organizing concept in process management. Thus, in order to assure or increase patient satisfaction, there is a need to establish mechanisms and apply techniques that will facilitate process improvement on a continual basis.

Nevertheless, macro-processes, such as those illustrated overleaf, are influenced by an infinite number of other meso and micro-level processes that cross-cut the traditional task-based hierarchies found within departments and thus, impact on service delivery both to patients and internal clients. Indeed, almost all hospital departments provide and receive services to and from one another. Medical staff for example, are internal clients of pathology and radiology; pharmacy provides services for patients, doctors and nurses in wards or special care areas; inter-professional referral and consultation is common between physicians, surgeons and other medical staff; and administrative departments, such as estates and human resources, are service providers to the entire organization. Moreover, client dissatisfaction occurs when service delivery fails to match expectations, but the latter may be influenced by inaccurate or incorrect assumptions about how, and why, activities are conducted in a certain way. Process management is therefore, a means of reducing uncertainty and enhancing inter-professional communication and is extremely applicable to healthcare provider organizations. But its success depends crucially on establishing process 'ownership' and delegating the authority necessary to effect improvement. In short, process improvement means employee empowerment.
FUNCTIONAL & PROCESS MANAGEMENT

Adapted From: Juran and Gryna, 1993, p. 541
Although employee empowerment in pursuit of process improvement may require cultural transformation, it need not involve radical change to existing organizational structures. Figure 7 (overleaf) illustrates how a process management steering team, led by an executive director, can be formed from senior members of established functional departments. This team can facilitate the improvement programme by focusing on chronic quality problems identified in macro-processes (Figure 6, above), thereby allowing for inputs from internal clients, patients and purchasers. Moreover, quality issues thus identified, are delegated for resolution by an operational management or work team which has major responsibility for the process in question - in Figure 7, teams are illustrated in relation to aspects of a pathology service. In addition, team leaders are members of the next senior team in the functional management hierarchy and thus, this form of organization allows for the integration of leadership, direction, control, and communication within the process management system. These features are important since, in multi-disciplinary groups especially, the team may not have direct line management responsibility for all process activities. However, a central feature of the system is that it allows for the delegation of responsibility and authority to those who do own specific parts of a process and whose expertise is, therefore, "...critical to understanding and documenting the process." (Rakich, et. al., Op. cit., p. 420) Where, for example, a process cuts across functional boundaries at operational level, multi-disciplinary groups, similar in composition to the senior steering team, can be established to lead and direct the improvement programme at lower levels in the organization. Hence, process management allows for a measure of integration between planning and execution and is thus, an improvement on outdated principles of scientific management. It is important to note however, that although the process management programme is permanent, improvement teams are project oriented and, apart from the senior management steering team, are temporary and have clearly defined objectives and time scales.

Nevertheless, in order to perform successfully, team activities must be conducted according to structured procedures that should be entrenched within an organization's central value system, and team members, potentially all members of an organization, must be trained to use a variety of quality improvement tools. Such tools have been developed in the industrial sector, but attempts are being made to refine their application within healthcare. These tools are designed to support the four technical stages of the process management system, viz, focus, definition, analysis and improvement, terms that are consistent with the Shewhart/Deming PCDA wheel (see p. 28, above).
PROCESS MANAGEMENT ORGANIZATION based upon FUNCTIONAL MANAGEMENT STRUCTURES

Figure 7

EXECUTIVE BOARD

EXECUTIVE DIRECTOR

PATIENT SERVICES MANAGER
HOTEL SERVICES MANAGER
CLINICAL SERVICES MANAGER
MEDICAL SERVICES MANAGER(S)
HUMAN RESOURCE MANAGER

COMMUNICATION FLOW
LEADERSHIP DIRECTION (CONTROL)

PROCESS MANAGEMENT SENIOR MANAGEMENT STEERING TEAM

PROCESS MANAGEMENT OPERATIONAL MANAGEMENT TEAM

PROCESS MANAGEMENT OPERATIONAL WORK TEAM

MLSO MICROBIOLOGY
MLSO HAEMATOLOGY
MLSO BIOCHEMISTRY
MLSO BACTERIOLOGY

TECHNICIAN BLOOD BANK
PHLEBOTOMIST
MLO BLOOD BANK
RECEPTIONIST (SPECIMEN RECEPTION)

COMMUNICATION FLOW
ACTION IMPROVEMENT (RESPONSIBILITY)

Abbreviations:
MLSO: Medical Laboratory Scientific Officer
MLO: Medical Laboratory Officer
The first stage of process management, focus or 'plan' after Shewhart/Deming, involves the construction of a mission statement based on the direction provided by a senior management or other steering team and may include feedback from patients or other client groups. In addition, all input issues are clarified, resource needs identified and time scales established for completion of the improvement project. Crucially however, process ownership must be determined and, where appropriate, issues may be deployed to other improvement teams (see Figure 8, overleaf). Stage two concerns process definition (or 'do' after Shewhart/Deming) and is facilitated by the use of flowcharts (see Figure 9, p. 37, below). Process flowcharts ensure that the sum of activities that contribute to the current design of a process are identified in order to allow for the development of the standards and measurement criteria required for Stage three, (analysis or 'check' after Shewhart/Deming). As Figure 8 illustrates, stage three is consistent with the medical audit cycle and may therefore include the QC function to restore a process to a state of control or provide reassurance (QA). Indeed, during the conduct of the process management definition exercise illustrated at Figure 9, team members identified quality controls that were inherent within the process, though no-one had thought to measure the scale or frequency of deviation from QC standards. Finally, the analysis and evaluation of data provides an indication about process performance, a requisite condition for identifying and prioritizing opportunities for improvement that, in turn, provide a basis for action in Stage four, (improve or 'act' after Shewhart/Deming). In sum, stages one to three in Figure 8 represent the central features of a quality management programme. However, when stage four is added, and the entire system is implemented throughout an organization as an integral and continuous aspect of the working practices of all employees, then the management of quality can be said to be total. Hence, TQM and the centrality of CQI within the concept.

Nevertheless, contemporary healthcare organizations contain considerable structural constraints to the successful implementation of TQM. On the one hand, healthcare is delivered through what McLaughlin and Kaluzny (1990) call the 'clinical professional model' where treatment and care are lead by relatively autonomous clinical professions which, traditionally, assign responsibility at the level of the individual. TQM in healthcare on the other hand, though it acknowledges clinical participation, presupposes managerial leadership, demands improvement rather than conformance, emphasizes process rather than individual performance and, in short, "...represents a paradigm shift in health care management [that] presents a series of potential conflict areas in the way health care organizations are organized." (McLaughlin and Kaluzny, Ibid, p. 7).
FOUR STAGE PROCESS MANAGEMENT SYSTEM

Figure 8.

Stage 1: FOCUS

Stage 2: DEFINE
(see Figure 9 overleaf)

Stage 3: ANALYSE

Stage 4: IMPROVE


Stage 1: FOCUS

Stage 2: DEFINE
(see Figure 9 overleaf)

Stage 3: ANALYSE

Stage 4: IMPROVE

Figure 9
MICROBIOLOGY (BACTERIOLOGY)
SWAB FOR CULTURE & SENSITIVITY
PROCESS DEFINITION FLOWCHART

PROCESS DEFINITION - EXAMPLE FLOWCHART

TEST ORDERED BY DOCTOR
Internal Client

PATHOLOGY RECEPTION
Microbiology?

QUALITY CONTROL
1. VERIFY ACCURACY OF INFORMATION ON REQUEST & SPECIMEN
2. REJECT AN IMPROPER SPECIMEN (EG, CONTAMINATED CONTAINER)

BACTERIOLOGY RECEPTION

QUALITY CONTROL
1. ASSIGN CORRECT MEDIA
2. INCUBATE

GRAM STAIN
SET-UP BENCH

QUALITY CONTROL
1. GRAM POSITIVE - NEGATIVE STAPH AUREUS
2. GRAM POSITIVE - NEGATIVE E. COLE

PLATE OUT SPECIMEN
SET-UP BENCH

QUALITY CONTROL
MEDIA ARE CHALLENGED WITH KNOWN STANDARD ORGANISMS. THE MEDIA MUST DEMONSTRATE ACCEPTABLE PERFORMANCE CRITERIA BEFORE BEING RELEASED FOR USE

INTERPRET & REPORT PRELIMINARY

QUALITY CONTROL
BIOCHEMICAL VERIFICATION & IDENTIFICATION

INTERPRET & REPORT PRELIMINARY

INTERPRET RELEVANCE OF FINDINGS
PRODUCE FINAL REPORT

Process Output

Note: Produced by the author as an exploratory exercise in clinical process definition in collaboration with colleagues in the Pathology Department, Armed Forces Hospital, Wadi Al-Dawasir, Saudi Arabia.
In contrast, other aspects of healthcare quality demand the retention of the traditional narrow view about performance. Quality Control, including its implicit QA feature, is essentially a mechanical function and is shown in Figures 4, 8 and 9 to be a necessary aspect of a healthcare quality programme. Such programmes may however, also include Risk Management. In brief, the risk management concept evolved in USA healthcare during the 1970s as a more systematic alternative to general safety programmes. It is concerned with risk prevention and to reduce the effect of untoward incidents on patients, visitors or staff, and to minimize financial loss to the organization. However, by the early 1990s the concept was expanded to include "...operational linkages between the risk management functions related to the clinical aspects of patient care and safety and [the] quality assessment and improvement function." (JCAHO, 1992, p. 144) Clinical risk management involves the designation of 'risk factors' that are associated either with a patient's condition or with treatment and care and it includes the development of protocols for clinical management following the identification of a risk factor. Consequently, risk management, QC and CQI tend to overlap with the former two providing inputs into the latter.

In sum, though the organization of CQI through process management is technically compatible with traditional hierarchical structures (see Figure 7, p. 32, above), the participative and collaborative nature of the improvement process is not consistent with the mechanistic social system inherent in formal bureaucracies. Moreover, although general managers may attempt to alter the central value system of a healthcare provider organization, they have little direct influence on the macro-level bases of clinical professional autonomy. However, for the medical profession, autonomy need not mean absolute control:

"...what is essential [for medical staff] is control over the determination and evaluation of the technical knowledge used in the work; important but secondary is control of the social and economic terms of the work....a [medical] professional may [thus] remain a professional when he is socially subordinate to someone who does not belong to his profession so long as he is not technically subordinate." (Freidson, 1988, pp. 185-6)

It follows therefore, that, where the technical evaluation of distinctly medical issues is conducted by medical staff, through medical audit for example, the success of TQM, being concerned with the totality of service delivery, will depend largely on the extent to which managers assimilate quality improvement concepts and adapt required elements of the formal organization to a more organic design, while retaining mechanistic features where necessary, in respect of quality control procedures for example.
This is not to say however, that the clinical professions should limit their quality related activities to audit. In spite of the new corporate identity that is emerging in many provider units, the medical profession in particular retain a large measure of traditional authority and may therefore, be regarded as key change agents. It is crucial however, that to avoid the TQM failure experienced by many business corporations (Flood, Op. cit.) and to describe health care quality management as 'total', executive directors and senior managers must find space at, or near, the top of their agenda, on a continual basis, for ensuring that quality issues permeate all organizational systems, relate to all functions and include all employees. This is so because 'quality', however defined, refers not only to the inherent utility or goodness of a product or service, but also to the extent to which it satisfies the primary criteria of a quality conscious organization, viz, meeting the expectations and needs of both internal and external customers. Finally, the word 'management' means that quality improvement is no accident, but is a deliberate, planned, systematic, measurable and continuous process.
CHAPTER FOUR

THE NEW CONTEXT
OF THE NATIONAL HEALTH SERVICE

The creation of an internal market in UK health care is a central feature of recent NHS reforms and is intended to promote 'managed competition' in pursuit of greater economy, efficiency and effectiveness in the delivery of care and services (Ham, 1991). Yet, government have retained the principles of providing universal access, free at the point of delivery and financed through general taxation. Thus, the impact of internal market arrangements is likely to be most visible at the meso level of the health care system where the roles of service provision and purchasing have been formally separated.

Moreover, as a result of the purchaser-provider split, the external environment and the internal organisation of health care provider units have altered considerably and have interacted to create a radically new context within which care and services are delivered. This new context can be considered essentially social in character because it involves the redefinition of existing relationships or the development of new relations within and between the constituent parts of the NHS. It follows therefore, that, since the objectives of the internal market are primarily technical in nature, (economy, effectiveness and efficiency), there are reasonable grounds for considering the impact of changes in the health care social system in terms of planned changes to the technical system that are inherent within the Medical Audit and Total Quality Management initiatives. Furthermore, many recent changes in the NHS can be considered as a practical manifestation of ideological approaches to management and economic issues in UK health care (Young, 1991; Mark and Scott, 1992; Maynard, 1993), issues that are rooted in structural flaws within the NHS that can only be explained by understanding something of its origin and development (Harrison, et. al., 1990, p. 31).

Given the universality of its founding principles, the creation of the National Health Service in 1948 is regarded as a watershed in British social policy. In practice however, gross inequalities remained in terms of the distribution of resources, accessibility and the health status of the population. While some studies have shown that health status is not merely (or wholly) determined by the availability of health care (Whitehead, 1987; Townsend and Davidson, 1988), others have pointed to fundamental deficiencies in the design of the NHS concept.
Aneurin Bevan's NHS blueprint involved the nationalisation of existing services, a process that included the transfer of extant weaknesses of resource allocation to the new health care system (Mays, 1991). Moreover, despite central control over health service funding and a measure of political consensus about objectives, the administration and organization of the NHS were significantly influenced by a powerful medical lobby which was largely successful in protecting professional interests. Conflict also existed between political parties about how objectives were to be achieved and rather than being a radical innovation, the nationalised health service represented a politically expedient compromise between the authority of medicine and principles of public administration (Klein, 1989).

Nevertheless, the NHS was established by a government faced with the task of post-war reconstruction, a task that was more immediate than were issues about the internal functioning of specific institutions (Richman, 1987). However, by the early 1950s the efficient delivery of health care had become an issue of major political concern and was formally linked to the management of the service. Costs had rapidly exceeded official estimates and although the first major inquiry into the NHS (MoH, 1956) found no evidence of inefficiency, its Chairman reported that there was no "...sufficient consciousness of responsibility for capital assets...comparable with that felt in a business concern" (quoted in Graham, 1993, p. 9). Official estimates were based on the mistaken assumption that universal access to health care would result in reductions in levels of morbidity, and thus, in costs. But the estimates did not allow for the impact of demographic changes, inflation or new technology partly because competing claims for public funds posed a dilemma for the Attlee government who were faced with the reconciliation of the irreconcilable. Responsibility within the hospitals was difficult to identify and define. These secondary sector health care providers, though delivering services locally, had administrative structures that were appointed by central government (Richman, Ibid).

It is clear therefore, that from the outset, the NHS was beset with fundamental problems concerning resources, organization and management that have "...bequeathed a long agenda for action to...NHS policy-makers....[while] the price paid for creating a consensus....was to introduce a bias towards inertia." (Klein, Op. cit., p. 58) During the past twenty years government have addressed these structural flaws by tackling the issues of organization and administration (DHSS, 1972a, 1972b), by addressing the problem of resources (DHSS, 1976), and more recently through an emphasis on management and accountability (DHSS, 1984, DoH, 1989a).
The NHS is one of the largest public organisations in the United Kingdom; it employs about 1.25 million people and salaries amount to around 75 per cent of its budget (Connah and Pearson, 1991). In addition, occupational stratification is an inherent feature of the NHS culture; Körner estimates for 1984 suggest that there were around 5,000 different NHS occupational combinations by grade or type of work (in Connah and Pearson, Ibid.). It follows that, with only a quarter of NHS costs devoted to material resources, the development of a modern health service presupposes an effective social system in order to underpin developments in the technical system. Moreover, many of the reforms outlined in Working for Patients (DoH, 1989a) are intended to increase service responsiveness to patients needs. However, as Graham (Op. cit., p. 12) argues, though the NHS is moving towards the "...right territory - health status not health services" it may be doing so at an inappropriate point in time given the contemporary economic and political climate, and that managerial skills and organizational structures may still be inadequate. Thus, before discussing contextual changes at the meso-level of the health care delivery system, it is necessary to illustrate the significance of macro-level changes in the formal structure of the NHS.

The proposals contained in Working for Patients were brought into force by the NHS and Community Care Act of 1990. This legislation also enacted proposals in two other White Papers which focused on Family Practitioner Committees (Promoting Better Health, DHSS, 1987) and changes in arrangements for handicapped and elderly people (Caring for People, DHSS, 1989). Although the success of these changes depended on the introduction of general management, the latter can be regarded as a pragmatic response to the debate over government expenditure (Young, 1991; Mark and Scott, Op. cit.; Maynard, Op. cit.). Nonetheless, recent macro-level changes to the NHS structure (see Figure 10, overleaf) have created a turbulent USA type context in which managers of provider units face a combination of uncertainty, instability and meso-level volatility as well as increased competition from other provider units and the pressures associated with the general shift away from hospital to community-based care (Berger and Kurtz, 1991; Goldsmith, 1985). Although the macro-level reform of the NHS appears to be purely structural it is clear that, given the projected numerical dominance of Trusts which, by 1 April 1994, will spend around 90 per cent of hospital and community service revenue (Health Services Year Book, 1994), the relationship between NHS health care provider units and their primary customers (patients) will be mediated solely by contracts through the third party purchasing organizations (see Figure 10, overleaf).
**NHS STRUCTURE (July 1994)**

Figure 10.

- **Secretary of State**
- **Department of Health**
- **NHS Management Executive**

- **Postgraduate Teaching Hospitals & Special Health Authorities**
- **Regional Health Authorities**
- **NHS Trusts (Provider Units)**

- **Family Health Services Authorities**
- **Health Authorities (Purchasing Authorities) (Non-Trust Purchasers & Providers)**

- **General Practice Budget Holders (Purchasers)**
- **General Practice Non-Budget Holders (Purchasers)**
- **Directly Managed Units (DMUs) (Provider Units)**

Adapted From: *The Health Services Year Book*, p. xxii, IHMS, 1994
In terms of service standards and quality, the contracting process presents managers of provider units with a major contradiction. On the one hand, accessibility, equity and social acceptability constitute three dimensions of quality against which a provider unit may be assessed (see Chapter Two, p. 22, above), but which may, on the other hand, be impossible to realise within the new contractual relationship. The various purchasing organizations are, for example, likely to have different priorities for the purchase of services and thus, levels of accessibility for their patients may also be different. Hence, though third party purchasing organizations may be satisfied with the contractual elements of service delivery, the primary customer may not consider service provision to be either equitable or socially acceptable. Moreover, though the primary care giver can justify such anomalies on bureaucratic grounds, that is, that it is not his or her responsibility, they cannot justify this position on ethical grounds (BMA, 1993) since the opportunity cost of variations in accessibility that are created through the contractual process may have an adverse effect on the health status of patients whose treatment is delayed and, as Lembcke (1956) argued, standards should be uniform regardless of the status of the doctor or the patient.

In short, the contractual relationship between purchaser and provider may generate conflict at the meso-level between managers and clinicians on the basis of quality precisely at a point in time when management are required to display a commitment to, and provide leadership and direction in pursuit of, continuous quality improvement. Indeed, while there are strong arguments for change in the way health care is organized and delivered, it is possible that some of the issues the reforms are designed to address merely reappear in a different guise. That is, they may be transformed from organizational, management and resource issues into contractual process related problems.

Nevertheless, the separation of purchasers and providers, together with the patient centred focus of the reforms, have also resulted in major organizational change at the meso-level of the health service. Individual patients, often regarded as mere beneficiaries of the service in the past, are now considered as customers by provider organizations who thus have an explicit obligation to ensure that quality, in all its dimensions, is an inherent feature of service delivery (Ellis, 1994). Consequently, new Clinical Directorate structures are now commonplace in provider units and are designed to effect greater responsibility and accountability for service quality and standards (see Figure 11, below). These macro and meso-level changes have however, further practical and theoretical implications for the management and delivery of health care.
On the one hand, macro-level changes have resulted in a complex and contradictory accountability matrix for provider organizations which, at the meso-level, can be considered, from a sociological perspective, to represent a major structural constraint for health service management. A hospital is, for example, accountable to the patient as the primary customer, to the state as the major budget-holder, to purchasing organizations as third party financiers, to the local community as the collective beneficiaries of the service and to employees as primary care givers.

On the other hand, the economic realities of the new arrangements may have limited the options for meso-level re-organization because of the predominance of financial control as provider related management criterion of success within the contractual process: financial issues in health care are resource issues and "...RM [Resource Management] is about organization." (Buxton, Packwood and Keen, 1989, p. 46) Indeed, the primary cause of the failure of 'management budgeting', the predecessor to RM, was the absence of a formal organizational structure that ensured managerial involvement by clinical staff in order to facilitate "...real output measurement against clearly stated management objectives" (my emphasis, from the Griffiths Enquiry, quoted in Akehurst and Drummond, 1989, p. 72). Consequently, the wide-spread adoption of Clinical Directorate structures based on traditional medical specialties, though effecting a solution for financial and resource accountability, may represent a practical barrier to meaningful quality improvement since it merely reinforces the functional, 'management by objectives' model of health care (see Figure 11) and does little to facilitate continuous improvement in the co-ordination of services or processes.

Hence, the outcome of meso-level re-organization might be to isolate medical audit activities while exacerbating the very problems that the Total Quality Management initiative is designed to address since, as Figure 11 illustrates, responsibility for the co-ordination of the work of what often amounts to several thousand employees is invested in a relatively small number of people who are organizationally grouped at a point in the hierarchy several tiers above the level of direct patient care or service delivery. In short, the meso-level organization of the health care system may prove to be inconsistent with its overall strategic direction, but is certainly inconsistent with the stated intention of government policy which states that the delivery of health care will be improved by establishing "...an organization in which those who are actually providing the services are also responsible for day-to-day decisions about operational matters" (Working for Patients, DoH, 1989a, quoted in Wall, 1993, p. 139).
Although intra-functional process co-ordination is facilitated within a clinical directorate or other hierarchical structure (see, Figure 6, p.32, above), and while a measure of cross functional process co-ordination is possible at middle management level (Figure 7, p. 34, above), there is no formal mechanism for co-ordinating inter-functional processes at the point of service delivery. This is not however, to say that provider units are totally devoid of inter-functional co-ordinating mechanisms. Control of infection, drug utilization, blood product and safety reviews for example, are co-ordinated through a hospital's committee structure. Nevertheless, reporting arrangements for such committees usually reflect, indeed may account for the reification of, the authority and responsibility relationships depicted in the formal organization, relationships that have been described as the representation of archaic hospital organizational structures that are primarily responsible for much of the inefficiency within health care provider units (Lathrop, 1993). This argument is illustrated at Figure 12 which shows, on the one hand, the direction and scope of some functional-based inputs into an admission process and, on the other, the task-oriented activities that contribute to overall process performance.

In short, while inputs tend to be controlled and managed independently, co-ordination of process throughputs is largely left to benefits or vices of the informal organization. Consequently, there is a lack of organizational awareness of process performance or capacity while patients, having no insights into process performance, can only manifest their satisfaction, or otherwise, in terms of their experience of what are usually visible process outputs such as waiting times, environment or staff attitudes. These latter issues thus become the focal point of quality improvement activities which tend, therefore, to address the manifestation of the problem rather than tackling its cause - an anomaly that may result, not from the lack of method or measurement skills, but from the absence of an organizational structure that is consistent with the philosophy of putting the patient first. Indeed, in a survey of fifteen health authorities, Carr-Hill and Dalley (1993) found that:

...providers have been preoccupied with the financial implications of the reforms, rather than with improving their quality-assurance systems...[there was] little co-ordination of [quality improvement] activities and little thoroughgoing strategic planning for quality....Accurate description and monitoring of what goes on in health care is lacking. Without this, quality assurance is nonsense. The tendency to introduce measurement systems based on no conceptual framework and only flimsy evidence only worsens the problem of developing a robust quality-assurance strategy.

Significantly, a recent survey has shown that patient satisfaction with certain aspects of hospital based services actually declined between 1989 and 1993 (National Consumer Council, 1993).
PROCESS and FUNCTIONAL MANAGEMENT REVISITED

Figure 12

It follows that NHS provider re-organization has largely been shaped by the external context and priorities of macro-level changes in the distribution, if not the source, of funding for UK health care. The resultant effect on the meso-level formal organization, rather than decentralization and devolution, has been re-centralization through a process of "...departmentalization by function", and delegation to a new breed of clinical and non-clinical general managers who may, nevertheless, become functional specialists with limited vision and who may therefore, further constrain effective co-ordination (La Monica, 1990, p. 479). In brief, the meso-level of the NHS has effectively retained a form of mechanistic organization that, though suitable in times of stability, is distinctly ineffective during a period of major change (Gibson, et. al., 1991; Burns and Stalker, Op. cit.). Against this background, it is relevant to consider the significance of the informal organization or, after Litterer (1965), of voluntary co-ordination of quality issues. Noting the complexities of modern health care provider units, Georgopoulos and Mann (1962, pp. 57-58) describe the importance of the informal organization by stating that the "...hospital is dependent...upon the motivations and voluntary, informal adjustments of its members for the attainment and maintenance of good co-ordination." Moreover, the total interdependence of the formal and informal organization is recognized by Blau and Scott (1962, p. 6) who argue that:

It is impossible to understand the nature of the formal organization without investigating the networks of informal relations and the unofficial norms as well as the formal hierarchy of authority and the official body of rules, since the formally instituted and the informally emerging patterns are inextricably intertwined.

Hence, the internal environmental context of health care provider units can be said to comprise both the formal and informal organizations, but while the former governs the activities of individuals, the latter is characterized by their specific behaviours, often governed by informal group values, in response to the inadequacies of formal structures. Thus, if, as argued above, the formal structure is indeed inadequate for co-ordinating continuous quality improvement, then an understanding of the informal organization of the NHS is central to any assessment of quality initiatives such as Medical Audit and Total Quality Management. Essentially, this means that the impact of these new policies can only be fully explained by examining the interaction of human agency with the new meso-level environmental context of the NHS. Nevertheless, the informal organization also has form; a structure, often complex and based on status, but which includes a leadership role (Rakich, et. al., Op. cit., pp. 226-7), and in the NHS, is strongly influenced by professional ethics.
Yet, in the UK, medical hegemony within provider units has been considerably challenged in two major respects. First, by general management, with the result that medical staff now underestimate "...the power of their leadership role, and the extent to which other staff feel leaderless when doctors fail to give direction" (Potter, et al., 1994). Second, as a result of the transition from an illness orientated, institutionalized system of acute inpatient care, to a preventative service based on sub-acute, outpatient care located within the community. Consequently, the values associated with the perceived stability of the former system tend to be undermined, and traditional authority, both formal and informal, within provider organizations may be brought into question (Koch and Fairly, 1993).

It follows, that when professional ethics and, ipso facto, associated group values, withstand the challenges posed by structural and meso-level organizational change, then the orientation and dynamics of the informal organization may become alienated from, and prove dysfunctional for, the strategic direction of the new provider units. This not to say that the clinical professions and health service managers are necessarily pursuing different goals since they share the common purpose of providing the best possible care for their patients. But, when this purpose is translated into a local agenda for action, conflict can occur (Kennerley, 1992).

In short, if the agenda for action at local level is considered to be inconsistent with professional ethics or if the national policy agenda is perceived to be incompatible with the retention of the fundamental principles of health care delivery in the UK, then there is considerable potential for meso-level conflict over policy implementation. Moreover, though the NHS has been radically re-organized, the medical profession, the traditional bastion of authority within health care organizations, has not. Thus, 'state sanctioned self-regulation' remains a definitive characteristic of the profession, but may be inconsistent with the concepts of 'managed care' and 'internal market competition'.

Similarly, in spite of some recent debate "...non-clinical managers have no formally stated ethical code or guidelines. How they exercise their responsibilities for the collective provision of care is far from clear" (Warner and Evans, 1993, p. 20). Hence, there is further potential for policy implementation conflict based upon the persistence, on the one hand, of established ethics in medicine and, on the other, the absence of a similar type of decision making base for managers.
In sum, the combined effects of macro-level change, the re-organization of provider units and the redefinition of their role, together with the absence of a common ethical basis for meso-level decision making, may undermine the impact of both new organizational structures and the traditional role of informal leaders. The prospect for continuous improvement in the quality of UK health care might therefore, be correspondingly weakened because, at the provider level, the concept of Total Quality Management is based on the premise of integrated collaboration between all members of the organization. The medical audit initiative is, on the other hand, by definition, the preserve of the medical profession and may thus become an isolated activity that contributes little, relative to its resource allocation, to the overall quality mission of a hospital provider unit.
CHAPTER FIVE

METHODOLOGY

Quality has become a central issue in both policy and practice in UK health care and is inextricably linked to organizational and technical developments within the NHS. These are aimed at improving accountability, efficiency and effectiveness, and include the re-organization of management structures in hospital provider units, the creation of a formal contractual process for the purchase and provision of health care, the development of comprehensive management information systems (MIS), and the application of quality management methods and techniques. However, as Hunter (1990, pp. 213-254) notes, many of these changes are based on theories derived from industrial management experience and thus fail to:

...appreciate sufficiently the NHS's power structure, the capacity of groups to bargain and influence (notably sections of the medical profession), and the development of policy at the front-line level rather than solely at higher levels.

Here, the conceptual adequacy of recent NHS reforms is questioned in relation to the potential for the health care professions to significantly alter intended policy outcomes. Moreover, though the aims of the reforms are largely technical and involve the development of new methods for assessing and improving performance, the most significant challenge is to establish new social processes through which these aims can be achieved (Hunter, Ibid.; Maxwell and Evans, 1984). It follows that, for health service policy makers and planners, an understanding of internal organizational dynamics is essential and, for sociology, there is a largely unfulfilled requirement for research that contributes towards this understanding (Hunter, Op. cit.; Cox, 1991; Jefferys, 1991). Nevertheless, since this research thesis concerns issues of quality in health care there is an additional need for a micro-level understanding of quality improvement methods and techniques. Hence, the overall research strategy can be said to combine a meso-level focus on the social system within hospital provider units with a micro-level consideration of the quality management technical system. The methodological implications of this strategy are twofold. First, there is a need to gain a comprehensive knowledge of quality methods, techniques and issues in health care. Second, in order to assess the conceptual adequacy of quality related policy initiatives it is necessary to place them in the context of other changes and to acquire evidence about changing social relationships and about how such change is achieved.
In these latter respects, although some background information was derived from a review of the literature, an ethnographic approach was considered most appropriate for gaining first-hand knowledge about quality issues and for the identification of the 'what' and the 'how' of social change in hospital provider units. Yet, it is important at the outset to note potential sources of bias and, in this respect, the choice of method was also influenced by the author's occupational immersion within the health care system in general, and with close vocational proximity to health care quality issues in particular. In addition, after Pollitt et al. (1990), the ethnographic approach is defined here as the tradition of obtaining data through observation and interaction with those who are centrally involved with the object of the study. However, given that the researcher was effectively an observing participant, required to actively intervene in, and observe the resulting impact on, some of the processes under investigation, then elements of the thesis may be considered to warrant the label action research (Gummesson, 1991; Brymen, 1989).

Nonetheless, in spite of its long history as a constructive social science research approach, ethnography continues to attract criticism on the grounds that it lacks the rigour and objectivity of scientific analysis and that its findings are thus of questionable validity (Hammersley, 1990; Pollitt et al., Op. cit.; Hammersley and Atkinson, 1983). Such criticism is part of a wider debate between exponents of positivist and qualitative methods, but may also reflect a measure of acceptance, by some scholars, of the virtues of a neo-classical economic variant of the positivist approach and of the inherent bias, in public institutions, against qualitative research into policy issues that are considered to be politically sensitive (Hunter, Op. cit.; Pollitt et al., Op. cit.). Jefferys for example, (Op. cit., pp. 229-230), argues that:

...it is likely that sociologists will only be able to make a contribution [to health policy research] if they ally themselves with epidemiologists, statisticians, health economists, geographers, social psychologists and business-study analysts...a sociological perspective may only be feasible in institutional settings dominated by health service managers, medical practitioners or proponents of other disciplines...[and] sociologists should accept it and use their energies in trying to ensure that their own contribution makes a significant impact on the research undertaken, even if it cannot permeate it to any great extent.

This argument is based on the assumption that the government agenda for health research will be limited to projects that are amenable to the application of quantitative methods, but the author does acknowledge a broader role for 'classical sociology' with regard to the determinants of social processes and the relationship between the "...organs of state authority" (Ibid., p. 231) and health care providers - recognition, perhaps, that such issues are not amenable to quantitative measurement.
In more general terms, a positivist approach to health care policy issues is limited in three major respects, viz, philosophical, methodological and practical. Although positivism reached its zenith in the first quarter of the twentieth century, its philosophical roots can be traced to René Descartes, (1596–1650), who argued that the world was essentially mechanistic and, in his *Discourse on Method* (1637) and *Meditations* (1641), developed philosophical theories that provided a mathematical basis for the extension of all areas of knowledge. The impact on medicine for example, was to establish a mind-body dualism in which the corporeal or material part of the individual was considered the appropriate locus for the investigation of disease. The mind, on the other hand, was considered incorporeal or immaterial to the diagnostic process and the body, as Hart (1985, p. 14) argues, was "...handed over to [a] new positivist science." Subsequently, the scientific method permeated and has come to underpin a discipline that emerged from a plurality of non-scientific healing systems based on combinations of mythology, magic, chemistry and both organic and mechanistic theories of anatomy and physiology - (for a more complete discussion, see Stacey, 1988, Ch 3., especially). The positivist paradigm gives epistemological priority to directly observable phenomena that can be analysed to provide evidence of relationships between variables and thus provides a high degree of statistical probability that such research based findings constitute universally acceptable laws (Hammersley and Atkinson, *Op. cit.*). However, such methods cannot provide insights into the variety of meanings applied to policy issues by social actors within a health care organization since different groups may apply interpretations that reflect professional interests rather than policy intentions. Moreover, it is rarely possible, in practical terms, to subject policy related issues to the experimental designs that are characteristic of both classical positivist and neo-classical economic research.

However, it is also difficult to establish the validity of ethnographic studies. On one hand, establishing confidence in the extent to which specific data collection techniques can be attributed with producing particular results is a central ethnographic problem, even though the external validity of the research findings may, on the other hand, prove generally applicable (Pollitt *et al.*, *Op. cit.*). Part of this difficulty involves the interpretation data, but the sheer scale of potentially useful information and the process of selection are also salient factors. Although the focus of this research limits consideration to two new policy initiatives, it does so at a time when the health care environment is experiencing other unprecedented changes, and it is therefore possible that the behaviour of organizational members will reflect their perception of the sum rather than specific aspects of these changes.
Consequently, the internal validity of qualitative research can be questioned on the grounds that the presence of the researcher and the methods employed may influence, or fail to capture, the context of the study. Research reliability is however, often taken to mean the extent to which there is consistency in terms of measurement, but, in this sense, is considered more appropriate to quantitative conceptualisations than to the methodological framework employed in ethnographic studies (Hammersley, *Op. cit.*). This is not to say that reliability is irrelevant, but to accept that human behaviour cannot, on ethical and practical grounds, be subject to the type of controlled experimentation that is characteristic of physical science. In addition, from both a qualitative and quantitative perspective, it can be argued that the researcher is inextricably present in social reality by virtue of the subjective judgements that are made with regard to research design and analysis. In effect, the question of reliability in ethnography is pursued through the adaptation of the research focus to what respondents regard as significant, and interpretation can be aided by the application of data collection methods that may be used both for exploration and confirmation.

With regard to external validity on the other hand, Hammersley, (*Op. cit.,* p. 56), argues that the function of ethnography is "...to produce knowledge that is of public relevance." Here, it is the findings of ethnographic research, based on inferences drawn from interpretations, that may be questionable insofar as they represent a plausible and credible account of the phenomena under investigation (Hammersley, *Op. cit.*). Plausibility, can be determined on the basis of existing knowledge, but where evidence is considered implausible then the researcher must provide information about the conduct of the research that is sufficient to enable his audience to make judgements about the credibility of the findings. For these reasons it is important to discuss the limitations of the data gathering techniques employed during the study, and to consider the contextual status of the researcher. Four major sources of data were utilized during the study. First, secondary literature provided much of the background information for health care quality issues and organizational change in the NHS. Second, documentary sources generated within the health care system provided data that were used for investigating the environmental context of NHS provider units. Third, primary sources were exploited through a variety of techniques that included participant, non-participant and structured observation and semi-structured interviews - techniques that provided material for investigating the social system within hospitals. Third, applied data became available through a process of interaction between the researcher and colleagues concerned with the implementation of quality management systems and thus provided a means of evaluating the technical adequacy of health care quality management systems.
Participant observation presupposes an extended period of access to the context of the investigation and may be defined as a means of providing the researcher with first hand knowledge of social behaviour within that context. Though centrally concerned with the observation of people during the normal course of their work, participant observation also involves listening, both to individual commentators and to group discussion. In policy and organizational studies, the approach has the advantage of flexibility, enabling the researcher to identify significant topics and themes that are revealed, implicitly or explicitly, through the observation of individual and collective behaviours set within the process of organizational events. Moreover, topics and themes thus identified are likely to be devoid of the reality distortion that can be created through the use of experimental methods and subsequent interpretation can be partly said to contain a measure of explanation derived from meanings attributable to organizational members (Pollitt et. al., Op. cit.; Bryman, 1989). Hence, policy induced organizational change within a health care setting, a setting that Strauss et. al. (1963) reported to be in a constant state of flux due to the continual negotiation and re-negotiation of the social order, is particularly suitable for the application of participant observation. Several difficulties can be associated with this approach however, in terms of accessibility, data collection and analysis.

The level of accessibility gained during most of this research was commensurate with the Type 1 classification devised by Bryman (Op. cit., pp. 151-161). Here, the researcher is an organizational member and, in this study, was a full observer with a mandate to engage directly in issues that provided the research focus. However, hospitals are large, multi-professional settings, and full access does not automatically follow from 'role access'. In health care, routine access to some activities, the treatment and care of patients for example, may be considered unethical on the grounds of privacy and confidentiality, or would be technically unsafe, in theatre for example, where non-essential presence could present the risk of cross-infection or other avoidable hazards. Neither is access to the confidence of professional groups an automatic extension of full observer status, but is something that is dependent upon the extent to which the researcher can establish personal credibility. In short, though full observer status may be granted, there can be occasions when covert observation is necessary, and situations where the researcher occupies an indirect role and thus, must either assume the status of a Type 2 semi-participant, Type 3 interviewer or, when in other health care units, a Type 4 multi-site observer after Bryman (Op. cit.). These differences in levels of participation have, as Bryman (Op. cit., p. 151) further notes, "...implications...for the kind of data that are acquired" and for its collection and analysis.
Although participant observation allows the researcher to explore primary sources, the nature of data and its mode of collection are clearly dependent upon the level of participation enjoyed at various points in the study. Full observation of the kind associated with the Type 1 classification is, for example, heavily dependent on the construction of field notes that need to be categorized, cross-referenced and periodically re-categorized as their significance emerges during the course of the research. This kind of data tends to be highly detailed, but, where the researcher pursues a dual role as an employee, it is rarely possible to construct a record of events at the time of observation.

Indirect observation on the other hand, of the kind associated with Type 2 semi or non-participant status, is common in three stages of institution-based health care research, viz, during the early period of organizational involvement when the researcher may suffer a degree of disorientation, in situations where the absence of technical skills constrain a peripheral role, and in Type 4 situations where off-site institutions provide the research setting. Here, not only is there an opportunity for simultaneous observation and recording, but also for an element of preliminary analysis through the immediate identification of themes and topics, or the recognition of associations between the data and issues revealed earlier in the study. This should not however, deflect the researcher from conducting a more rigorous analysis at a later date.

Alternatively, the structured, semi-structured or unstructured interview provides the bases for the Type 3 level of participation. In this study, the use of the structured interview was avoided on the grounds that it might obscure pertinent data if the significance of some issues did not become fully apparent until late into the research process - a common feature of qualitative studies (Bryman, Op. cit.). Semi and unstructured interviews were employed, but the latter were used primarily in an exploratory context, and the former mainly for confirmation. Both methods frequently provided new data however, and thus, created the need for a cyclical element in the framework used for data processing (see Figure 13., overleaf). This framework includes observation, reflection, analysis, interpretation and confirmation, and its use illustrates a rejection of the view that field notes can be treated as "...unproblematic sociological...data" (Atkinson, 1992, p. 17). But it also presupposes an acceptance that the research findings represent a reconstruction of 'reality' that is limited both by what was observed and by the researcher's interpretations conveyed within the context of existing knowledge and established theoretical paradigms.
While it is argued above that the observation and interpretation of human behaviour does not easily lend itself to quantitative methods, a form of structured observation was developed for use in the later stages of the research process. Though similar to Bryman's Type 2 classification in terms of the indirect or non-participant proximity of the researcher, structured or systematic observation involves the construction of a record of events or responses within a framework of predetermined issues (Bryman, Op. cit., Ch. 8). Exercises were conducted during three TQM educational seminars in a hospital provider unit and centred on gaining respondents views on three issues. First, on common health care quality problems that were essentially social in character; second, on problems within the technical system; and third, on those issues that might act as a barrier against the successful implementation of TQM in a health care setting. Although the exercises were designed by the researcher, the seminars were conducted by external consultants and thus, the status of the researcher may be considered to be that of a non-participant. For the duration of the seminars, respondents were grouped into six teams of eight and, on each occasion, were organized on a multi-disciplinary basis that included medical, nursing, clerical, managerial, engineering and both clinical and non-clinical support staff. In order to increase the probability of objective responses, the selection of topics was constrained only by a requirement for group consensus. Moreover, in an attempt to minimize the potential for distortion caused by the presence of the observer, and to obtain meaningful data, the exercises were conducted on the last of the three days of the seminars when it was considered more likely that participants would be familiar with TQM concepts, and less likely to be influenced by the peripheral presence of the observer. Finally, the issues selected for the investigative framework described above were developed from qualitative data collected earlier in the study and were thus considered to provide a valid basis upon which the informed views of respondents could be obtained.

Nonetheless, these structured observation exercises can be considered to represent action research projects, sometimes termed applied or participative research after Whyte (1984), that were conducted on behalf of the organization in which the researcher was an employed member. The resultant data thus proved useful in practical terms, that is for the development of a TQM implementation strategy and forward plan, but also provided both confirmatory evidence in respect of other data and an opportunity for further analysis and interpretation. Data confirmed, for example, the existence of a correlation between certain themes and distinct professional groups and contributed to the interpretation of the significance of such themes by revealing something of the extent of inter-professional conflict, and consensus, over the direction, priorities and constraints for developing TQM in a health care setting.
Documentary evidence provided a second source of data, but should be distinguished between the secondary literature used as a basis for background information and primary material, written at the time of the research, that emanated from within the health care system. In this latter respect, the health care system should be taken, in the broadest sense, to mean the sum of governmental, organizational and professional institutions concerned with the delivery of health care. Documentation obtained from these sources thus included official macro-level publications, letters and circulars; meso-level business plans, operational policies and documents relating to the design of both organizational structures and technical systems; and journal articles that are best described as secondary material on the grounds that there may be a significant time lag between submission, acceptance and publication.

On the one hand, consideration of secondary literature allowed for a critical review of the adequacy of the technical systems being developed in support of quality management in health care and may be considered constructive insofar as this resulted in the identification of questions and issues that provided both a preliminary investigative framework and a basis for applied research at a later point in the study. Moreover, a critical review of the implications of both structural and organizational change within the NHS helped to establish the appropriateness of questioning the conceptual adequacy of these aspects of the reforms in terms of their relationship to actual or proposed changes in the technical system.

The analysis of documents originating from within the health care system on the other hand, also proved advantageous. Official papers for example, set out the strategic direction and stated intentions of policy initiatives; organizational documentation reveals something of meso-level responses to the latter; and articles in journals illustrate professional concerns relating to issues raised in or by the former two sources. Journal articles can also be used both for the confirmation of data derived from observation and interviews, or to provide additional focal points for the research. Furthermore, documentary sources avoid the potential for various types of respondent bias that are often associated with observation and interview methods, may also illustrate the continuity of themes over time, and can provide the researcher with information about the professional views of élite figures who may otherwise be inaccessible (Bryman, Op. cit., p. 197). Nevertheless, documentary sources of the kind referred to above are rarely constructed for the benefit of subsequent research projects and thus, like many other forms of written and oral testimony, are subject to the limitations of the researchers interpretative framework.
The interpretation of any form of data presupposes either the acceptance of the truth of the data or the application of a method for determining its validity (Gottschalk et. al., in Bryman, Op. cit., p. 198). In the context of the documentary evidence explored in this study however, it is more appropriate to ask whether such sources displayed, or were intended to display, the whole truth. Here, the question of hidden agenda becomes central to the process of interpretation and, in the case of NHS policy statements and related meso-level responses, can be partly identified by discussing their practical implications and comparing these with stated policy objectives. Yet, it is important to consider that even when contradictions between intentions and outcomes can be inferred, this may have more to do with a lack of perception on the part of policy makers and NHS managers than with any deliberate attempt to mislead. However, where anomalies between policy and practice are exposed early in the implementation process, it is possible to detect an awareness of these in the form of new directives designed to overcome such discrepancies. Alternatively, when comparing responses to policies between different institutions it is necessary to be aware that local circumstances can lead to divergent outcomes and may not therefore be attributable to ambiguous or inadequate policy statements - or more briefly, to recognise "...that the unit of analysis [may not be] identical (Bryman, Ibid.). Hence the importance of site-specific observation and analysis and the relationship between qualitative methods and documentary evidence. Nevertheless, it follows that unintended consequences of health care policy initiatives might create the potential for politico-ideological exploitation, particularly when stated policy objectives are not fully realised.

Interpreting qualitative data also presents difficulties due to the dependence on observation and oral testimony. However, the use of more than one data source has already been mentioned as a device that facilitates cross-validation and is consistent with the concept of triangulation which is described as a means of relating "...different sorts of data in such a way as to counteract various possible threats to the validity of [the] analysis" (Hammersley and Atkinson, Op. cit., p. 199). In addition, a form of respondent validation was employed whereby feedback was obtained via a series of seminars, lectures and presentations based on preliminary research findings, sometimes including the distribution of written material, but always followed by individual or group discussion. Though conducted or delivered by the author within health care settings, these exercises were performed in the capacity of an employee and thus, the status of the observer during these events can be considered to be covert. Nevertheless, since the content was topical, participation proved to be illuminating, sometimes contentious, but always rewarding since the purpose was to seek validation of events rather than agreement on inferences made about events.
Action research provided a further source of 'applied' data, but establishing the validity and reliability of the results of such research presents different types of difficulty. Data can be regarded as valid insofar as it is based on a consensus of those involved in its production. Reliability on the other hand, may be tested through the application and evaluation of the results within the research setting, but only to the degree that time permits since, in the complex world of health care, it may take several years to establish a causal link between the application of quality management methods and improvements in health care or organizational outcomes. Nevertheless, action research projects provided data that were derived from the adaptation and refinement of industrial or business quality management techniques to health care settings. This work revealed where unmodified techniques were either limited or inadequate and therefore contributed to the development of more appropriate designs. Yet, the results were not merely of practical or technical significance, but also assisted in the identification, through covert observation, of some of the social characteristics of health care organizations that significantly impact on the design or implementation of quality management systems.

Finally, because of the dearth of published material on meso-level health care organizational or policy research (Pollitt et al., Op. cit., p. 188; Hunter, Op. cit., pp. 214-215) and since different types of data have implications for the style used to present the results of studies (Newby, 1977), consideration was given to the form of narrative to be used for the presentation of the research findings. In short, despite heavy reliance on data collection through observation, a first person form of narrative was rejected as inappropriate on the following grounds. First, on methodological grounds: though the development of a framework for data processing provided a structured and systematic approach to data analysis, confirmation and interpretation (Figure 13, above) this should not be taken to infer that data collection was a neat or tidy process. In actuality, the nature of the research setting often constrained retrospective note-making some hours after the observation of events and hence, verbatim transcription was rarely attempted. Second, on epistemological grounds since it was accepted, at the outset, that the presence of the researcher was part of, and party to, the re-construction of reality in the social arena under investigation. Third, on the grounds that the level of analysis and central aims of the research did not lend themselves to an intimate style of reporting. Fourth, on the premise that the intimate form of a first person narrative would not fulfil the research expectations, created by the level of analysis and study aims, of intended and potential readers. A more conventional form of interpretation combined with sociological analysis, followed by discussion, was thus considered more suitable.
In sum, the research design and research methods should be regarded as distinct (Bryman, *Op. cit.*, p. 28). Although an ethnographic approach was selected as the basis for the overall study design, it involved, ultimately, the application of a variety of research methods that were not clearly identified at the outset. Moreover, potential data sources and opportunities for their exploitation did not become fully evident until after the fieldwork had begun and thus, "...such [ethnographic] research...cannot be fully designed in the pre-fieldwork phase" (Hammersley and Atkinson, *Op. cit.*, p. 28). For these reasons the importance of developing a structured analytical framework can be regarded as more, rather than less, important and thus provides a justification for the inclusion, above, of discussions about the precise application of several methods of data collection and verification. Nevertheless, further consideration will be given to the problems and promise of the research strategy following the presentation of the research findings.
Although recent research suggests that only modest improvements in NHS performance have resulted from the 1991 reforms (Robinson and Le Grand, 1994), the environment within which hospital care is provided has undergone, and is likely to be subject to further profound change. Contributory factors include the development of larger purchasing organizations and more sophisticated contractual processes, a substantial shift towards primary and community based care, an expansion of the role of general management, and proposals for new accountability arrangements that will follow the planned dissolution of the eight remaining Regional Health Authorities (RHA's) and their replacement, in 1996, by Regional Offices (RO's) of the National Health Service Management Executive (NHSME). While most of these changes can be considered structurally external to provider units, the resultant impact on the internal organization and functioning of hospitals, on their relationship with other health care institutions, and on the morale of managers, clinicians and other staff, has been both complex and considerable.

The pragmatic consensus between purchasers and providers that corresponded with the uncertainty of the early years of the reforms has given way to a conflict between the market-place ethos of the latter and the public service ethos of the former (May, 1994; Tremblay and Wall, 1994). In this early period, primary importance was given to the development of NHS trusts and General Practice (GP) fundholders while District Health Authority (DHA) and Family Health Service Authority (FHSA) purchasers were advised to maintain the status quo with existing provider units. By 1993 however, both governmental and state agencies were advocating a stronger role for purchasers who, in a ministerial address to the National Association of Health Authorities and Trusts (NAHAT), were described as the pipers who 'must call the tune', a view endorsed following a subsequent recommendation for strengthening the purchasing role by merging DHAs and FHSAs (Audit Commission, 1993a; 1993b). Though economies of scale provide a rationale for this recommendation on the grounds that fragmented purchasing can raise unit costs if others contract for similar services elsewhere, this has lead to a narrow interpretation of health care improvement expressed solely in terms of greater throughput (Audit Commission, 1994a). Such an interpretation thus confuses efficiency with effectiveness and has led to a revised emphasis on the role of NHS trusts in developing long-term health care planning (Ibid.).
This ambiguity in the thrust of central policy may indicate an element of frustration, with both purchaser and provider performance, by a government entering the final two years of its current term of office. In a written answer to a Parliamentary question it was revealed that almost fifty percent of NHS trusts had failed to reach at least one of their financial targets in 1992/3 (Hansard, col. 541w, 20 April 1994). However, such failures are considered to be partly due to ineffective hospital management, including initiatives such as TQM that are designed to involve all staff in the change process, and partly because "...providers...[are] left at the mercy of last-minute changes of direction by purchasers" (Audit Commission, 1994, p. 11). Yet, the complexity of the contractual process, the relative risks associated with alternative purchasing strategies, and the lack of pertinent data may provide a more plausible explanation both for provider management paralysis and purchaser indecision.

At the outset of the reforms, most DHAs, following official guidance (NHSME, 1989; 1990), opted for simple block contracts based on the historical provision for their population, though some funds were reserved for extra-contractual referrals (ECRs) - referrals by non-fundholding GPs to providers with whom the responsible purchasing authority has no contract or for non-specified services. For providers, block contracts minimise potential disruption to existing services, but carry the risk that the provider will bear the costs of increased activity. Consequently, many providers negotiated more sophisticated combinations of block and cost-per-case contracts, though large cost-per-case contracts are unusual because they create incentives for providers to complete more episodes since the financial risk is borne by the purchaser. Nevertheless, the sophistication of the contractual process is not matched by that of management information systems (MIS). Although such systems are under development in most provider units, many are based on departmental networks that do not link with order communications systems (OCS). An OCS is the component that processes requests and results for diagnostic tests between patient areas and clinical support services such as radiology, pharmacy and pathology; OCS also provide patient-related data for costing and contract management, (see Figure 14, overleaf); and an OCS can significantly enhance the quality function in provider units. The computerised ordering of drugs for example, reduces transcription errors and 'on-line' information about drug interactions or doses facilitates improved clinical decision making among medical and nursing staff (Johnston et. al., 1994). Other studies in the USA have indicated that many diagnostic tests are overused or are often inappropriate and therefore represent non-value added costs that can be reduced by adherence to computer-based clinical protocols (Eisenberg et. al., 1977; Tierney et. al., 1988).
Furthermore, an OCS facilitates the development of meaningful quality systems than can monitor outcome indicators such as critical clinical incident rates, and measure process performance in terms of lengths or duration of stay for example. Nevertheless, though the management of both cost and quality in health care can be significantly enhanced through the application of OCS, it is noteworthy that only thirteen per cent of UK provider units have implemented OCS (Thomas et al., 1994), and that central funding for hospital MIS development ceased in April 1994. In short, while purchaser-provider social relations have largely been established through macro-level re-organization and the development of meso-level contractual communication mechanisms, the necessary technical support systems have not. In consequence, managers in both purchasing and provider organizations often find themselves discussing prices when "...they haven't got a clue about what things really cost" (a provider Chief Executive quoted in Crail, 1994, p. 16). It follows therefore, that because of the limitations of the information available for contractual negotiations, provider managers are constrained to place financial issues at the top of their agenda. Moreover, the limited funds set aside for ECRs is neither consistent, between purchasers, nor sufficient to cover their cost because there is no clear definition of an ECR due to variations in contracted service provision between different DHAs. In turn, this has two further significant consequences. First, it questions the principle of equitable accessibility, and second, it has resulted in increasing administrative costs (Maheswaran et al., 1994). On the one hand, just as the NHS absorbed the inadequacies of the old system, recent reforms have inherited, and may have added to, inequalities in the distribution and availability of resources (Ham, 1993). Regional geographic and socio-economic inequalities that permeate the UK health care system (see Townsend and Davidson, 1988) may for example, be further exacerbated by local variation in services that are direct result of the new contractual process - though some have argued that the new arrangements merely reveal the true, heterogeneous, nature of UK health care (Salter, 1994). On the other hand, the scale of cost-contract related problems is only becoming apparent as more hospitals undergo the transformation to trust status and thus lose the protective umbrella formerly provided by DHAs which had a responsibility for maintaining the viability of their directly managed units. The extension of the purchaser-provider concept has resulted in the removal of "...some of the old parochial loyalties" (Spurgeon, 1993, p. 121), and means that the pragmatically necessary high profile business orientation adopted by provider unit managers often conflicts with the public service ethos of their hospitals and with the ethics and professional standards to which their clinical staff owe allegiance. Hence, there is often a credibility gap between what management say about quality and observable management activity.
In addition, the provider environment has been altered by advances in medical technology, by revised assessments of health care needs by DHAs and by developments in primary and community-based care. Reductions in lengths of stay for example, and increases in day-case activities have been facilitated by the use of laparoscopic, microscopic and laser surgical techniques; purchaser re-assessment of priorities has led to the modification or closure of existing services; and specific funding is available for meeting the combined health and social care needs of the elderly, and of physically and mentally handicapped patients, within community settings (DHSS, 1988; DHSS, 1989b). Paradoxically therefore, many providers are experiencing greater throughput in core service activity while the demand for inpatient beds is in decline.

Changes in funding primary care have also had, and may have further impact on the provider environment. First, the creation of independent fundholding GPs has altered the power relationship between primary and secondary care with the result that, where a provider organization has contracts with several fundholding practices, service provision has become asymmetrical in terms of accessibility or other dimensions of quality. In addition however, the formulae for calculating fundholding budgets for hospital referrals is based on GP in-patient activity levels during the two years prior to the year in question. Yet, since most fundholders gave priority to clearing their waiting lists during the early years of the reforms, it is likely that their requirements will be much less than indicated by data that are two years old (Jones, 1994). Thus, the financial position of provider units may be undermined if fundholders do not generate anticipated activity levels. Almost inevitably therefore, some trusts will fail to meet their financial targets, and they may feel that their freedoms are being constrained "...for the benefit of increased GP powers and choice" (Cottam, 1994).

The freedoms enjoyed by NHS trusts are also perceived to be threatened by the proposed NHS executive management structure. The NHSME will function as the 'headquarters of the NHS' and will assume responsibility for monitoring the performance of both purchasers and providers through eight Regional Offices, for strengthening the purchasing function by promoting mergers between DHAs and FHSAs, for defining the rules of the internal market, and for allocating resources to health authorities, FHSAs and GP fundholders (DoH, 1992; DoH, 1993; NHSME, 1993a). It is also reported that the NHSME will support the development of guidelines for clinical practice - the subject of a recent Executive Letter (EL(94)74) - but, that in all other relevant respects, the new corporate management structure "...will not be involved in detailed operational matters" (DoH, 1992, *Ibid*.)
Although these latter proposals are not yet implemented, four major inferences can be made. First, the planned involvement of the 'centre' in resource issues suggests an acceptance that market mechanisms do not effect efficient resource allocation in UK health care. Second, that the inequity of the current fragmented purchasing system is also recognized. Third, that the inherent inequalities of the health care system, at least in terms of its inability to meet all demands, is to be formally recognized and reconciled through a contractual system based less on volume of activity and more on informed judgements, derived from clinical guidelines, about the effectiveness or otherwise of specific interventions. Finally, the state would have assumed control, but would avoid responsibility for 'detailed operational matters', thereby leaving purchasers and providers in a position of proximity, to responsibility for service specification and delivery, but effectively without the power to determine either the size of the market, in terms of resource availability and allocation, or the mechanisms through which such resources will be distributed amongst their population.

Irrespective of the outcomes of further policy changes, there is broad recognition that rationing of health care has become an explicit topic on the public agenda as a result of purchaser-provider reorganization (IHSM, 1994b). In addition, the development of clinical guidelines or protocols, an implicit function of the medical audit initiative, is considered crucial not only for the development of MIS, but for effective local prioritization of service provision by establishing what are or are not considered to be effective medical interventions. Medical audit may thus be considered to be the stimulus for the revised role of provider units in long-term health care planning, but this presupposes the active participation of hospital based medical professionals in a process that might effect the local demise, or as Maynard (1994, p. 19) argues, the retention of their specialty. Audit would thus be transformed, from a catalytic concept designed to promote and sustain change in practitioner attitudes and practices, into a technical mechanism that provides data that may either facilitate effective commissioning of services, or inhibit the contractual process (Maynard, ibid.). However, if medical audit develops primarily to facilitate the contractual process, then hospital boards will effectively make rationing decisions about the supply side of health care, but they will be bureaucratically rather than publicly accountable. Moreover, supra-regional, and possibly private sector specialist hospitals would likely fill the void left by any local non-provision, and purchaser and, ipso facto, patient choice would be further limited while some issues about accessibility would be reduced to little more than economic arguments.
On the other hand, if medical audit is used as a defensive mechanism by the medical profession, then public confidence in the health service is likely to decline and "...fuel the call for the next round of NHS disorganization" (Maynard, Ibid.). In short, given the proposed central-peripheral relationships mentioned above, the rhetoric about public consultation and choice will be substituted by increased bureaucratic determination of priorities effected through the device of 'technical politics' (Thompson, 1986) with the result that "...political accountability at local level is... sacrificed on the alter of the politically useful illusion of technical precision" (Hunter, 1994a, p. 21). Whether this scenario represents the outcome of a 'hidden agenda', or the unintended consequences of public policy, its realization would radically undermine the fundamental principles of health care provision in the UK. In addition, although official guidelines continue to place emphasis on the increased freedoms enjoyed by NHS trusts, and on the need for individual accountability for key performance indicators such as asset utilization, staff sickness and turnover (Audit Commission, 1994b), it is rarely acknowledged that trust provider units are policy contrivances created by statute rather than legally constituted business entities free to exploit the potential of the market. The conceptual adequacy of the provider relationship with the market can thus be questioned on the grounds that while the latter represents a dynamic and unpredictable process, the former are constrained by relatively static and predictable bureaucratic procedures. Consequently, provider units function in a potentially hostile environment and it is not therefore surprising to find that managers, concerned about their inability to achieve business objectives because of the lack of meaningful devolution and the conceptual inadequacies of 'independent' trusts and the internal market, are becoming increasingly involved in the debate about public sector accountability, management ethics and the re-assertion of public service values (Bayliss, 1994a; Bayliss, 1994b; IHSM, 1994c; IHSM, 1994d; Millar, 1994). As a result, a code of conduct and accountability has been drafted by the NHSME to compliment existing guidelines for the conduct of NHS staff concerned with fiscal issues (NHSME, 1993b) and, subject to consultative amendments, the new code will be implemented in April 1995. In a similar context, doctors representatives are also critical of the results of change to date and the Chair of the British Medical Association has recently argued that "...it was time to reform the reforms, to reinstate equity of access and to strive for equity of outcome in healthcare" (quoted in May and Miller, 1994, p. 14). These values, that are central to the profession of medicine in the UK, thus appear to be gaining renewed prominence amongst general managers in the NHS and illustrates, perhaps, that the socialization process within health care organizations continues to be significantly influenced by a medical culture that, though having apparently been somewhat subdued, is nonetheless alive and well.
Alternatively, this fusion of ideals may represent a temporary truce to compensate for an equally temporary gap in the information-base required by management if they are to successfully negotiate with the centre for resources, and with purchasing organizations for contracts. The view that provider unit management is simply about preserving what exists has been described as a 'dangerous illusion' that must be replaced by a proactive approach that reshapes the purpose and function of hospitals (Manning, 1994). However, the relatively favourable environment that existed for the development and expansion of hospital sector services during the 1960s and 1970s has clearly disappeared, partly as a direct result of the success of the NHS and other social programmes in improving the health status of the population, and partly because of increased public awareness of the economic and opportunity costs of modern health care delivery systems. In addition, the politico-ideological promotion of the concept of consumer sovereignty since the early 1980's has resulted in greater public expectations about the quality of care and standards of service provided by health care institutions. Yet, there is some evidence (see Chapter Four, p. 43 above) that suggests there is considerable public scepticism about the ability of the new NHS to fulfil these expectations - perhaps because of the constraints of the contractual process and other environmental issues that may limit or alter the intended impact of recent reforms: as Hunter (1994b, p. 19) notes, it was precisely because of the imperfections of the market that health care issues were "...located in the public sector in the first place."

Nevertheless, quality issues are likely to assume a more prominent place on the agenda of provider units for two reasons. First, in the financial year 1993-94, central funding for quality initiatives such audit included an additional allocation to "...facilitate and "pump prime" the development of multi-professional clinical audit." (NHSME, 1993c). This development is likely to rejuvenate professional interest in the audit process, partly because it represents an opportunity to focus the efforts of various health care groups on patient centred improvements, though, conversely, these groups may also try to defend established 'tribal' boundaries (Pollitt, 1992). Second, central funding for audit will cease at the end of the financial year 1994-95; such funding must then be sought from purchasers and included within the overall costs of contracts. It follows therefore, that there is likely to be competition between health care professionals for these limited resources, and that both managers, who will effectively become the budget holders of contract-related funds earmarked for quality activities, and purchasers, being the source of such funding, will each be in a stronger position to demand a more prominent role in specifying the content and direction of audit and other quality improvement programmes.
However, the politico-ideological and economic arguments that have underpinned the NHS reforms have resulted in a neo-Taylorist form of scientific management which makes little distinction between management tasks in the public and private sector, that assumes management to be both a specialist and executive activity, and that demands the quantifiable demonstration of the attainment of predetermined objectives (Hood, 1991; Ranade, 1994). Thus, although politically induced macro-level change has clearly altered the meso-level organizational environment of health care in the UK, the model of public sector management and the resultant management culture that has evolved within the NHS may not be conducive to progressive improvements in the quality of care and services that are conceptually consistent with the philosophy of Total Quality Management. Yet, during what is clearly an important transitional phase in the development of UK health care, questions about the quality of both care and services will become crucially important for provider units if they are to retain the confidence of purchasers and if they are to re-establish the virtues of public sector health care provision.
CHAPTER SEVEN

THE IMPACT OF SOCIO-CULTURAL AND TECHNICAL SYSTEMS ON MEDICAL AUDIT AND QUALITY

A review of the literature and other documentary sources relating to recent changes in the NHS provides a necessary research overview of the development of quality issues in hospital-based provider units, but there are several grounds for arguing that it produces a substantially inadequate 'cognitive map' (Weick and Bougon, 1986) for the participant observer. First, the anticipated conflicts implied by the literature are concealed within a complex network of formal social relations that are based partly on tradition and partly on new forms of interaction between the various professional groups concerned with the delivery of care and the management of services. Second, although these formal social relations convey an image of structured hierarchies, linear authority and rational decision making processes, they reveal little about either the nature or significance of the informal organization within health care provider units. Third, variations in the technical aspects of the work are often considerable between different disciplines and can have a major influence on the degree to which they are amenable to the application of audit or other quality techniques, or the extent to which they are dependent on the efforts of other services. Fourth, the organization and control of the medical audit process often precludes external verification and thus raises questions about the validity of results and about accountability. Finally, the researcher is constrained to search for evidence of major social change precisely because of the de-stabilizing effects of the reforms on the role of the hospital, but may thus fail to observe that the resultant incertitude, though mediated through new mechanisms, involves a substantial degree of adherence to the conventions of an established social order in which the actual distribution of power and authority does not mirror the formal bureaucracy.

Nevertheless, in spite of some justifiable scepticism about the overall impact of the NHS reforms (Robinson and Le Grand, 1994), the medical audit initiative can be regarded as a qualified success insofar as audit has rapidly permeated medical practice and has been extended to nursing and other clinical areas. This success, its advantages, limitations and variations, will be explained with reference to the different socio-cultural and technical systems that are found to co-exist within hospital provider units, and by placing their development within the wider context of other aspects of the reforms. Consistent themes identified during the study concern environmental, organizational, technical and ethical issues, and their effects on medical audit, on other quality initiatives and on organizational culture will be discussed.
Within provider units, two distinct environmental settings are observable. On the one hand, the medical setting is characterized by a measure of predictability, clarity, limited formal and extensive informal relationships with other clinical professions. Conversely, non-clinical managers occupy a relatively turbulent setting characterized by ambiguity, limited informal and multiple formal communication and accountability relationships. However, to account for the features of the managerial setting it is necessary to understand something of the changing composition of health service management and the diversity of management tasks and roles. Contemporary provider units contain five broad groups of managerial staff, viz: Senior general managers, including the Chief Executive Officer (CEO), who have responsibility for planning, human resource management and service development, and who are ultimately accountable for the overall performance of the hospital. Specialist managers who, for example, are responsible for financial accounting, estates management and management information systems (MIS). Clinical directors who perform a dual medical-managerial role and are responsible for the operational performance of medical specialties. Divisional managers who function in support of clinical directors and have largely displaced the role of nurse managers. Finally, supervisory managers are responsible for various support service departments such as medical records, supplies, and patient services.

During the early years of the reforms, all clinical and non-clinical directors, the CEO, the chairperson of the medical staff and the postgraduate medical tutor normally provided the membership of the hospital board. However the size and composition of these ‘executive teams’ proved to be ineffective, inefficient and incompatible with the needs of the organization. On one hand, hospital-wide membership effectively led to the return of consensus management, resulted in incremental or non-decision making and was thus, both ineffective and incompatible with the concept of general management. On the other hand, the inclusion of a large number of senior medical staff consumed a substantial part of clinical time and, given that meetings lasted half of one day and agenda items were often considered to be ‘not clinically relevant’ (1), it was not uncommon for medical staff to be ‘bleeped’ out of such meetings - usually for valid reasons, but sometimes by contrived prior arrangement. However, these weaknesses are being addressed through a reorganization of the executive function that allows for Directors of Clinical Services to represent the interests of all medical specialties, but who may also be considered as senior line managers.

(1) Single quotation marks are used throughout this Chapter to indicate the actual words used by respondents, or to denote the use of conventional terms that were observed to be used by subjects.
A more recent development involves the appointment of executive directors of nursing and quality and, in NHS trust hospitals there are, of course, an additional number of non-executive board members. Yet, since the latter have no formal organizational powers, and the former perform a coordinating role in respect of quality activities and a consultative role with regard to nursing - they are rarely responsible for operational nurse management - new board-level arrangements have, to some extent, resulted in a measure of internal de-politicisation of the executive management function. None the less, the transformation from what was essentially a reactive administrative organizational culture to one characterized by proactive managerialism has clearly resulted in a multiplicity of formal interfaces for the generalists.

In addition, although the advent of general management in the NHS has resulted in increased authority and responsibility for former administrators, who account for 60 per cent of Unit General Managers (Jones, 1994, Table 11.3, p. 452), their peers include a substantial number of former medical and nursing practitioners (29%), other health service workers (3%) and a significant proportion (8%) of staff with no previous health sector experience (Ibid.). Moreover, the separation of the purchaser and provider roles, together with the ensuing contractual mechanisms, created a need for middle management skills that were not readily available from internal sources. Consequently, health service management has experienced a large influx of staff drawn from industry and business in the private sector where values and belief systems are somewhat different from those traditionally associated with public institutions - and competence in the former does not imply competence in the latter. Management in provider units does not merely involve internal co-ordination and control, but requires the often sensitive management of the interface with a highly politicised external environment. Furthermore, though it has been argued above, (Chapter 6, p. 70), that managerial values may be influenced by the clinical professions, former administrators have become involved in the public sector management socialisation process for new recruits to the health care arena, staff who have often expressed experience of the 'cultural shock' of having to substitute 'tactical political behaviour' for what they formerly understood as the implementation of 'strategic business planning'. Thus, while the primary intention of the introduction of general management was to effect change in organizational performance, senior managers also have a role in maintaining a measure of continuity with regard to the health service managerial ethos. Yet, the style of management in health care, and the career path of managerial post-holders has changed in several important respects - some of which may not be compatible with the concept of quality improvement.
In contrast to the pre-Griffiths era, when health service administrators could reasonably expect a measure of upward occupational mobility during the life-time of their employment, new management appointments tend to be of fixed term duration and continuity of employment is often dependent upon the realisation of specific objectives. These objectives also provide the criteria for Individual Performance Review (IPR) and thus, for the disbursement of Performance Related Pay (PRP). Although such objectives are overwhelmingly financial in character they have necessarily involved the development and implementation of new organizational structures designed to facilitate the devolution of some budgetary responsibilities, the development of national initiatives such as resource management, and the negotiation of new practices designed to ensure demonstrable conformance with politically determined standards for patient care (NHSME, 1992). To these can be added: the requirement to achieve a return on capital assets, the operational need to re-determine staffing levels and skill mix in response to purchaser service specifications and a fundamental requirement to update management information systems. In short, despite the financial underpinning of many of these objectives, the sheer potential for overload demands achievement through other people. Yet, since responsibility and authority for the organization of provider units has been transferred to the general manager, whose performance, as noted above, is individually determined against specified criteria, the resultant style of 'management by objectives' is clearly reminiscent of the Taylorist thesis on scientific management (Taylor, 1947), and is wholly inconsistent with the central TQM concept of employee empowerment. Within the TQM concept 'objectives' are regarded as planning tools rather than management techniques and it has not been uncommon to observe the devolution of control over directorate budgets to divisional managers, only to witness the unit-wide re-centralization of such controls following failure to meet budgetary targets - even when divisional managers had little or no input into the determination of such targets in the first place. This is not to say that there is necessarily a shortage of intra-organizational collaboration or goodwill, but to argue that there is a major contradiction between what health service general managers are required to achieve and the management style that they have been constrained to adopt. It may therefore be this contradiction, illustrated in Figure 15 overleaf, rather than the influence of other health care professionals, that has fuelled increasing management concern with issues about public service values, ethics and accountability. Nevertheless, in the operational arena managers often express their dissatisfaction with current arrangements in terms of their frustration with 'the arrogance' and autonomy of medical practitioners, but, in doing so, they may have failed to recognise that the changing role of hospital doctors has extended rather than limited their range of career opportunities.
MANAGEMENT BY OBJECTIVES & SPAN OF CONTROL

Figure 15

General Management
Specialist Management
Directorate Management
Divisional Management
Supervisory Management

Planning
Information
Operational Decisions
Operational Consumption
Supporting Services

Critical sphere of influence & locus of internal objectives - (though constrained by external factors)

Critical span of control & locus of major performance indicators

Note: General and Specialist Management performance may thus be measured on the basis of indicators over which they have little direct control.
Just as the world of health service managers has undergone a radical transformation, so too has that of consultant grade medical staff who practice in the hospital sector. Although the reforms have affected all medical practitioners, consultants have been most affected partly because they are the senior line managers for all other grades of doctor and thus continue to control the medical socialization process, and partly because consultants accept responsibility for the clinical management of patients admitted to hospital within his/her specialty, and, must “...remain responsible for the patient’s subsequent care until another [consultant or specialist] doctor has agreed to take over that responsibility.” (General Medical Council, 1993, para. 93). It can be argued therefore, that consultant medical staff possess at least two, and sometimes all three Weberian forms of authority, viz, rational-legal authority, by virtue of their appointment; traditional authority, by virtue of their clinical status and expertise; and perhaps charismatic authority - depending on their experience and other personal qualities (in Albrow, 1970). Thus, while consultant staff may have lost a measure of power to set the organizational agenda due to executive level reorganization (see above, p. 74), their retention of various forms of authority effectively ensures their monopoly over the clinical management of patients and, ipso facto, of the continuity of their power to influence the professional behaviour of other clinical staff groups - a productive form of disciplinary power according to Foucault (1973), or, from a structuralist perspective, a form of domination and control (Lukes, 1977). However, it is usual for consultant medical staff to specialize within their specific discipline - a physician may, for example, specialize in pulmonary (respiratory) medicine or cardiology (heart function), a surgeon in orthopaedics (the skeletal structure) or urology (kidney or urinary tract procedures) or an obstetrician in in-vitro fertilization (fertilizing human ova outside the body). This trend towards specialization is due in part, to advances in medical science and technology that have created both the scope and demand for such services, is partly due to individual aspiration for professional development, but is also because the demand for hospital based specialist services has resulted in a specialist qualification often being a precondition for a consultant grade appointment. In short, the increasing costs associated with infinite social demand for health care are substantially influenced by the, albeit well intentioned, supply-side activities of consultant-specialists who control a large volume of revenue expenditure. It follows, that changing the behaviour of hospital consultants is both a central aim of many new policy initiatives and is a necessary precondition for achieving the objectives of increased efficiency and improved effectiveness in the hospital sector. However, some changes could lead to an expansion of medical power and may have occurred regardless of changes in policy.
Recent or planned changes that affect hospital consultants are both social and technical in nature and their significance can be distinguished at either the level of the individual, the organization or the profession (see Figure 16, overleaf). Social changes include: the development of new personal contractual arrangements (individual level); the implementation of Clinical Directorate management structures (organizational level); and proposed performance procedures, (professional level), that are planned for implementation in 1995 (Kilpatrick, 1994; General Medical Council, 1992). Technical changes include: setting Clinical Directorate budgetary targets (organizational level); the development of guidelines for clinical practice (individual specialty level); and the introduction of medical audit which, although it has both individual and organization-wide implications, is essentially a professionally led activity. This is not however, to say that either the above changes or their identified level of impact are mutually exclusive, but is, on the other hand, to place such issues within the context of their implications for continuity or change in power relationships. Moreover, many other changes in working practices and provider unit organization can be associated with those outlined above, but, as will be described below, may underpin the potential for increased medical power which is illustrated in Figure 16. Nevertheless, the transfer of consultant's contracts from Regional Health Authority control to that of the District Health Authorities, in respect of directly managed units, or to trust provider units, represents a considerable change in social control over the working practices of senior medical staff. General managers are now in a stronger position to specify the nature and number of consultant sessions and may also, though the issue is by no means settled, be able to implement a form of IPR for assessing consultants performance. However, this change in social relations does not merely underpin the authority of general managers, but may also facilitate the managerial role of consultants who are elected or appointed to Clinical Director posts. Clinical Directors are managerially accountable to the hospital board, either through the CEO or through the Director of Clinical Services, and their specific responsibilities include elements of directorate ‘business’ planning, the delivery of services according to purchaser specification, and budgetary responsibility for staffing, and sometimes for resource consumption. Yet, they have little formal (rational-legal) authority, nor do they generally seek such authority, to enforce issues on their clinical colleagues who can, and do, ‘cling rigidly’ to the concept of ‘clinical freedom’ - a concept that the British Medical Association (1993) states:

...is subject to the limits of the law, ethics, contracts, professional standards and resources so that Clinical Directors cannot commit colleagues to workloads or resource agreements, discipline or sanction colleagues, or override the clinical judgement of colleagues. (in White, 1993, p. 35)
NATURE, LEVEL & IMPLICATIONS OF CHANGES AFFECTING CONSULTANT MEDICAL STAFF

Figure 16

<table>
<thead>
<tr>
<th>Social</th>
<th>Technical</th>
<th>Level</th>
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<td>Employment Contracts</td>
<td>Clinical Guidelines</td>
<td>Individual</td>
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<tr>
<td>Directorate Management</td>
<td>Clinical Directorate Budgets</td>
<td>Organizational</td>
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<td>Performance Guidelines</td>
<td>Medical Audit</td>
<td>Professional</td>
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Substantial Managerial Control

Substantial Medical Control

Substantial Medical Control over resource usage, but with Significant Managerial & Contractual Influence on resource availability and allocation
It follows that where the role of Clinical Directors requires them to exercise a form of control over the work schedules of colleagues, their authority to do so is essentially based on the *de facto* devolution of new powers available to management. Moreover, in practice, Clinical Directors often have mere 'figure-head' budgetary responsibilities because formal accountability for directorate finances is commonly invested in Divisional Managers who thus, function within an ambiguous dual line-management relationship with clinicians and general managers. However, the advent of the directorates, together with the controls attributable to service contracts, have brought further changes that might reinforce the position of the medical profession. On the one hand, meso-level organizational change has resulted in the dis-organization of nursing insofar as its former hospital-wide professional base has become fragmented. On the other hand, while nursing staff are involved with the implementation of the orders of medical staff, for example, in terms of drug administration, conducting ward-based tests and in co-ordinating the interface with other clinical services, cost-efficient changes in nursing skill-mix have resulted in the employment of partially trained auxiliary staff and a reduction in the number of 'level one' Registered Nurses (RNs) and nurse specialists. In spite of their supportive role, these latter two groups are sufficiently qualified to often question the appropriateness of medical decisions, but the reduction in their number limits the scope for this informal type of control. A further change relating to the establishment of new structures involves the merging of clinical services, most commonly between Obstetrics and Paediatrics - often re-constituted the Directorate of 'Women's and Children's Services'. Yet, since such measures are essentially designed to effect more efficient resource usage and better co-ordination between, in this case, the clinical management of childbirth (obstetrics) and the neonatal care of the new-born (paediatrics), it may prove difficult to alter clinical behaviour given that distinct specialty and discipline specific medical hierarchies are retained. Indeed, specialization can subvert the formal organization in the sense that, although cross-specialty referrals will be documented in the medical record, discussions that both lead to, and follow from referral decisions are often conducted informally during 'corridor consultations' between doctors. Consequently, there are no recorded data that might be used to verify the appropriateness or effectiveness of many referrals and, though such issues are often discussed by doctors, this usually takes the form of an educational exercise rather than a performance review of practice. Thus, though the provider organization may be able to determine what work was done and how much it may have cost, it will rarely be able to determine why! Moreover, if such questions were to be raised, new organizational structures have effectively placed formal 'gate-keepers' (Directors of Clinical Services and Clinical Directors) between general managers and the mass of consultant grade medical staff.
However, there are other issues that provide incentives for greater co-operation between managers and clinicians. Management, usually through the CEO, now have a major input into the allocation of consultant merit awards, and meso-level reorganization has generally provided clinicians with access to decision-making forums from which they were previously excluded precisely because of organizational inadequacies. Consequently, many doctors who are regarded as 'local leaders', but who expended their leadership energies at RHA level where major decision-making powers were formerly located, now function as local 'champions' or change agents at provider level. But, it follows that it is through these local 'champions', rather than general management, that major changes in consultants behaviour will likely be achieved. Thus, the conventions of the established social order within the medical profession, that have, in a sense, been reinforced by the presence of professional 'gate-keepers', will continue to be adhered to. Furthermore, the proposed implementation of professionally determined performance procedures, perhaps designed to pre-empt management led IPR, are likely to further strengthen the position of unit-based medical leaders. The General Medical Council (GMC) currently has statutory powers for dealing with professional misconduct and criminal negligence. However, these powers are considered inadequate for dealing with the non-specific, but generally poor clinical performance of some members of the profession. Thus, it is proposed that a system of peer review monitoring of clinical performance be implemented, and conducted and assessed at local level by “...two doctors from the same field of practice”, but referred, if necessary, to the GMC by a ‘responsible senior medical officer’ (Kilpatrick, Op. cit., pp. 123-129). Again, this proposal, if enacted, represents a considerable change in medical social relations, but one that may be dependent upon the technical development of guidelines for clinical practice and therefore shares a measure of consistency with related central policy objectives (NHSME, 1993d; NHSME, 1994). Nevertheless, such changes would also represent an extension of the principle of 'state sanctioned self-regulation in medicine', (see Chapter 1, p. 5, above), and could reasonably be expected to enhance the formal professional authority of those consultant medical staff, such as Clinical Directors, and others who are recognised as ‘responsible senior medical officers’. It is important however, to note that while there is a direct technical relationship between medical audit and the development of clinical guidelines, the GMC have indicated that they do not wish to see a direct link between their proposed performance procedures and the process of medical audit which they regard to be fundamentally underpinned by the principle of ‘confidentiality’ (Kilpatrick, Op. cit., p. 128) - a principle which, together with other issues, has resulted in extremely limited management involvement in the medical audit process.
An account of managerial involvement in medical audit can be explained within three specific contexts. First, in terms of legitimate management interests insofar as these have been recognised and accepted by both managers and clinicians - essentially a descriptive exercise. Second, in terms of what has actually occurred, which, though also a descriptive exercise, demands a measure of explanation. Third, in terms of what is theoretically desirable, or likely to occur given the progressive impact of other aspects of the reforms - essentially a predictive, and perhaps, a prescriptive exercise.

The implementation of the medical audit initiative became a formal requirement within hospital-based medical practice in April 1991, and was organized and promoted, at unit level, by Local Medical Audit Committees (LMACs) and audit support staff in accordance with government guidelines (DoH, HC(91)2, 1991). While general managers had little option but to accept the official line that medical audit was ‘primarily a matter for the medical profession’ (DHSS, 1989; see Chapter 1, p. 7, above), the financial arrangements designed to support the audit initiative constrained a measure of management interest from the outset. Audit funds were provided by the centre, were ‘ring-fenced’ for audit use only, contained distinct capital and revenue components, were distributed to provider units through the RHAs, and were largely, though not always, devolved to LMAC control. However, the potential for expenditure, both on staff and capital equipment, that had recurrent revenue implications, in terms of salaries or equipment maintenance for example, thus created a legitimate need for a measure of managerial involvement in LMAC decisions. Managers also had formal authority (DoH, Op. cit.) to receive regular reports on the general progress and results of audit activity, but in all other relevant respects, during the formative period of audit implementation (1991-2) these latter issues represent the extent of management involvement in the audit process - an involvement considered by some medical staff to be limited to 'the signing of the relevant cheques'. During this early period, the audit initiative was substantially supported by the RHAs. The RHAs provided funding for regular meetings of LMAC Chairs - partly to facilitate the dissemination of new ideas and partly to obtain feedback on implementation. They also supported similar forums for the education and training of audit support staff, and for various ‘working parties’ whose terms of reference included, for example, the development of ‘Audit Information Flows’. The ‘working parties’ excepted, general managers were neither present at regional LMAC meetings - which were dominated almost exclusively by consultant grade medical staff, nor at those involving heterogeneous groups of audit support staff whose backgrounds characteristically included junior managers, middle and senior grade nurses, medical records officers, statisticians and newly qualified social science graduates.
The general development of medical audit was thus directed by consultant medical staff who form the nucleus of LMACs and who have often had prior audit training or experience. Audit committees are, in turn, supported by staff who, at the outset, were relatively inexperienced in audit principles or techniques, and were therefore susceptible to a socialization process that involved external and supra-regional education and training provided by a variety of institutions that included some of the Royal Colleges, the medical faculties of some universities or private sector consultancy firms that had a vested interest in propagating the virtues of the literature - a literature that was largely based on work produced by medical practitioners. In short, if audit support staff were considered to be, albeit junior, change agents, they rapidly and understandably developed a degree of empathy with the values of the medical profession.

Moreover, given the high regional profile in audit development during what was clearly a major transitional period in both the structure and internal politics of the health service, management were at a distinct disadvantage since their ranks were dominated by former administrators who were educated and trained to function at, and within, a district-based system that was in the process of being discarded. Consequently, they suffered from a lack of 'traditional authority' because of the newness of their occupational role and status, and from a related absence of relevant expertise that limited their potential to utilize the rational-legal authority associated with their new appointments. This meant that their agenda was already dominated, not merely by financial matters, but by the need to learn new skills in order to attend to issues arising from organizational, environmental and technical change. In short, against the background of their environment, and given the limitations for their involvement in medical audit implied by governmental and professional definitions of the concept, managers had neither the incentive nor the time to either assimilate audit concepts or to devote to the audit process. Thus, although management interest in audit and other related issues has altered more recently, the relative absence of external interference in the development of medical audit in the hospital sector, for the reasons outlined above, has, with some justification, led to the commonly held belief that the implementation of the medical audit initiative was the least contentious of the post-1989 reforms. However, medical audit has effectively been internalized within the profession and within provider institutions: LMACs have now been established in all units, formal audit programmes are common in all clinical directorates and sub-specialties, dedicated audit information systems have been developed, and annual reports on audit are routinely produced. But, these successes are subject to variations and limitations in terms of their effectiveness.
Variations and limitations in the effectiveness of medical audit programmes can, again, be best described in relation to the multiple social and technical systems that exist within hospitals, but which affect different groups or impact on certain activities in different ways. Nevertheless, since audit activity, not to be confused with the LMAC role which is essentially concerned with development, monitoring and support, is organized on a directorate and sub-specialty basis, variations in effectiveness must be placed within the context of those factors that are central to, or impinge upon the audit process, viz: directorate 'structure and function'; information systems and 'ownership' of data; and audit information flows.

Although clinical directorates have evolved in response to the need for better forms of internal management, they also represent a distinct form of the specialized division of labour in secondary health care institutions. Each directorate represents a specific faculty of medicine and is externally supported by colleges that, among other things, specify many of the discipline specific technical standards to which members owe professional allegiance. Moreover, there is mutual recognition, between the colleges, of their rational-legal authority to specify such standards, and individually and collectively, they represent a powerful lobby that has 'insider' access to both the legislative and administrative organs of government and that can either facilitate or inhibit the process of change at the 'front line'. In short, just as the medical profession as a whole can draw upon similarly powerful resources, in the shape of the British Medical Association (BMA) and the GMC, that protect and advance their social interests (pay and conditions for example), the colleges represent a secondary level of nationally-based professional bureaucratization that is centrally concerned with the development and maintenance of technical aspects of the work of their members. Thus, while there is much common ground between medical staff in terms of their educational background, economic and social status, values and beliefs, this commonality tends to be socio-cultural rather than technical in character. Hence, given that a directorate that includes say six consultants, each of whom have expertise in a different sub-specialty, it follows that in addition to the ethical limitations on the ability of these doctors to impinge on the work of their colleagues (see p. 79, above), there are additional, technical and rational-legal, reasons why such influence may be limited - reasons that are underpinned by the demand (see, p. 78, above) for hospital based specialist services. The implications for medical audit are thus, that although clinical practice can be subjected to peer review at provider unit level, and guidelines for such practice, including resource usage, can be agreed at this local level, their implementation and application is often subject to the results of supra-regional specialty-based audit which is, by definition, conducted outwith the formal sphere of influence of the directorate structure.
In addition, the design and execution of an audit study, and the validity of its results can be significantly influenced by the sophistication, in either technological or 'artistic' terms, of the type of procedure(s) under review, or by the nature of the disease and condition of the patient to which such procedures are applied. In the Directorate of Surgery for example, while it is relatively easy to investigate, treat and measure aspects of orthopaedic practice concerned with, say an uncomplicated femoral fracture, (fracture of the femur or thigh bone), the same may not be true for the urological investigation and treatment of renal failure, (kidney disease), which can have multiple causes such as drug-related abuse, trauma or infection, or be related to other complications such as chronic heart failure or hypertension that require the intervention of a physician who specializes in cardiology.

Similarly, in the Directorate of Medicine, while it is reasonably straightforward to establish guidelines for the clinical management of acute respiratory diseases, in the investigation of a progressive illness such as acute lymphatic leukaemia, (a malignant disease characterized by large numbers of immature blood cells), although the diagnosis can be determined, pathologically, with a degree of certainty, the uncertain progress of the disease, which may periodically go into recession, represents a major constraint regarding the determination of normal or 'best' practice in respect of the treatment of the disease. Indeed, in such cases, it is common for ‘best’ practice, with regard to drug therapy, to be determined through randomised control trials (RCTs) that are a form of medical research regulated by a stringent ethical code, are usually organized at national or international level and are thus, outside the conceptual and technical scope of the audit initiative. However, this type of limitation is recognized and medical audit activities are thus intended to focus on practices that are ‘common’ within localities.

Nevertheless, it is clear that the focus of medical audit activity is not simply a matter of study design, data collection and analysis, but will vary depending on the disease profile of the population, the availability of relevant expertise, and the extent to which audit is appropriate in practical terms. Practical considerations include the number of patient episodes available for comparison, the availability of relevant data, the time and other resources available for the study, and the period over which the study is conducted. Where, for example, there are few local instances of a particular disease, the results of studies conducted over a substantial period may be invalidated by intervening results of research. Alternatively, supra-regional or local inter-unit audit can be considered, but it might prove difficult to implement changes in practice unless the unit representative is in total agreement with his/her clinical colleagues.
As with many other aspects of the recent reforms, the success, or otherwise, of the medical audit initiative is often assessed quantitatively, that is, with regard to levels of participation by medical staff, and in respect of the volume of audit activity with which they are associated. Moreover, in addition to the environmental, structural and technical constraints mentioned above (pp. 85-86), other directorate-level barriers to effective audit include social issues regarding personality conflicts and rivalries, access to and the availability of audit education, and the question of authority. In this latter context, those identified as 'lead clinicians' for the promotion of audit are not necessarily senior members of the directorate's medical staff. Indeed, during the uncertain formative period of audit implementation, it was not uncommon for the less senior consultants to be 'elected', by their more senior colleagues, to the 'non-remunerable position of lead clinician for audit'. Furthermore, there can also be conflicts, if not of interests, then of priorities when the posts of Director of Clinical Services, Clinical Director, lead clinician for audit, Chair of the Medical Staff and Chair of the LMAC all, or in some combination, fall within the remit of a single directorate, but are occupied by different individuals. Although new executive level arrangements (see pp. 74-75, above), together with the growing acceptance of audit as a 'legitimate and obligatory part of professional practice' have done much to overcome some of these initial 'social problems', the directorate-level organization of audit can result in the marginalization of minority opinion, especially that of the junior doctors. Consequently, definitions of what constitutes 'best practice' may thus amount to little more than the re-statement of what is already being done by those who perceive their interests to lie in continuity, and who may therefore, exercise any of the three Weberian forms of authority that are inherent within medical hierarchies. Nevertheless, the outcome or qualitative aspects of audit activities have had other variable effects in terms of their impact on practice and the integration of audit with other organizational issues. However, these kinds of variations and limitations have much to do with the question of data and data systems, with the flow of information and, most importantly, with the issue of confidentiality.

The majority of data required by provider units, not only for medical audit, but for resource management, budgeting, contracting and statutory reporting - many of which are new 'data consumption activities' - originate at the substantial interface between clinicians and their patients. Consequently, the sheer volume of such data, and the various new uses to which it must be applied have resulted in the recognition that health sector data management procedures and data capture systems were wholly inadequate. Large-scale changes are therefore either in progress, or have recently been implemented.
The operational requirements of the ‘internal market’ have effectively demanded that provider units develop fully integrated management information systems (MIS) such as that illustrated at Figure 14 (p. 66, above). Yet, central funding for projects of this scale has been limited to a small number of ‘pilot demonstration sites’ and has, in any event, ceased to be available. Other units were assisted, though to a lesser degree, as part of the Resource Management Initiative (RMI), but almost all hospitals have benefited from the capital element of funds that are intended to facilitate the development of information systems in support of medical audit. Nonetheless, variations in both regional and local policies, constrained to some extent by national policy on the distribution and use of audit funds, have resulted in the development of a diverse range of audit information systems, some of which are technically incompatible with either Resource Management (RM) or other integrated MIS. Such diversity includes the range of application software, hardware platforms and operating environments, and concomitant variations in training requirements and service maintenance contracts were, perhaps, inevitable. Subsequently, it has become clear that the contradictory and often ambiguous nature of central and regional audit funding guidelines must bear the brunt of the criticism for these latter developments.

On the one hand, although technical compatibility between audit and resource management systems was a major concern of the centre, the lack of relevant information technology (IT) skills at local level resulted in a correspondingly slow rate of RM systems implementation and denied LMACs the specialist support they required to properly execute their responsibilities for the use of the capital component of their audit budgets. To compound the issue, continued capital funding for medical audit depended on the ability of the LMACs to demonstrate, in their annual reports to the RHAs, significant and salient use of the previous year’s capital allocation. It follows, that the development of audit information systems was, in many instances, thus constrained to precede those relating to resource management projects. Consequently, some provider units, usually those in the ‘vanguard of audit development’, lost the potential to benefit from the economies of scale that would almost certainly have been available through the application of a more integrated procurement policy. The lessons from these early experiences have since been applied to subsequent IT developments which should result in a greater degree of technical integration between the various components of future information systems. However, the technical inconsistencies associated with earlier developments have not only limited the capacity for the expansion of some systems, but have also resulted in largely medical ‘ownership’ and control of audit data, and on the resultant use and dissemination of that data.
It would be both naive and inaccurate however, to imply that the medical profession’s control over data pertaining to the practice of its members can be explained solely in terms of technological determinism. There are, for example, other meso-level political reasons why early audit information systems did not always interface with Resource Management. First, the devolution of control over audit funds to LMACs was neither uniform nor complete, but where it did occur, there tended to be greater medical interest in audit development. Second, the lack of local expertise meant that management were also ‘blind’ to the strengths and weaknesses of alternative IT strategies. But, they expressed a comprehensive vision of the recurrent revenue implications of LMAC decisions and thus, since this latter issue was within their traditional sphere of competence, and was central to their new general role, it provided the primary focus of management attention on the use of the audit budget. However, in all other respects, the LMACs, to whom audit budgetary control had been devolved, were presented with an opportunistic occasion upon which they might fulfil their obligations in respect of the co-ordination and development of audit without really ‘caring less whether the Resource Management [systems] actually worked or not’. This ‘cavalier’ attitude, though characteristic of the past, has since been replaced by a more mature relationship between managers and clinicians, particularly since the latter are more aware of the opportunity and resource costs of their decisions: “Wastage of resources is unethical because it diminishes society’s capacity to relieve suffering” (BMA, 1993, p. 300). Nevertheless, RM was generally regarded by clinicians as a management-centred initiative. It was perceived in this way partly because of the relatively greater emphasis, than was evident with regard to audit, on ensuring the technical integration between the new RM computer software applications and existing management tools such as patient administration systems (PAS). Management ownership of PAS was confirmed by a frequent criticism, expressed both by clinicians and audit support staff, about their general inability to gain management authority to access PAS for audit purposes. This type of observation might therefore, be regarded as an example of internal political behaviour, but confirms that control over data in health care is perceived as a form of power. In a similar vein, medical staff displayed a comparable form of conduct by forming a protective ‘bull ring’ around the audit systems that they had helped to develop. Clinicians thus control the type of data entered into audit information systems and exercise a measure of direction over data entry through audit or secretarial support staff. In addition, by virtue of the rational-legal authority of the LMACs, they can control the use of, and access to, much of the data stored in such systems and though the reasons for the retention of such controls may be implicitly political, they are explicitly retained on the basis of ethical arguments about the principle of confidentiality.
The confidentiality of audit data is maintained through a combination of social and technical mechanisms. In a social context, these include the development of extremely close working relationships between consultant grade medical and audit support staff - though this relationship is commonly reinforced by 'signed confidentiality statements' that are essentially technical and potentially punitive devices that can result in an employee's dismissal for any breach of what are often ambiguously defined concepts of confidentiality. The directorate based organization of audit is also a social characteristic that protects both the confidentiality of data and of the information that can be obtained from its subsequent analysis and interpretation. Yet, here too, a variety of standards, written by professional colleges and that can be considered as 'technical specifications [instruments] for the conduct of audit', together with the formal unit-level constitutions that outline the terms of reference of the LMACs, also reinforce this latter aspect of the social system. However, these formal mechanisms often conceal rather simple technical devices that effectively limit access to audit data. At the level of the individual, control over data input, both in a physical or remote sense, that is, through other people, or by direct involvement in IT system design and 'data field definition', means direct personal control over information that relates to a clinician's professional practice, and, of course, medical staff have a substantial measure of influence at the patient interface where much data originates. At supra-regional level, control of specialty-based audit information is exercised through the device of 'data anonymization' - the National Confidentiality Enquiry into Perioperative Deaths (Campling et al., 1993) being a well known example of this process. At directorate level, the device of data aggregation is used to prohibit the individual identification of practitioners, and at provider unit level, control over audit related data is ensured through a process of generalization - (see Figure 17, overleaf). Thus, the higher the flow of audit data, the less meaningful it is for individual assessment. However, the mechanisms described above are designed to 'maintain the integrity' of the principle of confidentiality which, though often attacked by management as a mere substitute for unwarranted 'secrecy', has nevertheless, a degree of practical substance.

The International Code of Medical Ethics states that all doctors must ensure "...absolute confidentiality on all he [she] knows about his [her] patient" (BMA, 1993, p. 37). However, the BMA go on to argue that this "...council of perfection rather than [practice]" (Ibid.) goes much further than contemporary professional perceptions and that, in any case, confidentiality is a concept that is inherently contradictory. Moreover, managers also have an interest in the maintenance of confidentiality, albeit of a different nature, but one that could, paradoxically, undermine their desire for more open communication.
* The production of improved clinical guidelines does not necessarily result in changes in clinical practice.
On the one hand, the principle of confidentiality is regarded as the formal basis of trust between the doctor and his/her patient. Where such trust cannot be guaranteed, then the patient may withhold information that is crucial to their health status, or to the health status of others including patients, visitors or staff (BMA, Op. cit.) Confidentiality may thus be regarded, not only as a means of facilitating appropriate treatment, but as a necessary principle that underpins the management of risk. In either of these respects, there is little disagreement between managers and clinicians. Indeed, the new corporate identity associated with most provider units has constrained their management bodies to adopt a 'market sensitivity' to some kinds of information. However, poor clinical practice also creates potential risks to patients, and to the organization in terms of the financial implications of litigation if it can be shown that a provider unit does not have effective procedures for monitoring the performance of its staff. In this respect, unit-level discord is more common since medical audit is, definitively, concerned with clinical practice and not with clinical performance - though, given the emphasis on audit confidentiality, it can be inferred that there is at least an implicit relationship between the two. In short, while the GMC's proposed performance procedures might fill this void in the future (see p.p. 79 & 82, above), there are no current mechanisms at the meso-level for monitoring the effectiveness of individual practitioners. It follows therefore, that managerial reliance on medical audit as a measure of clinical effectiveness also means assuming corporate responsibility, and liability, for activities over which the management function has no direct control.

Nonetheless, given the absence of any alternatives, provider unit managers are not generally dismayed with either the conduct or development of audit. On the other hand, few can 'see any direct relationship between audit and quality assurance', and many are 'concerned about the lack of impact that audit has had on the rest of the organization'. Therefore, on the grounds of clarity, it is worth re-stating the distinction that medical audit is concerned with the quality of medical care, with ensuring that it meets acceptable standards, and does so through an educational process based on the peer review of practice. Medical audit is neither concerned with individual nor organizational performance, and certainly, in its current technical and organizational form, cannot influence organizational improvement - this is the purpose of TQM and the quality management function. However, in the sense that audit is conducted to the exclusion of other clinical groups who not only have a direct impact on patient care, but may also indirectly influence the outcome of medical interventions, then the medical audit concept, though not completely inadequate, is limited in scope for achieving some of its declared objectives.
With regard to this latter observation, and in respect of the issue of confidentiality, one further point ought to be considered however, viz, that precisely because medical staff participate in the creation of the data against which their practice is reviewed, and since they are directly involved in the analysis and interpretation of this data, then it follows that effective medical audit demands a guarantee that the 'good faith' that is central to the audit concept is not breached for punitive reasons. If it were, then the 'hidden costs' of poor practice would, by definition, remain hidden. This issue is one of several that have prompted recent commentators to express a measure of unease about plans to extend and integrate medical audit with similar activities conducted by other clinical groups (Lord and Littlejohns, 1994). Yet these authors underestimate, perhaps, the extent to which the various clinical professions in hospital settings are already occupationally interdependent and express a 'we already work as a team' measure of enthusiasm for continuing to do so. Moreover, in spite of the variations and limitations of medical audit, and despite the continuity of an element of scepticism amongst some doctors (Black and Thompson, 1993), the audit initiative has resulted in successes that are well documented elsewhere (see, for example, BMJ, 1994; Hopkins, 1994; Walshe and Coles, 1993).

Conversely, on the basis of the interpretations of the observations presented in this chapter, and on other limited evidence that reveals similar process related inadequacies in the audit concept, (Buxton, 1994 in BMJ, 1994, Op. cit.), it is not yet clear whether the social and technical constraints on audit can be sufficiently overcome to justify further investment in the initiative. Nevertheless, as Lord and Littlejohns (Op. cit.) further note, it is most likely that the question of continued audit and other quality related funding will be determined in the 'market' where increasing 'tensions' are creating a growing demand for more visible audit outputs. Planned changes in the source of audit funding may however, create further variations in both the level of commitment to, and effectiveness of, medical or clinical audit programmes. On the one hand, research has shown (Hopkins, Op. cit., pp. 111-120) that only 30 per cent of purchasing authorities receive copies of LMAC minutes and that an identical proportion of LMACs had no formal relationships with their GP counterparts in the Medical Audit Advisory Groups (MAAGs). Hence, there is reason to suppose that the level of interest in audit that will be expressed in financial terms by purchasers is likely to vary depending on the level of interest formerly expressed in terms of information by the providers. This would clearly result in inter-unit variation in the ability of providers to sustain the audit initiative, could potentially lead to inter-locality inequity in the quality of care and thus, impact on the ability of providers to retain contracts in the future.
On the other hand, a recent and somewhat frustrated 'we'd like to shut them down, be we're not allowed to' comment, made to the author by a lay member of a health authority, indicates that the early limitations on purchasers' placement of contracts has seen a partial revival as the centre focuses more of its energies on the 'managed' than on the 'competitive' elements of market relations. Moreover, the increasing emphasis on promoting mergers between DHAs and FHSAs (see Chapter 6, p. 64, above) constrains a similar conclusion, and suggests that the centre is becoming increasingly sensitive to the fact that, although a 'market' might prove to be more efficient, it rarely produces this outcome with equal effect on all of its customers.

Nevertheless, new funding arrangements will undoubtedly provide purchasers with greater influence on, and perhaps, greater responsibility for all quality developments within provider units. Thus, the need to compete on quality rather than simply on cost will become more pronounced and will therefore, create very real incentives for both managers and clinicians to expend more of their energies, collaboratively, to overcome the deficiencies and limitations of current arrangements for the conduct of medical and clinical audit. Yet, since audit is solely concerned with the quality of clinical care, and given the continuities and complexities of the social order within hospital institutions, it is unlikely that managers will gain any meaningful increase in their level of direct control over clinical practice. This, together with the realisation that patient and purchaser satisfaction is dependent upon their overall experience with or within the provider organization, provides sufficient grounds for concluding that provider unit managers will engineer a deliberate and planned change in emphasis from what has largely been a central concern with clinical quality to one that focuses the efforts of all members of the organization on the concepts of 'total quality' and 'continuous improvement'. 
CHAPTER EIGHT

THE APPLICATION OF TOTAL QUALITY MANAGEMENT IN HEALTH CARE PROVIDER UNITS

The origin, theory and methods of the Total Quality Management (TQM) philosophy have already been set out and discussed in Chapter Three. However, the application of TQM in UK health care is a relatively recent and limited development that has, on the basis of available evidence, largely failed (Ovretveit, 1994). Ovretveit cites four main reasons for this failure: first, continuing change caused by centralized political control over the NHS; second, the lack of investment in quality management; third, the complex mixture of internal and external customers; and fourth, the internal political nature of the NHS. In response however, it can be argued that: first, almost all developed societies are experiencing government intervention in health care, largely because of increasing costs; second, a central TQM argument, espoused by Crosby (1979), is that ‘quality is free’, that is, that the investment required to effect quality management is substantially less than the costs of poor quality and will thus, be cost-effective; third, a central tenet of TQM is its explicit emphasis on improving the quality of service to both internal and external clients; and fourth, market competition in the NHS is likely to become more centrally focused on quality rather than cost (see Chapter 7, p. 94, above) and thus, all health care professionals will be provided with the incentive to integrate internal social and technical processes in pursuit of quality improvement. Nevertheless, Ovretveit (Ibid.) acknowledges that two other reasons can account for the failure of TQM in the NHS. First, there is a general lack of understanding of both the concept of TQM and the technical instruments associated with its central objective, viz, Continuous Quality Improvement (CQI). However, it can be demonstrated that, while CQI is central to any meaningful quality improvement programme, TQM, as a philosophy, has little to do with quality and much to do with management. The second constraining factor is related to the above mentioned lack of technical awareness insofar as provider organizations have attempted to substitute external forms of standard setting and review, such as, for example, accreditation to one or other of the various industrial models that are available through the British Standards Institute or the International Standards Organization. Again, the limitations of these forms of what are effectively ‘quality assurance’ programmes, as opposed to quality improvement systems, have already been discussed and have been thus acknowledged by the King’s Fund Institute (see Chapter 3, p.26, above) which conducts ‘Organizational Audit’ on behalf of health care organizations in the UK.
In short, because of the limitations of both the application and success of quality initiatives in the NHS, the remainder of this paper will focus on the distinct features of TQM in health care by drawing on both the literature regarding the fate of TQM initiatives in the UK, the United States, where they have had greater exposure within health care provider organizations, and on experience of TQM implementation in US styled hospitals in the Middle East. While it is acknowledged that the socio-cultural and political environments of this latter setting are largely in-comparable with those of the NHS, a literary review of the US experience may be less so. However, the intention is to focus on social and technical issues that could be applied or be relevant to any health care setting. Nonetheless, where there are opportunities for meaningful comparisons to be made, then they will be included. For example, such a comparison is possible in terms of changes involving the general shift from direct resource allocation by governments towards a more indirect, though heavily regulated, form of contract negotiation and competition. Similarly, within this new context, developments such as organizational restructuring and the application of new technology that facilitate improved investigative procedures, for example, Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI), have, respectively, resulted in greater efficiency and higher standards of medical care. Nevertheless, the costs associated with technological developments, and the emergence of distinct agencies, Health Maintenance Organizations in the US for example, which have explicit third party responsibility for the purchase of health care, have combined to mount a formidable challenge to what has largely been a provider based monopoly over the question of health care quality. These changes, together with increased patient awareness of variations in quality standards, have created an urgent need for provider organizations to develop patient-centered total quality improvement environments within which their staff can begin to respond to social, economic and political demands for more care, better care and cost-effective care.

It is also relevant to note that the combined failure of external, internal and professional regulation, together with new forms of funding, to significantly improve the quality of health care is not unique to the UK experience. The US experience of similar approaches have shown that neither cost-and-volume contracts, professional review organizations (PROs), nor external accreditation have resulted in effective solutions for improving the quality of "...internal systems [and] processes" within provider organizations (Milakovich, 1991, p. 10). Indeed, "...cooperative opposition or passive resistance from primary care givers" (Milakovich, Ibid.) was a common outcome, and is similar in some respects to the lack of clinical involvement in TQM initiatives in the UK (Joss et. al., 1994).
Health care quality is often considered to be the preserve of the clinical professions because the ‘clinical intervention’ is usually regarded as the most important determinant of quality (Normand et al., undated). However, the complete and sustained involvement of all members of a provider organization is the cornerstone of any TQM initiative. Yet, in the NHS and elsewhere, when strategic business plans have been produced for service delivery and development, the issue of quality is often addressed in eloquent unit, directorate or departmental mission statements which ‘speak’, for example, of the “…holistic nature of patient care…the need for empathy with relatives and friends...[and] how the patient is the epicentre of all activity” when the reality is staff who are “…as frosty as the day and the mood on the ward [is] one of misery” (Henry, 1994, p. 35). Henry’s testimony is of course, anecdotal and may represent both an extreme and minority type of experience. Nevertheless, it does illustrate a common problem with many provider approaches to TQM insofar as, although they may present their vision of the concept adequately on paper, its practical manifestation is either inadequate or non-existent - perhaps because the primary purpose of the ‘business plan’ is to ensure continuity of income and provide a basis for the development of the ‘business cases’ that must be produced in support of bids for capital developments (Moriarty, 1994).

Yet, there is considerable evidence from health related TQM case studies in the US (see, Main, 1994, Ch. 11, for example), and agreement elsewhere, to support the assertion that, if TQM is to mean anything at all in practice, then it must become the central organizing concept of a strategic mission that is shaped and shared by all members of the organization who will thus, both individually and collectively, accept responsibility for its implementation (Milakovich, Op. cit., p. 10; Harrington, 1995, p. 91; JCAHO, 1991, p. 24; see also, Manning, 1994, pp. 24-26, for a brief, but salient discussion on the need to ‘redefine the purpose and function of health care organizations). This latter assertion is not unknown to most health care organizations however, but, given the constraints of their overtly political external environments and the complexities of their internal social and technical systems, the crucial problem that they face is that of how to gain, and sustain, the necessary commitment of their staff. Two approaches will thus be used to provide some practical suggestions for overcoming this problem. First, the solutions espoused by mainstream ‘quality gurus’ will be examined and discussed. Second, the results of structured observation exercises, that were conducted within provider units and reveal some of the relevant concerns and views of staff will be presented and their implications discussed in terms of identifying the strengths and weakness of the application of mainstream solutions to the world of health care.
Although the abundance of mainstream paradigms that have been used in industry to facilitate the implementation of TQM rarely share a common terminology, which is perhaps one of their major weaknesses, they do generally share a common vision of the major philosophical, social and technical changes that must be assimilated, effected and applied if the ‘search for excellence’ (Peters and Waterman, 1982) is to be successful. In philosophical terms, the single most significant factor concerns the requirement for a shift in organizational focus from profits to people, and on this basis, for continuous improvement through a change in emphasis on individual performance to processes performance, and on collective rather than individual responsibility. Within the social context of such paradigms, the issues of leadership, management style and organizational structure are of central importance while, in technical terms, the application of measurement techniques is considered, fundamentally, to underpin all other efforts.

On one hand, the change in emphasis from profits to people represents a strategic response to, and an acknowledgment of, the failure of regulatory and cost-containment policies to achieve desired improvements in productivity, particularly in service industries (Scherkenbach, 1986). Similarly, the combined orientation towards a concern with process and collective performance can be considered to represent an operational strategy that finally, and conclusively, recognizes the contemporary inadequacies of scientific management. The resultant cohesion that can be effected by re-aligning the control relationship between employees and their work-related processes is designed to bring ‘hands on’ expertise to operational problem solving and, though the most successful use of this strategy has been in manufacturing industry, it often results in mutual benefits to the individual in, terms of job satisfaction, and to the organization in terms of greater output capacity, reductions in the ‘down time’ of equipment, reduced ‘product failure’ and a correlative improvement in customer satisfaction. (1) Nevertheless, such transformations in organizational vision are fundamentally dependent on changes in management style and structure, and both of these are unlikely to occur without a dynamic and specific form of leadership. Such leadership is characterized by the willingness to learn about quality, about the central importance of the ‘customer’ and that there are multiple internal and external customer interfaces within most organizations. Yet, as Main (1994, Op. cit., p. 263) has illustrated, it is usually the most senior members of an organization who display the greatest reluctance to absorb and apply TQM Concepts.

(1) Based on the findings of a case-study into the results of a TQM initiative at the Harley Davidson Motorcycle Company, presented by Tom Peters during a televised presentation.
TQM thus presents the leaders of organizations with a fundamental personal challenge, for if they cannot be persuaded to extol the virtues of the concept in every aspect of their work, and be seen to do so, then both their individual credibility and that of the TQM initiative will soon be discredited. In short, if they are to effect the necessary transformations and changes in management style and organizational structure, then leaders must be seen, as one American colleague put it, to 'walk the talk'.

There is on the other hand, little that is new about the type of change that TQM implies for styles of management or organizational structures. Since, as outlined above, the concept of TQM is intrinsically concerned with changes in attitudes, values, perhaps beliefs, and certainly in organizational practices and procedures, it can be considered, and indeed usually is, essentially de-stabilizing in character. Thus, as Burns and Stalker (1961) have previously argued, an organic rather than mechanistic structure provides the most suitable form of organization, but is one that constrains a participative style of management, rather than the top down bureaucratic style that is commonly practiced in many organizational settings.

In sum, to gain employee commitment to the TQM concept, both the literature and the experiences of those who have traveled the TQM route suggest: first, the development of a corporate vision, and strategy for its implementation, that sets out the organization's purpose, clearly states its values and beliefs about both customers and employees, and, crucially, involves its employees in the development of such statements; second, that leaders must do so by example; and third, that management must delegate responsibility, and devolve authority to the lowest possible levels in order to provide their employees with a personal stake in the enterprise and to empower them to make 'front line' changes in working practices and procedures that will result in their greater contribution to the overall well-being of the organization and that of its customers or clients. However, effecting such change demands substantial financial investment in education and training, especially in quality management methods such as teamwork for example, and in the principles of measurement that are necessary to determine, monitor and improve process performance where possible or desirable. Moreover, in order to sustain commitment to quality management, and to maintain the 'learning culture' of the organization, continual investment will be required. Finally, all of these activities will require a similarly substantial investment in time since it is commonly believed that successful TQM implementation takes up to ten, but not usually less than five years - depending upon the complexity of existing organizational arrangements. What then, are the prospects for TQM in health care?
On the basis of the above discussion, and on that contained in the previous Chapter, some general observations can be made about TQM in health care provider units. First, there will need to be a greater level of 'ownership' of the corporate vision among middle-grade managers, doctors, nurses and other 'front-line' staff if the philosophies, values, beliefs and objectives of organizational business plans are to be achieved. The people who do the majority of the work also use, and thus control, the mass of available resources; but they are also centrally, and crucially, involved in direct interaction with the organization's 'primary customer', the patient. Although a clear sense of organizational direction must be established, the most important 'vision' will be that which is held by those who use or purchase the service. But, since this latter 'vision' is essentially conveyed through those people with whom the user most frequently interacts, it follows that it is the actions and attitude of the employee, rather than those of the CEO, which will ultimately determine how the organization is perceived in actuality. Moreover, the greater the number who share the corporate identity espoused by the board, the less there is potential for unintended subversion. In short, the first step on the road towards TQM is to ensure that everyone is walking in the same direction. Nevertheless, the route towards TQM in health care is likely to be littered with obstacles that are not found in other types of industry. For example, the increasingly bureaucratic form of centralized accountability that currently afflicts, or is planned to afflict the NHS will not easily be replaced by paradigmatic exhortations preached from the pulpit of private enterprise management consultancies. Control over health care in the UK is not merely about cost-effective and efficient use of the public purse, but has developed into a politico-ideological battle, between the somewhat ideologically confused anti-interventionists of the right and the reluctant collectivists of the centre, that is likely to continue at least until the electorate are given their next opportunity to comment on the future of one of their most revered institutions. Hence, whether in the name of TQM, or for any other reason, NHS provider unit managers, and possibly their purchaser counterparts, are unlikely to be able, in the short term, to significantly alter the formal structure of their occupational world. However, it is a world that is distinctly different from the conventional world of the quality guru. It contains an extraordinarily dynamic mixture of informal sub-cultures that are substantially interconnected by a mixture of professional ethics, work-driven interdependencies and entrenched traditional values that, in combination, may have the capacity to fly in the face of contemporary TQM wisdom and provide, nonetheless, a basis for its successful implementation. For, in spite of this anti-logic, the scope, indeed the need for some form of TQM in health care is partly illustrated in the views of some care-givers that are reproduced in Tables 2-4 overleaf.
<table>
<thead>
<tr>
<th>SOCIAL SYSTEM ISSUES</th>
<th>TECHNICAL SYSTEM ISSUES</th>
<th>RESOURCE &amp; ENVIRONMENTAL ISSUES</th>
<th>OUTCOME ISSUES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perceived Problems</strong></td>
<td><strong>Perceived Causes</strong></td>
<td><strong>Perceived Consequences</strong></td>
<td><strong>Perceived Outcomes</strong></td>
</tr>
<tr>
<td>Poor staff attitudes</td>
<td>Lack of education and training</td>
<td>Lack of investment</td>
<td>Poor quality of staff</td>
</tr>
<tr>
<td></td>
<td>Recruitment problems</td>
<td></td>
<td>Shortage of skills</td>
</tr>
<tr>
<td></td>
<td>Lack of finance</td>
<td></td>
<td>Stress</td>
</tr>
<tr>
<td>Poor management communication</td>
<td>Inadequate communications policies and procedures</td>
<td>Poor staff facilities</td>
<td>Lack of commitment</td>
</tr>
<tr>
<td></td>
<td>Inappropriate reporting arrangements</td>
<td>Poor working environment</td>
<td>Dissatisfied staff</td>
</tr>
<tr>
<td>Low technical standard of work</td>
<td>Absence of written protocols</td>
<td>Failing internal bleep and telephone system</td>
<td>Feeling of lack of appreciation of staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Absence of standard performance measures</td>
<td>Lack of organizational discipline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lack of relevant and timely data</td>
<td>Lack of positive reinforcement incentives</td>
</tr>
</tbody>
</table>

**Note:** These findings are presented from an employee perspective. But, if re-interpreted from a quality management perspective, Column 1 can be considered as the small minority of 'Underlying Causes' of the vast majority of the 'Problems' identified in Column 4, and Columns 2 & 3 can be transformed into potential solutions.
### TABLE 3: DIAGNOSTIC REVIEW: TECHNICAL SYSTEM QUALITY PROBLEMS: THEIR CAUSES & EFFECTS - IDENTIFIED BY EMPLOYEES

<table>
<thead>
<tr>
<th>TECHNICAL SYSTEM PROBLEMS</th>
<th>LEVEL</th>
<th>OUTCOME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over-booking of appointments</td>
<td>Process</td>
<td>Unacceptable waiting times</td>
</tr>
<tr>
<td>Incomplete Discharge Summaries</td>
<td>Individual</td>
<td>Delay in discharge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay in communication of results to GP</td>
</tr>
<tr>
<td>Out of date or inappropriate Guidelines or Protocols</td>
<td>Process</td>
<td>Inappropriate treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ineffective treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inefficient use of resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Opportunity costs</td>
</tr>
<tr>
<td>Missing medical records</td>
<td>Process</td>
<td>Unacceptable delay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unacceptable risk to health status</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inefficient co-ordination of inputs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss of data</td>
</tr>
<tr>
<td>Inappropriate use of investigative procedures</td>
<td>Individual and process</td>
<td>Inefficient use of resources</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Avoidable discomfort</td>
</tr>
<tr>
<td>Non-availability of information</td>
<td>Process</td>
<td>Lack of performance feedback</td>
</tr>
<tr>
<td>Poor communications</td>
<td>Process and Resources</td>
<td>Lack of co-ordination and co-operation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Creation of conflict</td>
</tr>
<tr>
<td>Out of date technology</td>
<td>Process and Resources</td>
<td>Limited services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lack of personal and professional development</td>
</tr>
<tr>
<td>Incomplete and illegible documentation</td>
<td>Individual and Process</td>
<td>Lack of accurate data</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Overuse of resources through re-work</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Delay in service provision</td>
</tr>
<tr>
<td>Inadequate review of practice</td>
<td>Process</td>
<td>Lack of information and feedback</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hidden costs of poor quality</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lack of opportunity for improvement</td>
</tr>
</tbody>
</table>

**Notes:**

1. As with Table 2 (overleaf, above), from a quality management perspective the 'Outcomes' would be perceived as 'Quality Problems', and the 'Problems' considered to be their 'Underlying Cause'.

2. By focusing on the potential locus of the problem, some indication can be made about whether the problem is 'sporadic' in nature (Individual Level), or 'chronic' in nature (Process Level) - see Chapter 3. Nonetheless, measurement of the scale of the problem will usually be necessary to effect a solution.

3. Although the above issues were identified as pertaining to the 'technical system', they may be influenced by aspects of the management style or structure of the 'social system'.

4. The data presented in the Tables in this Chapter were collected at 3 day TQM seminars during observations of structured exercises involving provider unit staff who had no prior exposure to the concepts of quality management - though these exercises were deliberately designed to occur on the last of the three days when it is assumed the subjects had some understanding of such concepts.
### Table 4: Diagnostic Review: Problems & Solutions for TQM Implementation

<table>
<thead>
<tr>
<th>TQM Implementation Problems</th>
<th>TQM Implementation Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fear of job losses</td>
<td>Empower staff to make changes</td>
</tr>
<tr>
<td>Fear of failure</td>
<td>Ask staff where to make changes</td>
</tr>
<tr>
<td>Lack of management support</td>
<td>Management must demonstrate commitment</td>
</tr>
<tr>
<td>Negative attitudes of colleagues</td>
<td>Education and training</td>
</tr>
<tr>
<td>TQM not value for money</td>
<td>Cut the costs of poor quality</td>
</tr>
<tr>
<td>Lack of training</td>
<td>Provide in house training</td>
</tr>
<tr>
<td>Need to focus on patients basic needs</td>
<td>Prioritize aims</td>
</tr>
<tr>
<td>Lack of a unified staff structure</td>
<td>Work in teams</td>
</tr>
<tr>
<td>Inappropriate use of working hours</td>
<td>Reallocate staff where needed</td>
</tr>
<tr>
<td>Budget constraints</td>
<td>Isn’t that the whole point?</td>
</tr>
<tr>
<td>No hospital development plan</td>
<td>Produce Five Year Service Development Plan</td>
</tr>
<tr>
<td>No development plan for TQM</td>
<td>Put ‘quality’ at the top of the agenda</td>
</tr>
<tr>
<td>Maintenance of old rules and regulations</td>
<td>Remove them</td>
</tr>
<tr>
<td>External influences</td>
<td>Identify them</td>
</tr>
<tr>
<td>Lack of communication</td>
<td>‘Walk the talk’</td>
</tr>
<tr>
<td>No follow up after initial TQM training</td>
<td>Identify issues</td>
</tr>
<tr>
<td>Inconsistent decision making</td>
<td>Involve staff in decisions</td>
</tr>
<tr>
<td>Potential loss of control</td>
<td>Establish a steering team</td>
</tr>
<tr>
<td>No open door management policy</td>
<td>More management visibility</td>
</tr>
</tbody>
</table>

**Notes:**

(1) The group which produced the above data was comprised of six teams of eight participants. Each group included members of the following professions: Nursing (7), Medicine and Dentistry (24), Management(1), Maintenance and Engineering(2), and Clinical Support Service Staff (Radiology (1), Pathology (3), Pharmacy (2), Physiotherapy (1) and Respiratory Therapy (1). In addition, six participants represented Non-Clinical Support Services (Medical Audit (1), Catering (1), Ambulance Services (1), Quality Management Services (2) and Housekeeping (1). The data are aggregated from the responses of each group and reveal a considerable degree of consensus.

(2) Although the group can thus be considered to be reasonably heterogeneous, and again, the exercise was conducted on the last day of a 3 day training course, the responses are likely to have been substantially influenced precisely because the participants had just been exposed to TQM concepts. However, the strong presence of the medical profession is noteworthy, as is the weak representation of management.
It is common in the early phases of any health care quality management initiative, for employees to react, to what are essentially unrecognizable propositions, by responding defensively and, though unwittingly because of their lack of exposure to method and measurement, sometimes inaccurately to questions about the quality of care or standards of service. This is, to some extent, illustrated in Table 2 (above, overleaf) where a quality management analysis of the same issues would lead to rather different conclusions than those drawn by respondents. For example, the small number of quality ‘problems and causes’ perceived to be located within the ‘social and technical systems’ can be considered rather, as the ‘immediate causes’ of the many ‘outcome’ issues (problems) illustrated in column four. In a textual form the argument is thus:

‘...the lack of education and training, difficulties in recruitment and the shortage of funds that constrain a low level of investment, are responsible for the shortage of skills that cause employee stress due to the inappropriate use of their skills that results in low morale, a lack of motivation, poor attendance, inter-staff conflict, yet implies that it is the attitude and quality of our staff that is the problem when, in fact, this is clearly not the case’

This indulgence into what can might be regarded as an element of poetic licence is not however, intended to mock or alter the testimony of the respondents, but to illustrate the often complex and sometimes hidden relationships between dependent variables that have not, or cannot, be subjected to a form of measurement. Measurement is central to the management and improvement of quality, but, the value of the exercise outlined in Table 2 is that, had it not been conducted, we would not have known where to start measuring in the first place. The involvement of staff in the ‘focus’ stage (see, Chapter 3, p. 36, Figure 8, above) of the continuous improvement process is thus, both necessary and central. A similar, though perhaps clearer, argument can be developed on the basis of the data contained in Table 3 where issues identified as ‘outcomes’ are in fact, quality problems that might be caused by what are mainly process failures. The importance of identifying the locus or nature of a quality problem has been discussed above (Chapter 3, pp. 24-25) but, to restate the point, ‘sporadic’ problems, usually individual or functional in nature, and ‘chronic’ problems, mostly process related, have distinct methodological implications for their resolution. Moreover, it is clear, that when employees are brought together to address the question of ‘poor quality’, as distinct from the more usual type of forum that produces standards for ‘good quality’, then the range of issues that are identified and the resultant scope for improvement is likely to be far in excess of that produced by traditional quality assurance.
However, perhaps the most revealing testimony is that contained in Table 4 (p. 103, above). Here, respondents were asked to identify the major constraints and potential solutions for the implementation of TQM in a health care provider setting, and, in doing so have illustrated one major difficulty that they did not actually identify, viz, that all of the potential barriers that were identified have something to do with someone else! Although this 'defensive' stance is common, for reasons already outlined, it represents a considerable hurdle in large organizations such as hospitals since there will likely be a pervasive 'wait and see what someone else does' attitude before individual employees will commit themselves in earnest to a new and largely unproved form of activity. In short, if nothing else, this subtle revelation reinforces the need for clear, decisive, consistent and unwavering leadership on the part of senior management. Moreover, Table 4 also illustrates an element of simplicity attached to the TQM concept since the suggested solutions to many implementation problems are merely the antithesis of the problem itself. Yet, such simplicities may be rare in the health care arena where the TQM concept probably does require a major 'paradigm shift' (McLaughlin and Kaluzny, 1990, p. 7) in terms of the way that the health care professions both think about and conduct their work. The explicitly participative style of TQM contrasts sharply with the long tradition of professional authority and autonomy enjoyed by doctors, and the concept of empowerment must sit uneasily on the shoulders of those who have only recently been given greater control over administrative issues. Hence, managers too, will need to work hard to overcome the organizational and operational contradictions with which they are confronted.

In sum, in an 'industry' where the safety of the 'customer' and of the 'customers purse' are largely regulated by statute, the management of quality in health care will, for the time being, depend upon the continuation of a three dimensional strategy which includes professional self-regulation and professional audit together with a determined and sustained effort to harness the efforts of the considerable human potential that exists within the social organizations of health care provider units. While there are many social, economic, political and professional grounds for the development of total quality management in health care, it cannot be the same TQM that has been applied with varying degrees of success, and failure, in industry and commerce. It can however, if pursued with integrity, clarity and honesty, be adapted and integrated with other initiatives such as Medical Audit for example (see, Chapter 3, Figure 8, p. 36), to provide those who actually deliver care and services with the methods they require to measure, monitor and continually improve the processes within which they are required to work.
CHAPTER NINE

CONCLUSIONS

The Eleventh International Congress of the International Society for Quality in Healthcare, held in Venice in May, 1994 was described as a 'nostalgic' occasion (Palmer, 1994), and, in a word, illustrates both the problems and the promise for health care quality in the UK. On the one hand, while much of the developed World in the Americas, Europe and Australia were learning from their journey through 'quality control', 'professional audit', 'accreditation', 'quality assurance' and finally on to 'total quality management', we in the UK, having taken the 'quality assurance' concept on board at somewhere around 1989AD, have quickly abandoned what had never really worked anyway (see Chapter Three), and have, or might think we have, finally caught up with the latest in a long line of fashionable attempts to get more out of less for nothing. A contentious condemnation, perhaps, but if we consider the substantial financial investment that has been made in Medical Audit to promote something that was already happening anyway (see Crombie et al., 1993, in Chapter Two) it may be prudent on the other hand, to capitalize on being one of the 'last industrial nations' to jump on the quality management bandwagon and reflect, reconsider and try to devise a workable implementation plan rather than attempt to persevere with a concept that has simply not worked in the way it was supposed to, and thus, is in need of 'continual improvement', albeit, one that will be achieved by the same level of intellect that created it in the first place. Consider Peters (1992, quoted in Main, 1994, p. 308) for example:

\textit{TQM is flawed...or so I used to think. Now I think it is fatally flawed. Prediction: Twenty years from now, when the history is written of the epic transformation of American business during the 1980s and 1990s, TQM won't even get a footnote (though maybe a couple of laughs).}

Peters is, according to Main (1994, p. Ibid.), attacking the manner in which the TQM concept has been executed - "...efforts that are all charts, graphs, meetings, and procedures, with but little empowerment or results" - rather than being critical of the concept itself. In many respects this is sufficiently similar to the findings of this research to provide an authoritative basis for conclusions that might be considered by some health care practitioners to be just a little more than contentious given that they are based on something other than the rigorous methods of the positivist approach to which they are more accustomed.
The findings of the study, with regard to the Medical Audit initiative, will be presented within the context of the environmental and socio-technical issues outlined in Chapters Six and Seven respectively, and will be discussed in relation to the conceptual design of the audit process that is described in Chapter Two. Similarly, the findings in respect of Total Quality Management will be presented within the context of the assessment contained in Chapter Eight, and with due regard to relevant aspects of the environmental and socio-technical issues outlined in Chapters Six and Seven, but will be discussed with reference to the conceptual design of TQM which is described in Chapter Three. Finally, the limitations of the findings will be discussed in relation to the research methodology which is outlined in Chapter Five.

The systematic review of medical practice that is 'Medical Audit' is both a necessary and increasingly important activity that has proved to be technically successful in improving the quality of medical care. Such successes, the result of both national and local audit studies, are regularly published in the appropriate journals or as publicly available reports, and there mere existence provides one indication that audit is a necessary activity and is recognized as such by all of the Royal Colleges who continue to support and promote the audit concept (see for example, Hopkins, 1994, Section 2 especially). In addition, the importance of audit, from a provider perspective, is implied by the growing maturity and influence of the health authorities who, in forging links with other purchasing organizations, will have greater financial potential to exert pressure for demonstrable improvements in provider performance (see Chapter Six). Such pressure may, for example, result from the economic logic of contractual negotiations that establish a lower unit cost per case in return for larger service contracts that effect a greater level of throughput. The review of medical practice will be thus become vital to ensure, if nothing else, that socially, professionally and contractually acceptable standards are maintained. Indeed, the forthcoming allocation of audit related funding to purchasers, for distribution through the contractual process is likely to provide the audit process with a clearer sense of direction by virtue of what might become a mandatory requirement to focus on specific issues. Similarly, the likely managerial control over such funds, given their contractual integration with other income, may also provide a basis for a more central role for managers in the audit process. In sum, both the process of medical audit and the results of audit activity are likely to come under a larger microscope than has hitherto been the case. Yet, in both senses, it may be found wanting. This conclusion is constrained as much by the evidence that is not available, or is inconclusive, as it is revealed through an examination of the socio-technical systems within provider units.
On the one hand, Buxton (1994, p. 33) has argued that the "...skills and commitment" that are necessary to substantiate the 'systematic' criterion contained in the audit definition (Chapter Two, p. 14, above) are simply not available. This claim is partly underpinned by Hopkins (1994, p. 118) who reveals that "Many consultants" are not over enthusiastic about either the audit process or the methods used to conduct audit review. Buxton (Ibid., pp. 31-34) supports his arguments on the grounds of the technical inadequacy of the audit process with reference to 'inadequate sampling', questionable standards, the lack of 'research underpinning' and of 'scientific audit'. However, it is not clear whether he is confusing audit with research, suggesting that audit ought only to be conducted on the basis of recent research, ought to become a research activity, is merely limited by the absence of social 'scientific' (sampling) skills, or is inadequately based on 'local' standards that are derived from local experience of the application of existing knowledge on a particular population. Buxton may of course, be suggesting all of these, but might be challenged on the latter on epidemiological grounds, and on the basis of the argument, outlined in Chapter Two, about the distinction between audit and research. Conversely, he can be supported in general terms, as can Hopkins (Op. cit.), who bases his findings on the results of survey research, in the sense that it is the conceptual adequacy of the audit initiative that can be criticized for its substantial failure to create a greater impact - a failure that has much to do with provider unit social and technical systems rather than the technical adequacy of audit methods. Three issues support this conclusion. First, the nature of the work, and the historical development of audit may have constrained different levels of participation and effectiveness of discipline specific audit programmes. Surgery, radiology and obstetrics for example, gain from the long history of audit with which they are associated (Chapter Two, p. 15), surgery also, from the association of 'measurement' with the precision of cutting and sawing, radiology from its inherently investigative and thus, by implication, inquisitive nature, and obstetrics from the technological advances, such as ultrasound, that have facilitated a large degree of precision and prediction in child birth. Pathology has also gained from the automation of much of its work and the related development of a system of Quality Controls used to measure the upper and lower control limits of calibration settings for instruments. These measures are plotted daily, on run charts that can be accessed by any member of staff to determine degrees of confidence in the results of tests, variation is identifiable prospectively and 'sporadic' problems thus addressed with sufficient speed to maintain a high level of performance. Conversely, more artistic disciplines, such as internal medicine, or the somewhat subjective world of psychiatry for example, have greater difficulty in applying measurement techniques to their work and thus, variation in audit activity or its impact is almost inevitable.
Second, social relations in health care also impact on the technical system, and on the audit process. In respiratory medicine for example, much of the medical work involves interaction not with other doctors, but with respiratory or physiotherapists - professional colleagues perhaps, but not professional members - and, in what is effectively a sub-specialty of internal medicine, since "...most people are converted [to audit] by their colleagues" (Stocking, 1994, in Hopkins, Op. Cit., p. 135), such single handed 'specialists' will have less opportunity to interact, locally, with similarly qualified colleagues and will thus, be less susceptible to 'conversion'. However, there are other adverse 'social system' influences on the conduct of audit, of which the question of ethics is, though perhaps the least visible, is one of the most profound. For example, it is not possible, for practical reasons, for a Clinical Director, say a specialist in gastroenterology, to influence the specialist practice of one of his 'managed' physicians, say a cardiologist, indeed, the former will often require and must accept the clinical advice of the latter if cross-specialty referral is required. Yet, if it were possible for such influence to be exerted in practical terms, it is prohibited on ethical grounds (see Chapter Seven). Thus, all than can be achieved in a formal sense, regardless of the adoption of directorate structures, is that a doctor be directed to conduct audit review, but his or her application, commitment and output is largely a personal matter.

Finally, the local internal environment of a provider unit may, or may not, have been equipped with either or both a Resource Management information base and medical audit information system. However, where such systems are distinct, then ownership is also commonly distinct with the medical staff controlling the latter and management the former. At directorate level, this lack of systems integration can result in the medical secretary working within an audit system, inputting data and producing automated, and thus improved, discharge summaries, while the divisional manager and his or her secretary use different computer hardware and software to access the resource database and update the financial status of the directorate. In short, the contradiction caused by the poorly planned or incomplete development of information technology (see Chapter Six, including figure 14) is that while data pertaining to clinical practice is entered into one system, there is no integrated link with cost-related activity data in the other. Some units will on the other hand, have developed fully or partially integrated systems, but this will inevitably result in, and to some extent explains, inter-unit variation in audit activity. In addition, such variations may be exacerbated if audit funds are more unevenly distributed through the contract system, though, if anything, this possibility should spur both managers and clinicians to greater efforts to improve a process that has been found to be somewhat conceptually inadequate.
Total Quality Management is less well developed than professional audit in UK health care, but may, if implemented in the form of the industrial TQM model, prove to represent a policy variant of the common ‘unrecoverable application error’ generated within computer systems. Again, though with different emphases, the reasons can be found within the socio-technical and environmental contexts of health care provider units. On the one hand, the industrial model of TQM clearly demands both an organic organizational structure and highly devolved style of management (see Chapter Eight). Yet, the complexities of the purchaser-provider relationship, together with continuing uncertainty about the ‘what’ and ‘when’ of the next stage of an almost continuous period of change, have substantially filled the managerial agenda to the exclusion of many other important operational issues. Moreover, as Figure 15, Chapter Six, p. 77, above) illustrates, neither the operational sphere of influence nor the realistic span of control of the general manager are conducive to the application of the type of leadership role that they would be deemed to assume within the industrial model.

In addition, the almost complete erosion of democratic accountability has forced NHS managers to publicly restate the integrity of their role at the interface between a powerful external environment and a complex local arena adding to the multiplicity of formal relationships of new relationships, responsibilities and accountabilities that have resulted from a complex, contradictory and potentially hostile environment within which the contemporary provider unit manager must mediate the resultant conflicts of interests between the state, the hospital, the employee and the patient. TQM might however, represent the greatest potential for conflict, at a time when it would clearly not be advisable, since it challenges the very basis of professional autonomy and traditional authority that is held so dear by the medical, and perhaps other professions, and is underpinned by the persistency of the ethic of confidentiality.

Furthermore, a major implication of the continual quality improvement (CQI) process that is so central to TQM is the need to collect relevant and timely data, as close as possible to the source that generates it, to reduce the potential for error. Yet, given the sheer volume of activity that occurs within a hospital setting, the availability of an integrated Management Information System is thus a practical precondition for meaningful CQI, but, for reasons outlined above, is unlikely to be forthcoming, at least in the short term since, like audit, funding will need to be extracted from the total value of contracts placed with purchasers who may, or may not, be inclined, or be able, to promote such developments and will likely prioritize on, and persevere with the less costly manual process of peer review.
Finally, representatives of the primary 'customer', the patient, are unlikely to demonstrate any substantial support for what is a relatively untried and untested, but potentially costly programme. In the survey previously referred to above, it was revealed that only 2 per cent of LMACs reported that they had arranged to conduct audits on behalf of their local Community Health Councils (CHCs). Similarly, only eight CHC members were reported be members of one or other of the 187 LMACs who responded to the survey (Hopkins, Op. cit.). Though this may be substantially due to shortcomings in communications regarding the conduct and effectiveness of medical audit, it may impact on the perceived credibility of other quality initiatives. In short, there is likely to be little external demand for a concept that is little understood. Nor, given that the internal re-organization of provider units has, in some respects, strengthened the medical voice, will there likely be much internal enthusiasm for TQM in the format designed by private enterprise. In spite of the greater managerial role of some consultant medical staff, the continuities of the established social order, and the planned extension of professional self-regulation (see Chapter Seven, especially GMC, 1992), represent considerable constraints for further, self inflicted, change. Nevertheless, as the overview of the TQM concept in Chapter Three (Figure 6) illustrates, there is a need, if meaningful improvement is to be made in health care delivery, for a change in orientation from functional to process based management. Since the outcome would, or should result in better care and increased patient and staff satisfaction, then it is perhaps, to the professions that the TQM concept should be addressed for pre-implementation modification to ensure that when the stage for take-off is eventually reached, total means everyone, management means devolved responsibility and authority, and 'quality' is transformed into demonstrable continuous improvement. Small scale trials can be conducted within cohesive units such as the clinical laboratory for example, where both the internal structure, the availability of relevant skills and the nature of the work, in brief, the social and technical systems, are reasonably compatible with quality management (see Chapter Three, Figure 9, p. 37). In its current form however, TQM, like audit, is also conceptually inadequate, though perhaps not internally, but in the sense that it simply cannot be effected within the current socio-technical systems and environmental settings that are entrenched within health care provider units. Medical audit can also be integrated (see Chapter Three, Figure 8, p. 36) as can risk management and external accreditation, all have some role to play in an environment where the safety of the customer is, fortunately, regulated as much as the 'customers purse' - but, rather like golf, the secret of the game will be to determine which one to use, for what purpose, and when. Quality is never an accident, it is the result of high intention, sincerity, integrity, and, above all, effort - and, it takes time.
The methodological limitations of these findings must however, be briefly discussed. On the one hand, less attention was given to the successes of audit and other quality management initiatives on the grounds that where these have occurred, they are generally available for review. The research focus was thus directed to seek out the reasons for the limited impact of quality initiatives, but in doing so will, however justifiably, display an element of bias, the difference between what was observable and what was observed, against those enthusiastic former and current colleagues who provided, wittingly or otherwise, much of the material upon which this thesis is based. Nevertheless, they are, and they know they are, in the minority. Thus, if some insight should result from the material thus presented, and further progress can be made, both their efforts and those of the author might prove to redress the imbalance.
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