Quality management in the NHS: the doctor's role—I

D M Berwick, A Enthoven, J P Bunker

The doctor and the patient enter the examining room and the door is closed. For even the most jaded doctor and the most cynical patient the click of the door catch creates a special and privileged space. In that space trust can develop, needed disclosures can occur, tears can flow, lifelong burdens can be lifted and explored, and information of the most delicate and significant character can flow from one attentive human being to another. Doctor, patient, and society have conspired to create that space because, in the end, we all need it.

But no door bolts tightly enough to exclude the realities that have come to besiege modern medicine. Doctor and patient can ask for—and have a right to—privacy, but they will not be assured insulation from the times. Real life enters the consulting room through seams and pores. Care costs too much in America, and payers are asking why. They are studying the practice of medicine and manipulating the rules of payment. Studies show levels of variation in clinical practice that offend logic.¹ Patients, made wary by newspaper accounts of malpractice and by their own experience of rushed, insensitive systems, approach formerly trusted doctors with increasing confusion and uncertainty. Doctors, experiencing the unexpected burden of scrutiny and accountability, become unhappy in their work, defensive, and perhaps even emotionally less available to the patients who need them.

To be sure some of these trends have been far more pronounced in the United States and in several western European countries than in the United Kingdom. In the United Kingdom the NHS as a structure has tended to diffuse the anger and anxiety that has come to characterise medical care in the United States. In addition, the cost of health care—the most important single source of pressure on the American system of care—has been maintained in the United Kingdom at a remarkably low level (as a percentage of the gross national product). Health care absorbed 11.8% of the United States gross domestic product in 1989, but only 5.8% in the United Kingdom.² Though it has taken its share of criticism for its queues and rationing choices and for the development of a privileged private care market, the NHS remains overall a system that compares favourably to the American system in its commitments to equity of access and cost control.

But the seams of the NHS are worn thin. Expenditures, though rising more slowly than elsewhere, are a matter of increasing political controversy. There are widespread concerns that care is too often delayed, that access to technology is too severely rationed, and that NHS resources have failed to keep pace with needs. Complaints of deficiencies in service levels have become commonplace. It seems unlikely that increases in spending alone can cure this. Moreover, the full potential of truly community based care that the regional and district structure offers has never been fully realised. As in other countries trying to absorb the wonders of high tech medicine, health care in the

United Kingdom has become fragmented in its relationships among general medicine; public health medicine; and hospital based acute, largely technical care. A system that would best operate as a seamless whole works instead in functional compartments that leave many patients unhappy and providers of care frustrated. For some even the quality of care provided in the NHS is now seriously in doubt.³

NHS reforms

One of us (AE) has suggested that the seeds of poor service, fragmentation, and rising costs were planted in the very structure of the NHS.⁴ That structure has survived because of the quality and dedication of the people who work in it and the underlying social commitment to equity, but it lacks strong incentives for the improvement of care and service. In fact, the incentives regarding improvement in the NHS have been perverse: better performance may be associated with higher workload but without a commensurate increase in resources. The widely criticised waiting lists for inpatient surgery are one result.

Recent reforms in the NHS have been directed toward establishing structures and incentives that can encourage quality and efficiency.⁵ The reformers of the NHS intend to make it more sensitive to the needs of those who depend on it for service and care and to encourage providers of care to discover better ways to do their work. Under the new rules those who improve their performance would benefit from increased resources with which to handle their expanding share of the medical marketplace.

The central idea is to create incentives for improvement by creating internal “markets” among components of the health care system. Under the new rules the district health authorities become selective purchasers of services that they were formerly obliged to “purchase” only from themselves. It now becomes the duty of the general manager of the district health authority to seek better deals for the patients for whom he has responsibility. With a fixed budget it is in both the patient's and the manager's interest for the authority to contract for services not only at lower prices but with better outcomes, as a poor outcome may necessitate further treatment at additional cost. When the general practitioner is the budget holder it is similarly in his or her interest to contract for the most cost effective care available.

From the perspective of classical economic theory structural reforms based on a market model seem to offer a particularly attractive solution. They suppose improvement to occur as a result of reliable, natural laws of economics in which customers and providers find efficient solutions to their respective needs and constraints. With three basic components—freely available information on the quality of available goods and services, consistent and rational buyers, and competent producers—a market can unconsciously

Harvard Community Health Plan, Boston, Massachusetts 02215
D M Berwick, MD, *associate professor*

Graduate School of Business, Stanford University, Stanford, California 94305
A Enthoven, PhD, *professor*

CRC Clinical Trials Centre, King's College School of Medicine and Dentistry, London SE5 9NU
J P Bunker, MD, *visiting professor*

Correspondence to: Dr D M Berwick, 131 Lake Avenue, Newton, Massachusetts 02159 USA.

BMJ 1992;304:235-9

(through the "invisible hand") achieve efficiency and quality levels beyond those attainable by even the most talented planner.

Failures in market conditions of health care

The problem, of course, is that the conditions of an effective market have not been met in medicine. Information by which to judge the quality of medical care is inadequate and has not been freely available to the purchasers of care, whether patients or their agents, insurance companies, or the government. Purchasers of care in America, again whether patients or their agents, have been inconsistent and often seem irrational in their demands and expectations. Evidence of variable quality and widespread "inappropriateness" in the medical care of both countries³ has cast doubt on the competence of the producers of medical care—doctors, hospitals, and others. No one in health care seems to face simultaneously all of the costs and benefits associated with his or her decisions, and there seems to be no market forcing all to make responsible, cost conscious, consistent choices.

The concerns about health care go far beyond worries over the competence of individual clinicians. They are concerns rather about the properties of the system of care—a system in which excess costs and failures in quality can occur despite the best intentions and the best efforts of the people involved.

These imperfections in the medical marketplace are the object of much activity in the United States, and are addressed directly in the plans for a revised NHS in the United Kingdom (while still trying to retain universal, comprehensive services, financed by tax and free at the point of service). In both countries many propose to solve deficiencies in information with more aggressive and sophisticated forms of measurement and publication of the results of care, often using new and powerful computer technology. American payers and regulatory agencies have vastly increased their demands that hospitals release data on their own performance, and in at least some states laws have been passed requiring that hospitals purchase commercial software packages allowing standardised reporting of both the costs and outcomes of care. Recently American doctors have begun to be drawn under the same microscope of performance measurement. In the proposals of the NHS reforms measurements of performance of care givers will also be intensified.

Better information should lead to more consistent and rational behaviour of buyers. The current governmentally supported development and promulgation of standards and preferred practice guidelines in the United States, its sponsors hope, can help to inform a confused public as well as to control the variable practices of the medical profession. In addition, there is renewed interest in financing reforms designed to shift a portion of payment from insurance systems to the pockets of patients themselves, so that the patients become more "sensitive" to the costs of the care they consume and, presumably, therefore consume that care more prudently.

Under the NHS reforms the job of making cost effective and consistent market choices will fall largely on the district health authority and on budget holding general practitioners, whose choices are supposed to reflect priorities among the needs and desires of patients. Purchasing services on behalf of patients is a new responsibility, of which these decision makers have had little previous experience. While there has been some success in the cost effective contracting for care by insurers in America, the obstacles are many and the start up process will be difficult, requiring new data, new data systems, and new skills. Much assistance could be made available, however, from the largely

untapped epidemiological and quantitative knowledge of the public health doctors.

Management of care and its quality: the missing link

Better and more widely available information on the outcomes of medical care, together with consistent and rational purchasers, are essential to an effective market, but these alone are insufficient to produce real improvement in quality. For improvement in effectiveness and efficiency to occur the producers of a good or service must also have the capacity to improve performance and to function in a system that facilitates improvement. Of course, if the marketplace is already replete and competent producers working in an optimum system, information and consistent buyer behaviour may achieve a great deal by putting the incompetent out of business—a darwinian solution to the pursuit of excellence. But when the problems of production are more diffuse—that is, when excellence is not the rule or deficiencies are widespread—then the primary hope of society lies not in selection but in reform. Survival of the fittest will not suffice; the fit must be created.

When the producer is not competent to improve, then available information on quality and lucid purchasers induce only better marketing, not better performance. People tend to limit their attention only to the information and to neglect the need for reform of the products and services the information is supposed to represent. That is exactly what was experienced in the United States when the Health Care Financing Administration (the federal agency that purchases care for elderly people in the United States) publicly released data on mortality in hospitals across the United States.⁶ Instead of rededicating themselves to reducing mortality the hospitals attacked the administration's data and analyses. Seeing no easy way to improve their results, the hospitals spent their energy disputing the accuracy of the information and defending the acceptability of their results.

We contend that, in its current wave of reform, the NHS has a clear opportunity to avoid the errors of policy that have drawn the health care system in the United States into a costly cycle of surveillance, contention, and stagnation. We believe that a focus on measurement and prudent purchasing, though essential steps toward improving the quality and efficiency of the NHS, alone will not be sufficient. What is required in addition is an aggressive plan for strengthening the capability of the various components of the NHS to improve the processes of their own work. Physicians must play a central part in the development of that capability, acquiring, in one sense, a new set of "clinical" skills, equipping them to be physicians to the system in which they work as well as to the individual patients who rely on that system.

The TQM approach

Our proposed approach rests largely on the experiences of industries outside health care that have faced an urgent need to improve. It was the Japanese, challenged by the massive task of postwar industrial reconstruction, who led the way in applying the principles of management that have since come to be called "continuous quality improvement" or "total quality management" (TQM). Taught largely by American experts sent to Japan to help in the 1950s, Japanese manufacturers developed their skills in making products and services that could better satisfy their customers. The result is international economic history. In many areas of production Japanese firms have acquired worldwide dominance in the past two decades, forcing the developed countries of the West to re-examine their own approaches to management.

GPs will need to acquire new skills for their purchasing role in the medical marketplace

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Cause and effect diagram composed from data from national demonstration project on quality management in health care.¹² Issue of interest was timely transfer of hospital emergency room data to satellite medical office buildings. Some 24 theories were advanced by the team. Understanding these interrelations allowed the team to design tests and collect data to confirm or rule out the hypotheses

In more recent years several American and European firms have become expert in the methods of TQM and have begun to reap the same results as the Japanese. Early concerns that "quality management" was, in its essence, bound to the cultural circumstances of Japan have now been allayed as Western firms, too, have used the methods to their own advantage with Western workforces.

The principles of TQM are not arcane, but neither are they obvious to those schooled in classic general management. The theoretical background of TQM reaches deeply into several disciplines: industrial engineering, social psychology, statistics, and systems theory, to name a few. At its core, TQM relies on four general theses: firstly, that organisational success depends fundamentally on meeting the needs of those it serves (its "customers"); secondly, that quality (defined as the ability to meet the needs of the customers) is an effect caused by the processes of production, in which the causal systems are complex but, with effort, understandable; thirdly, that most human beings engaged in work are intrinsically motivated to try hard and to do well; and, fourthly, that simple statistical methods, linked with careful collection and analysis of data on work processes, can yield powerful insights into the causal systems within processes, on the basis of which those processes can be improved.⁷⁻¹²

Management in the TQM world is guided by these four basic notions, the implications of which are challenging to many prevailing beliefs about the best ways to lead organisations. As most workers are presumed to be trying hard most of the time, for example, the TQM approach places little reliance on incentives and exhortations to encourage people to try harder or to do better. "They are already trying," says the practitioner of TQM, "and so how much can be gained by imploring them to try harder?" Instead, TQM theory directs attention not at the workers, but rather at the processes of work in which those workers are bound. Most flaws come from processes, not people, and it is the duty of managers and leaders to assure that those processes are designed and improved so as to permit the "willing workers" to do what they already want to do—their very best.

TQM seeks improvements not by simply measuring results and offering feedback. If processes of work are the sources of excellence or flaw, then the road to improvement lies in deepening knowledge about the causal systems within those processes. In medicine the process of patient care, as it would be defined in the context of TQM, includes administrative procedures by which care is brought to the patient as well as the diagnostic and therapeutic procedures themselves. That breakdown in administrative procedures can cause serious damage to patient care is well known to clinicians but has been largely ignored in quality

assurance programmes. The figure gives examples of how such breakdowns can be identified and analysed.

The manager of TQM becomes a doctor to the work process. Just as a doctor listens to the patient's symptoms and engages in scientific inquiry to understand the causes behind those symptoms, the manager in a TQM environment "listens to" the work processes—the patterns of success and failure—and, through disciplined use of a scientific cycle of data collection, analysis, hypothesis formation, and hypothesis testing, gradually introduces changes in those processes designed steadily and forever to improve their ultimate performance—their "quality" in meeting customer needs.

Investment in improvement

TQM goes a step further in suggesting that the scientific method for the improvement of work processes need not be the work solely of managers and executives. As has been proved time and again in manufacturing companies, even workers at the lowest levels of formal education and skill can be taught to use simple statistical methods in their own approach to their own, local process of work. This "democratisation of science," as Professor George Box has called it, can give an organisation enormous leverage toward improvement. Mature quality management organisations of several thousand employees can have at any one time hundreds of process improvement teams at work, involving most employees actively in the step by step improvement of their own work methods.

This widespread deployment of improvement requires investment by organisations in the continuous education of all of their employees. Workers in such companies spend weeks each year learning and refining their skills in statistical thinking, crossfunctional co-operation, and awareness of the real needs of external and internal customers. In addition, managers in these environments must pay special attention to potentially toxic aspects of the organisational culture that can inhibit learning and sharing of information. "Drive out fear," counsels W Edwards Deming, one of the leaders of the modern quality revolution, as one of his famous "fourteen points for top leaders."⁸ If people are afraid of each other within an organisation, if information can be used to harm someone, or if managers blame people for failures built into the processes of work, then real quality improvement can easily grind to a halt. Information is withheld, functional areas retreat into their own walls, and people seek safety instead of learning. Reducing fear and apprehension in the TQM world is a job for leaders.

Most importantly, TQM entails a steady search for opportunities to improve, even in systems that historically function at satisfactory levels. In a TQM organisation people do not ask "Did I pass inspection?" but rather, "How could I do this better?" TQM rejects reliance on inspection to improve quality and it equally rejects minimalist "pass or fail" standards of performance. Inspection of final results and scrapping of rejects is a costly way to overcome failings in a production process, and alone it offers little knowledge about the underlying causes in the processes that caused those results. Standards—especially minimalist standards that seek to sort the acceptable from the unacceptable—tend to lead to defensive behaviours and tend to quell the search for improvement in the vast majority of those who are being judged.¹³ If the "standard" for postoperative infection rates is, say, 2.0% then people tend to spend their time trying to get their rates just below that level. Those whose rates are 1.0% have little incentive to find a way to make them even better. The result is mediocrity, or at least missed opportunities for improvement.

Can TQM help in health care?

Methods of management that have developed in manufacturing environments are naturally regarded with scepticism in non-manufacturing settings. The service industries have been slow to learn and adopt TQM, although in recent years major advances in service quality management have begun to occur.

The scepticism of health care leaders towards TQM has been even greater. Many of the basic principles of TQM are difficult to translate directly into the medical world.¹⁴ For example, how can medicine adopt meeting the needs of the customer (patient) as its driving purpose when so many patients do not seem to know their own needs? Indeed, there is a widespread (but not well documented) opinion in America that many patients demand tests, treatments, and procedures that their doctors know will not help them.

Furthermore, what about the notion that processes not people are the sources of quality and defects in quality. Surely when errors occur in medicine it is more often than not the doctor—a person—who is the underlying “cause.” How can we assert that improvement in medicine requires attention to “processes of work” when everyone knows that deficient doctors can cause so much trouble?

The corrosive effect of fear and apprehension on improvement are all too visible in public systems like the NHS. As the object of continuous political debate the NHS must answer daily for its performance, including explaining undesirable events that inevitably arise in complex systems. TQM requires an open, honest search for errors and inefficiencies, which are, in fact, opportunities for improvement. This openness seems at best naive and at worst suicidal when the same information can readily be converted into a weapon used to attack the discoverer of the flaw, the discoverer’s institution, and the Ministry.

Most of all, how can medicine afford to tackle “continuous improvement” at a time in history when its resources must be constrained. Quality costs money; and there will be in the medicine of the 1990s not more money, but less, relative to demands.

Doctors and managers in a few pioneering health care organisations (for example, Henry Ford Health Systems, Detroit; SSM Health System, St Louis; Park Nicollet Medical Center, Minneapolis; and West Paces Ferry Hospital, Atlanta¹⁵) are beginning to discover that these concerns about the applicability of TQM to medicine may rest more on myth than on fact. “Meeting customer needs,” they think, is not a bad definition for health care quality, and organisations that wish to remain effective and proud in a time of declining resources must be increasingly precise in understanding exactly what those needs are, including knowledge of the degree to which medical interventions restore or preserve health status. Patients, these organisations believe, have sensible, understandable, reasonable expectations of health care, by and large, and they become distressed, and rightly so, when health care systems fail to meet such basic requirements as answering questions, providing access, and easing pain.

Rising costs, these health care organisations think, may reflect the absence of quality in processes of work. Flawed processes produce a great deal of wasted effort, duplication of effort, and complexity, and they perform unpredictably, leading to frustration among both customers and workers. In manufacturing the costs of poor quality (waste, duplication, unreliability, and so on) routinely have amounted to 25-40% of the costs of production before TQM. Those industrial quality experts who have begun to venture into medical organisations to help them are reporting costs of poor quality just as high, or even higher.¹⁶⁻¹⁸

The more those innovative organisations understand

the causes of poor quality, the richer have become their notions of where flaws arise and why. Surely some defects in care are, in fact, traceable to the doctor, and the doctor alone; but, it turns out, the causes of most failures of care are not explained at all by appealing to the myth of “doctor as cause.” In health care, as in other complex production systems, quality fails often despite the best efforts of the people who are trapped in the processes of work. As George Labovitz has said, in health care, as elsewhere, quality fails not because people are doing the right thing wrong, but because they are doing the wrong thing right.

One hospital’s associate medical director, who is committed to learning and using TQM methods, likes to recount a conversation he had with a receptionist in his own internal medicine unit. Wanting to learn more about local processes of work, the doctor spent an hour at his receptionist’s side, watching her perform a long list of pressing tasks. The tasks looked endless and frequently conflicted with each other, but the receptionist struggled gamely through them.

“Your job seems impossible to me,” said the doctor, “No one can really do it right.”

“I know that,” replied the receptionist, “I just try to do my best. It helps to be philosophical about it.”

“But, who designed the job this way?” asked the puzzled doctor. “Don’t they know any better?”

The receptionist paused, embarrassed, for a moment, and then said sheepishly, “You did, doctor. You did.”

Coordinating the elements of care

Often “the wrong thing” happens not within single functional areas—like medicine, nursing, pharmacy, or administration—but rather at the boundaries or interfaces among functions. In health care staff and organisations remain largely bound in well fenced functional subdivisions or compartments, making it easy for people to blame each other (doctors blame nurses, nurses blame technicians, one department blames another) and difficult for any of them to see the processes of work as a whole—the way the patient experiences it. In technical terms medicine, like oldstyle manufacturing, has tended to suboptimise functions at the expense of its customers and at high financial cost. This lesson applies as well to the modern hospital as it ever did to the factory production line.

In a demonstration project applying TQM methods in the University of Michigan Hospitals one team was assigned to examine reasons for delays in patient discharges, which resulted in delayed access to beds for new patients. Because it was cross functional in its make up, involving doctors, nurses, clerks, and technicians who otherwise rarely talked with each other, the team was able to discover multiple misunderstandings among departments, whose smooth cooperation was logically necessary to the proper functioning of the “discharge process.” With simple clarifications of tasks and needs, and with deepening knowledge of how the discharge process really worked, the team was able to shorten the average time new patients spent in the admissions area awaiting an available hospital bed from 3.1 hours to 21 minutes. To achieve these gains required not a penny of additional resources—only new understandings among inter-dependent functional groups.¹²

The experience of process failure is frustrating and demoralising for people at work. Those symptoms—frustration and low morale—are seeping into health care widely today. The early practitioners of TQM in health care think they understand a good deal about why that is occurring. Health care is frustrated because it has not learnt how to get better. TQM, with its emphasis on continually improving the overall process

Total quality management has enabled the Japanese to dominate many areas of production

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by which we administer care, offers a plausible mechanism. Indeed, we have already taken the first step in our attempts to set standards or guidelines for the process of medical care. It has even been recognised that standards will have to be regularly reviewed and updated on the basis of new knowledge. When this process of review has been accepted and incorporated into practice, and when we have expanded the review of process to include processes of the organisation and delivery of care (as we discuss in next week's issue) we will have achieved TQM.

Modern medical care is a complex enterprise entailing interactions among doctors, nurses, and other health professionals; complex information systems; an immense array of pharmaceutical products; and complex devices, equipment, and rules of procedure. For good results these complex elements must be assembled effectively, and improvement depends on the processes of care and management that orchestrate these many elements. Such orchestration is not easy. The NHS reforms are designed to increase the freedom and willingness of hospitals to identify and seize opportunities for better coordinating of the elements of care. TQM is a method for achieving just that.

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(Accepted 7 January 1992)

Medicine in Europe

Prescribing in Europe—forces for change

David Taylor

Legislation existing in or planned by the European Community (EC) already affects the pharmaceutical sector in a wide variety of ways (box, p 241). It relates not only to how medicines are licensed, priced, labelled, and distributed but also to how they are manufactured and how clinical trials may properly be conducted.^{1,2} Ultimately, every aspect of supply, from the post marketing monitoring of drug safety to the funding of research, may be influenced more by decisions made in Brussels than those agreed in individual member states.

The development of the EC single market is primarily intended as an economic measure. In the context of pharmaceutical trading it also has the potential to bring about considerable changes in the differing medical cultures of the EC's member states, influencing both the prescribing rights of the community's 600 000 practising doctors and the access to treatment of many of its 350 million citizens.

This article examines the extent of and reasons for the existing variations in consumption of medicines in Europe and the nature of the challenge facing those wishing to build a more unified EC medicines market. It then assesses the importance of current political debate about issues such as the costs of and access to medicines, safety of medicines, and the promotional standards of drug companies.

Differences in use of medicines among EC states

All international comparisons may be subject to distorting factors. Nevertheless, the data presented in the figure and the table are broadly consistent with a range of sources.^{3,5} They give an overview of differences in spending on medicines and dispensing volume in the EC. Key points about the European pharmaceutical market include:

Consumption of pharmaceutical products at manufacturers' prices and spending on research, per head of population, 1989

(1) Overall, richer countries spend more of their gross national product on health than do poorer ones, and in cash terms will usually spend more on medicines. Yet less affluent countries like Greece and Portugal spend much more on pharmaceuticals relative to their

This article is the eighth of a series of articles looking at medical issues in Europe

King's Fund Institute,
London NW1 7NF
David Taylor, BSc, fellow in
health policy analysis

BMJ 1992;304:239-42