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policy, process, and pragmatic considerations

Sheila Leatherman
Kim Sutherland

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ABOUT THE AUTHORS

Sheila Leatherman

Ms Leatherman has an extensive background in health care management including public and private sector experience in hospitals, long term care, managed care and public health. Sh< currently functions both within the private health sector as ar executive manager and in the public sector performing academi(research and policy analysis. Her research and publications have beer primarily in the fields of health care quality measurement performance analysis of integrated delivery systems and managed care policy. As Executive Vice-President of United HealthCare Corporation (the largest managed care company in the United States she advised on key strategic functions of the corporation principally in the areas of health policy, issues management, government affairs informatics, international strategy and health services research Sheila Leatherman founded the Center for Health Care Policy anc Evaluation of United Healthcare Corporation. Since January 198S the Center has conducted research and evaluation on the performance of health care delivery systems in the areas of quality access, cost and consumer perceptions of health care. Research collaborations exist with universities, government agencies and research institutes including Centers for Disease Control, US Agency for Health Care Policy and Research, Federal Food and Drug Agency Harvard Medical School, University of Pennsylvania, Rand Corporation and the Department of Defense. In her academic and research roles, Ms Leatherman was appointed a Senior Fellow at the Institute of Public Health Services Research of the School of Public Health at the University of Minnesota in 1994. In 1997 she received an appointment at the University of Cambridge (England) as Senior Associate at The Judge Institute of Management Studies. In October 1997 Ms Leatherman accepted an invitation from The Nuffield Trust, the leading health care foundation in the United Kingdom, to conduct

a year long evaluation regarding quality management in the National Health Service, the report of which will be published and presented in November 1998. In December 1997 she was elected as a Distinguished Associate Member of Darwin College (graduate school) of the University of Cambridge. In March 1997 she was appointed by President Clinton to the National Advisory Commission on Consumer Protection and Quality in Health Care to study changes in health care in the United States and recommend policy options to the President and Executive Branch. The Advisory Commission delivered a final report to President Clinton in March 1998. Ms Leatherman chaired the sub-committee recommending a quality measurement strategy for the United States. Ms Leatherman is active in numerous organisations including: Board of the American Association of Health Services Research; Board of the Association of American Health Plans; Board for Health Care Services of the Institute of Medicine, National Academy of Sciences; and the Board of The Johns Hopkins University Institute of Bioethics.

She has worked internationally through commissioned consultancies or lectureships in Bulgaria, France, Czech Republic, England, Poland, Puerto Rico, Romania, Russia, Scotland and Slovakia.

Kim Sutherland

Kim Sutherland is a Research Associate at the Judge Institute of Management Studies, University of Cambridge. Her research interests focus on health services management, particularly in the areas of managerial and implementation issues in the context of clinical effectiveness initiatives, managing change, the diffusion of medical innovations and the organisational and social influences on clinical decision-making.

FOREWORD

Summarising a seminar on Quality in Health Care, held at the Nuffield Trust on 23rd June 1997, Dr Fiona Moss, the seminar facilitator, concluded that delivering health care is a combination o: many complex processes and often includes the frequently inarticulated co-operation between many people - professionals anc patients; nurses and doctors; managers and health care professionals The way in which health care works has developed over many years and incorporates much tradition. A lot of this is good but the outside world has perhaps changed faster than the NHS internal worlds of norms and expected behaviour. "Understanding these complex processes and their tensions is crucial if we are to begin to work with all those in health care to improve health care quality".[1] This was very much the theme of the Prime Minister a year later addressing the conference celebrating the 50th anniversary of the National Health Service when he said that quality of care is patchy "there are huge variations in efficiency and quality. The NHS is good and in many places it is excellent but it is far too inconsistent".[2] He acknowledged that the service has seen much innovation and technological breakthrough but "has in many ways failed to modernise". Fifty years into the NHS there are no routine systems foi assessing the clinical- and cost-effectiveness of treatments, what patients think of the service, no universal clinical audit; too many treatments prescribed on the basis of perceived wisdom instead of the latest scientific evidence, poor use of information technology and inadequate arrangements for spreading good practice around.

The new NHS. Modern. Dependable

The government's current policy for the new NHS "will have quality at its heart. Without it there is unfairness. Every patient who is treated in the NHS wants to know that they can rely on receiving high quality care when they need it. Every part of the NHS and

everyone who works in it should take responsibility for working to improve quality. This must be quality in its broadest sense - doing the right things at the right time for the right people and doing them right first time, and it must be quality of the patient's experience as well as the clinical result - quality measured in terms of prompt access, good relationships and efficient administration". '

To make a difference the government is establishing a National Institute of Clinical Excellence to evaluate new and existing treatments, technologies and drugs; setting up teams to help spread best practice and improve performance, giving the Chief Executive of every NHS Trust a new duty of quality; introducing new rules to guarantee more rigorous and systematic review of the performance of every doctor and nurse; requiring all hospitals to publish success rates of treatments and establishing a Commission for Health Improvement.

The public and health care

The Prime Minister has also challenged the professions that, to regain public support, they have to make professional regulation swifter and more open. "Never again must the scandal of Bristol - an unforgivable failure to act on the signs of poor performance - be allowed to tarnish the reputation either of the vast majority of good and able doctors, or of the NHS."[4]

The quality challenge

This quality agenda is highly ambitious. The Trust's June 1997 seminar heard a succession of presentations focussed on the quality of health care, sharing UK and Australian experience. A central feature was the importance of understanding and coming to terms with the role of a series of opposites or how to cope with the tensions

generated by different approaches to health care improvement. For example, there is a need to understand and embrace both a holistic approach to care and Cartesian principles. Whilst most people would support the reflective team-building non-threatening principles of Total Quality Management, there is also clearly a place for externa' assessment of quality and accreditation, such as the King's Func Organisational Audit. While voluntary approaches to quality improvement are likely to be the most effective, if robust anc vigorous enough, they may need to be accompanied by mandator} standards. Quality indicators are also important, particularly for external consumption, but being able to understand and motivate the appropriate change in behaviour is crucial if real change is to happen.

The Nuffield Trust welcomes the priority given by the government tc the theme of quality. The Trust has had a long and substantia] interest in the issue of quality of medical and health care in the United Kingdom, as demonstrated by its fellowships, publications and grants over the years. Noteworthy in its contributions is Archie Cochrane's Rock Carling monograph *Efficiency and Effectiveness* (1972) and in 1977 the Trust support for the Confidential Enquiry into the deaths associated with anaesthesia. In collaboration with the King's Fund, it funded a research study in three NHS regions in 1985-1986 which subsequently led to the nationally-based enquiry CEPOD, recently reviewed by CASPE.[5] Also relevant is the Trust's recent initiative on the role of humanities in medicine and the Windsor Declaration.[6] The objective of including the humanities in medicine is to assist in improving the quality of life for patients and the communities in which they live and work through helping the professionals to be more compassionate and to have a greater understanding of the patient perspective.

The Nuffield Trust seminar on quality and health care in June 1997 was in line with this tradition.

Because of the disparate quality initiatives in the United Kingdom, fragmented, unco-ordinated and with no discernible programme or system across the UK NHS, the Trustees invited Sheila Leatherman to review the quality agenda initiatives of the NHS. Further the Trustees supported joint work with some members of the Editorial Board of the BMA journal *Quality in Health Care* to organise a working conference entitled "Organisational Change. The Key to Quality Improvement" as a practical contribution to implement quality initiatives across the UK.

Concurrent with this evaluation Ms Leatherman served as an appointee of President Clinton on the Advisory Committee on Consumer Protection and Quality in Health Care which provided her with a unique insight to make US and UK comparisons. The Trustees will build on this initial international perspective jointly with RAND through a programme of invitational meetings to clarify policy thinking around quality issues, measuring the quality of secondary care and developing quality indicators of primary care. The Trust with the Commonwealth Fund will explore international population health based quality measures. OECD already provides data that enables comparisons on health care availability and use of services. The next step for OECD should be to build on sustained cost data to data on quality and outcomes and the development of population-based indicators that are sensitive to policy interventions, thus enabling policy makers to compare performance of the health sector in their country with health indicators in other countries.

Health reforms

The current government health proposals to modernise the NHS are in line with many OECD countries who are reforming their health care systems as a response to increased scientific, medical and pharmaceutical capabilities, ageing populations with increased demand on community health services, rising consumer expectations, the re-emergence of infectious diseases and constrained economies. Our own Treasury have recently conducted a comprehensive public spending review and, in keeping with treasuries in many countries, focus has been not just on outputs but on outcomes. In health services this has led to the elevated importance of evidence-based practice, protocols, guidelines and a focus not just on health system performance but on outcomes and the health status of the community combined with concern with universal access and equity.

Health gains - the bottom line

The bottom line on performance of any quality health service should be three measurable tests:

- the achievement of health gain, avoiding premature death and improving quality of life, adding years to life and quality to life years

- services should be people centred and provide information for individuals and communities to make choices and decisions

- services should demonstrate sound stewardship of resources in staff, buildings and equipment as well as intellectual and professional capacity.

Performance management and quality

There are many obstacles to effective performance and quality health care: the absence of leadership with an intermediate and long-term timeframe; political will and financial sustainability, appropriate resource allocation and budgeting systems; shortage of technical capacity such as classification and information systems; management skills to introduce complex financial and organisational arrangements and appropriate ways of involving health professionals. Overcoming the obstacles will require systems appreciation, networks, a clear strategic intent and direction, a social consensus of values, appropriate management arrangements including the creation of learning organisations, project management, clear allocation of responsibilities and accountability and each part of the organisation adding value,- relevant legislation including a regulatory framework using outcomes, benchmarking, monitoring and evaluation; adequate levels of investment in staff development, particularly interprofessional education, training and research and development with a balanced continuum and co-ordination of care between primary, secondary and tertiary levels. Care should also be provided in the right settings, home, near home or hospital. The internal restructuring and external arrangements for hospital management should be coupled with enhancing the capacities of primary care and substituting more appropriate for less appropriate care.

Systems for quality - passion for quality

Sheila Leatherman's text clearly reflects her passion for the subject as well as the importance of having an orderly and systematic approach to implementation. She concludes "the significant changes being proposed in NHS policy and programmes have the potential to bring coherence to the diverse and fragmented initiatives which have dominated the quality agenda in the NHS". She recognises that major

tasks lie ahead in addressing the issues of clinical governance, operationalising measurement and intervention capabilities, integrating policy and processes and building the capacity to sustain a systemic approach to quality in the NHS.

There have to be systems for quality and passion for quality. Systems alone or passion alone is insufficient. Both are necessary.

John Wyn Owen
September 1998

1 Nuffield Trust Note No. 2. (1998). Report of a Nuffield Trust seminar on quality of care.

2 The Prime Minister. The Rt Hon Tony Blair (1998). Speech at the "All Our Tomorrows" conference.

3 The New NHS. Modern. Dependable (1997). Cm 3807. HMSO.

4 The Prime Minister. The Rt Hon Tony Blair (1998). Speech at the "All Our Tomorrows" conference.

5 National Confidential Enquiry into Perioperative Deaths: An external evaluation by CASPE Research. August 1998.

6 The Windsor Declaration. Arts, Health and Wellbeing: Beyond the millennium. The role of Humanities in Medicine (1998). The Nuffield Trust.

PREFACE

The NHS is both venerated and venerable. It occupies an almost singular position of privilege, and perhaps onus, as an icon of nationalised health systems. Not only does the NHS serve the complex health needs of the population of the United Kingdom but it serves as a beacon for the viability and desirability of government sponsored health systems in which health care is recognised as a public good. Given the multiplicity of audiences and the critical importance of success, the envisioned reforms for The New NHS are of universal interest. The quality agenda, part of the articulated New NHS, is described as an evolution, not a revolution. Therefore, although ambitious, it may be more realistically achievable and sustainable. 'Quality' is properly and explicitly recognised as a defining attribute of the NHS alongside efficiency, effectiveness and equity. This is challenging for a number of reasons, not the least of which is that quality may be even harder to define than the other abstract concepts. These other three have, however, been sufficiently defined in the NHS to allow them to become both goals and design factors. Quality can likewise be both conceptualised and operationalised. Operationalising quality will be daunting. An overriding goal must be to meld the already numerous existent quality-related initiatives and the equally many proposed new initiatives. The product must be a co-ordinated whole that is greater than the sum of the parts. Priority should be given to creating conceptual coherency, integrating established quality activities with new approaches and entities, as well as improving essential infrastructure. Tactical challenges will involve both process and policy, such as reconstituting the role of audit (a foundation of quality management heretofore), establishing a new legal framework of clinical governance, creating technical capacity for informatics and IT, and resolving public policy issues such as that of data disclosure. Previous experiences with audit, quality re-engineering, evidence-based medicine and clinical effectiveness

initiatives can be built upon. This is fertile ground, not fallow field. As an American, it has been both my pleasure and privilege to be invited to evaluate the quality initiatives and agenda of the NHS. Concurrent with the NHS evaluation, I served as an appointee of President Clinton to the President's Advisory Commission on Consumer Protection and Quality in Health Care Industry. This provided me a unique experience enabling US and UK comparisons. The differences in execution are striking although the commonality of needs is worth noting. The differences in conceptualisation and the state-of-art of quality reflect the fundamental ideological orientations regarding health care in each country. The NHS, recognising health care as a 'public good[1], incorporates values of inclusiveness and equity through central management of finite resources to serve the needs of the general population. In contrast is the United States, where there is no common notion of health care as a public good. Health services are viewed as a 'market' and approaches to quality emphasise the individual and the provider consumer transaction. Execution in the UK is characterised by great attention to policy - articulation, centralisation of effort, and production of information for managerial purposes and for the government. On the other hand, execution in the US is driven by competitive market dynamics: the use of comparative performance information for selection by purchasers and consumers of health care providers and services, and the need for providers to demonstrate accountability and value. Each country shares the same heightened interest and need for advancing the quality agenda. Within the US it continues to be done largely within the private sector as the role for government is contested and unresolved. Within the UK much of the momentum is driven by government, increasingly in tandem with the professions and patient advocacy groups. In both countries an artful blend is called for; the use of state-of-the-art evaluation and information sciences positioned in an ethos of health care

professionalism and patient-centred values. An apt ending for these introductory remarks, and segue to the project findings, are quotes from several (of the 45) interviews conducted for this project. They collectively provide a perspective on quality in the NHS - past, present and a vision for the future

PAST

'It didn't start with any initiative from government - it started really down in the system, people recognising that they needed to become rather more systematic in the way they address quality assurance issues and the result of that is a raft of initiatives springing up. Our perception is that we've got too many unco-ordinated initiatives, a lot of waste, a lot of duplication, and the whole thing is lacking conceptual coherence.'

PRESENT

'There was an unsaid recognition that simply professional self-regulation was not sufficient to assure the quality of care for patients - it had an important place but of itself, is not enough. It needs to be harnessed in a rather more systematic way and I think it is one of the most significant, but quiet, changes that has taken place in the last five years in Britain.'

FUTURE

'We employ one million people in the NHS. You cannot control a million people. You have to generate a sense and a commitment to quality - but you have to reinforce that bottom-up because there are so many million interventions every day. You can't watch them all so you have to believe in the instincts of people who are providing health services, provide them with standards for quality and then create a management ethos, if you like, a management culture, which values quality.'

Sheila Leatherman

INTRODUCTION

This paper examines current and proposed quality initiatives in the United Kingdom health sector. The evaluation was carried out during a time of enormous change in the wake of the 1997 elections, and was simultaneous with the emerging definition of *The New NHS. Modern. Dependable*[1] which encompasses many new initiatives specifically related to quality. This new focus is indicative of the growing importance of quality improvement as a function in healthcare systems[2] and has been accompanied by a shift away from a fixation on costs, in both the United States and the United Kingdom. In both countries, politics play an important part in explaining the high profile of quality in any public discussion of health care but more notably, quality is becoming an arena of responsibility and accountability perceived to be important by policymakers, managers, clinicians, payers, and patients. No longer is it acceptable for managerial and clinical leadership to view quality as discretionary.

This commentary on policy derives from a one year project, commissioned by The Nuffield Trust, intended to evaluate the context, policies, and processes in the NHS that influence the capacity for quality improvement in health care. The evaluation assessed the information from selective review of health policy and management literature; consultative documents,- and interviews with key leaders in the United Kingdom health sector. Over 45 people were interviewed, with a semistructured interview format, representing about 75 hours of interview time. Interviews were held with people in political and policy leadership positions, members of the NHS Executive, health service managers, medical and nurse leaders, academics, and quality experts. Interviews were conducted in England, Northern Ireland, Scotland, and Wales.

The project sought to capitalise on the different backgrounds of the researchers. The lead researcher brought to the work an outsider's perspective, from an American viewpoint, that has been shaped by a career that includes two decades of focus on healthcare quality through national research and policy projects as well as executive managerial roles in healthcare delivery systems. The second researcher provided the United Kingdom link with an appreciation of the contextual and historical background against which the quality agenda is set.

CONCEPTUALISING QUALITY

Quality has traditionally represented a relatively risk free and widely popular articulation of policy. It is, after all, extremely rare to find someone who is opposed to the notion of quality. However, it had lacked a shared understanding, a set of common standards, and an explicitly stated common goals which are universally subscribed to thereby making it difficult to drive forward a meaningful quality agenda. Yet, healthcare quality is an arena that must rely on objectivity and rational measurement.' It is essential to make explicit the objectives of, and rationale for, a quality agenda as well as to specify the expected contributions of quality evaluation and improvement.

Our conception of quality (fig 1) is based on the assumption that quality improvement activities can contribute to the performance of the healthcare sector, and to the nation at large, in many valuable ways. It reflects ideological principles which underpin the modern NHS, including efficiency, effectiveness, and economy[4 5] and sees quality in terms of the three key constituencies to whom quality is delivered: individual patients, patient populations, and the system as a whole. Each constituency has its own champions, particularly organisations, and conceptions of quality. For instance, individual patients may see quality as unlimited expertise, technology, and resources directed towards their particular problem, although a population may regard it to be the greatest good for the greatest number. The system, it could be argued, can be seen as an instrument for securing quality for the other two constituencies. However because of the complexity and size of the NHS, the system itself requires specific quality considerations and initiatives if it is to function effectively. We therefore consider the system to be a key constituent in its own right. Importantly, the three constituencies also contribute to quality, for example, individual patients can affect

quality through their choices of lifestyle which subsequently impact on demand for services; patient populations exert influence through collective social conditions and specific demand for services, and the system impacts on quality by the efficiency with which it operates.

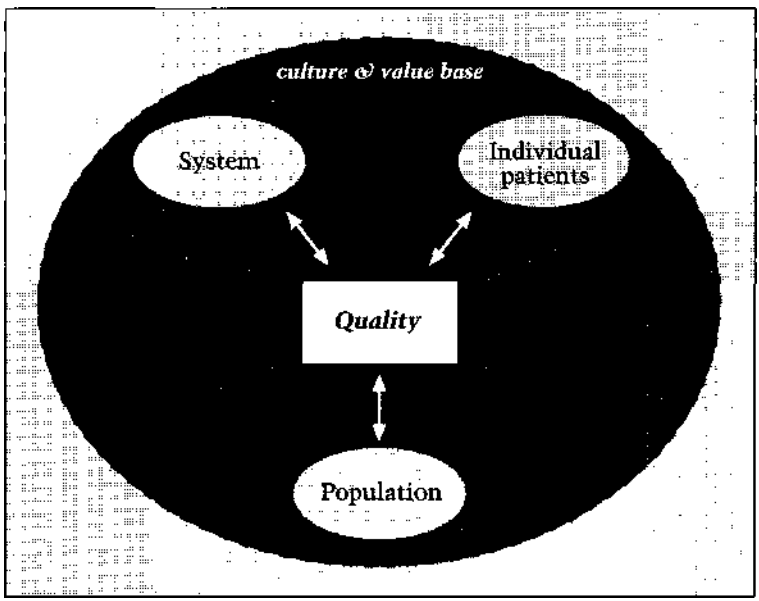

Figure 1 Conceptualisation of quality

Figure 1 shows other contributory factors which shape quality in health care, namely, staff (both professional and non-professional groups), strategies, technology, resources, and the environment. These factors are often the levers used to secure change. Underpinning all of the factors and constituencies which comprise the quality field is the ethos derived from the values and culture of the health service, the sense of public service, and the motivation to improve.

CONCEPTUALISING QUALITY

An evaluation of NHS quality must ask how do current and proposes policy initiatives deliver quality to these three constituencies Several objectives emerge as critically important (box 1). Firstly, in terms of the system, do quality initiatives enhance the design and management of discrete health systems, programmes, of organisations? Do they provide information for and allow evaluation of macro-health policies? Secondly, in terms of individual patient care, does the quality agenda optimise that care by providing appropriate services (diagnostic and treatment processes) and tracking individual outcomes of care? Thirdly, is population health supported through the provision of appropriate resources and interventions? Is health status monitored and fed back into planning and policy making processes? Is the public engaged as informed consumers and active patient participants? And fourthly, across all three constituencies, is the effectiveness of interventions recorded analysed, and used as information for future decisions?[2]

Thus in evaluating the quality agenda in the United Kingdom, we explore how current policies and initiatives support these purposes and seek to identify possible gaps where policymakers may have overlooked the link between specific quality initiatives and the purpose or justification for investing in a comprehensive quality programme.

Our conception of quality encompasses the notion of continuous quality improvement at a system level.[6] It requires interplay and mutual understanding between the constituencies. It allows for the necessary and timely attention to the areas of individual poor, or even outrageous, performance but does not unduly dedicate precious resources to only anomalous events, which would thereby prejudice the system and concern the population.

Objectives for a national quality agenda
• To improve design and management of discrete health system programmes or organisations
• To provide information for and allow evaluation of macro-health policies
• To optimise individual patient care by:
Providing appropriate services, that is, diagnostic and treaement processes
Tracking individual outcomes of care
• To manage population health through:
Provision of appropriate resources and interventions at the level of defined population
• Monitoring of population health statis for purposes of revising plans,programmes, policies and resources to better serve health needs
• To engage the public as informed consumers and active patient participants
• To record and analyuse effectiveness of interventions

Box 1 Delivering quality to key constituencies.

CONTEXT IN THE UNITED KINGDOM

A look at the past

Organisational performance and in particular issues of efficiency and economy, have long dominated health policy in the United Kingdon and have acted as the primary drivers for health sector reform.[5] Quality has often been taken in under the heading of organisational performance, and in viewing policy developments, it is important to acknowledge that although it has long been the subject of rhetoric until recently there has been little in the way of comprehensive policy or implementation. Nevertheless, key policy developments although not specifically targeted at improving quality, have had a considerable bearing on it.

The history of the NHS has been shaped by an extensive catalogue of structural reform. Noteworthy developments include the introduction of consensus management by the Joseph report[8] which sought to unify the system in a quest for greater efficiency; the introduction of annual performance reviews in 1982 which sought to shift focus from concerns with input to output; and the Griffiths report' which rejected consensus management in favour of the general management model. The subsequent introduction of the internal market in *Working for Patients* (1989)'° sought to secure for health service managers, greater control over their organisations through the establishment of contractual transactions between purchasers and providers. It was envisaged that contracts would be agreed on the basis of such variables as cost, volume, quality, and timeliness." However, the opportunity to put right differences in quality through contractual mechanisms met resistance in the shape of political and professional factors - such as the protection of clinical autonomy[12]- and the lack of meaningful comparative data. These factors mitigated against the ability to engage in selective purchasing based on performance.

One of the mechanisms used to secure improved performance in the NHS has been the use of target setting. Since 1982 managers have been accountable for output measures, such as cost per case, or operations completed "*The Health of the Nation*" targets sought to reduce the incidence, and improve outcomes, of particular disease groups: coronary heart disease and stroke, cancers, mental illness, HIV/AIDS and sexual health, and accidents. These targets were revisited in the recent green paper, *Our Healthier Nation* (1998).[15] Similarly, the *Patient's Charter* (1991) laid out the rights available to all citizens as well as service guarantees and targets, and published league tables of *Patient's Charter* performance. Targets, however, have long concentrated on non-clinical aspects of quality[16] [17]nd even the more clinically oriented *Our Healthier Nation* targets concentrated on population based indicators rather than individual clinician, or unit performance. In terms of the constituencies in figure 1, these initiatives have secured some benefits for specific populations, and to some extent for the system. However, they have tended to be discrete and not take a systematic approach to quality.[18] By and large, control of quality at the individual patient level has been left to processes of professional values, trust, and clinical autonomy.

Also, there have been several programmes implemented over the past decade including audit, total quality management, business process re-engineering, clinical effectiveness, and so on. These are all examples of knowledge generating processes and functions that should affect quality of care but the impact of which may have been compromised in effecting systematic change. None of them created a conceptual coherence or operationally integrated national approach to initiatives in quality evaluation and improvement in the NHS.

Assessment of the current situation

There is currently an opportunity to act on the well articulated but largely rhetorical agenda and to bring coherence to the diverse range of fragmented initiatives which have dominated quality in health. In 1997-8, the new Labour government set out its plans for reform in a series of white papers and consultation documents: *The New NHS. Modern. Dependable* (England);' *Designed to Care* (Scotland);[15] *Putting Patients First* (Wales)[20]; and *Fit for the Future* (Northern Ireland).[21] These documents feature quality as a prevailing purpose rather than a desirable accessory. However, this change in emphasis should be seen not as a revolution, but as part of the evolution of the health service, building on and bringing conceptual coherence to earlier, disparate policy initiatives. As the Labour reforms for the NHS are implemented and quality moves to centre stage, it is critically important to reassess the mechanisms for evaluating and improving quality of care in a systematic and systemic fashion.

Advancing quality in the United Kingdom means building on the legacy of the past, capitalising on existent knowledge, experience, and technologies, and integrating these with a vision for the future of quality in the new NHS. The timing for the newfound vigour in pursuit of quality is both opportunistic and essential. It is now that major statutory reforms in structure, organisation, and programmes are being proposed and instituted. Many of these explicitly set the stage for defining the principles, responsibilities, and desired outcomes for quality of care. Establishing a common understanding of the problems, gaps, or deficiencies will allow for a more judicious and sustainable set of quality reforms.

In stark terms, what needs fixing? Emerging from synthesis of the interviews, and substantiated by or derived from publications, are several common themes on deficiencies in the scope, capabilities, or

policies of the systemwide quality inititiatives. Correcting these concerns could and should provide a basis for directing the evolution of a quality approach in the NHS. The following represents a list, admittedly incomplete, of priority concerns to be considered:

- *Identifying and ameliorating unjustified variation in clinical practice and service*

This is a priority issue and the consensus with which it was identified in the interviews was striking. It is viewed as a problem at both the individual and system level. Unidentified and patterned variation from normal practice has been implicated in several recent cases of individual notorious performances which have been highly publicised in the media and heighten political and public pressures for reform in quality responsibilities and accountabilities.

- *Lack of conceptual coherency and operation integration*

Existent initiatives, although in many situations resulting in laudable actions, are compromised in their effectiveness due to a lack of conceptual coherency and operational integration. For example, it is not commonly understood how clinical effectiveness initiatives dovetail with practice guidelines and presumably provide information for selection of audit topics and performance monitoring.[3] These initiatives too often exist in their own orbits unlinked to other related activities of evaluation or intervention.[18]

- *Lack of clear authority and accountability has been problematic*

Quality of care has been historically viewed as the domain of the medical profession but physicians may be reluctant to accept responsibility for cases of suboptimal performance among colleagues.

Managers in the NHS were either unwilling or unable to take responsibility for, and implement specific actions for, problems in care. Sometimes this was because problems and performance issues were not sufficiently identified or validated.[18] In other cases, it was an unwillingness or perceived inability to act on known problems of quality. (It should be noted that clinical governance seeks to rectify this deficiency.)[1]

• *Insufficient objective measures or indicators of quality*

For the most part, previous indicators and league tables were focused on cost and resource and efficiency measures, as opposed to quality of care. This had two untoward effects: firstly, constraint of attention throughout the NHS on efficiency and resource issues without balance on quality of care issues,- secondly, creation of a jaundiced view of performance indicators as being associated with financial issues rather than patient care.

• *Lack of sufficient incentives*

At interview a commonly identified area of policy that has for a long time needed considerable appropriate and effective attention is the lack of incentives to encourage quality and to implement sanctions in the cases of poor performance.[22]

• *Data capacity*

In the absence of market forces and traditional command and control structures, a primary lever for quality improvement, particularly at clinician and unit levels, is the use of comparative performance data.[23] Considerable investment is needed to generate the human and technological resources for the collection, analysis, and reporting of

data through fair and valid instruments, if this is to be an effective mechanism for delivering quality.

- *Clarify the assumptions and roles of professional self regulation versus government regulation*

In two recent and highly publicised episodes professional self regulation has been criticised as failing to provide sufficient safeguards to ensure clinical quality - for example, the high mortalities in the paediatric cardiology unit at the Bristol Royal Infirmary and the anomalies in the results of the cervical screening service at Kent and Canterbury Hospital. What is reasonable and prudent in the domain of professional self regulating conduct requires explanation. It is also essential to elucidate the rationale for professional self regulation versus external regulation, and to define how the two may complement one another optimally.

- *Role of primary care*

Key themes in the NHS reforms are primary care, a commitment to quality, and the emergence of clinical governance as a concept and approach to responsibility and accountability.[19 20 21] However, the feasibility and methodology for linking these three is an acknowledged challenge. Specifically, the means of including primary care practitioners into a clinical governance structure must be considered.

- *Organising quality*

Evolving quality in the United Kingdom is now dependent on rationalising and integrating past and proposed policies, processes, roles, and accountabilities. There must be a scheme that is coherent

and logical to stakeholders, to conceptualise, organise, and implement quality. The scheme, illustrated in figure 2, is introduced to consider this need. It encompasses several stages: policy formulation, the definition of criteria for performance; definition and application of indicators of quality; identification and remedies for problematic or substandard performance; and continuous improvement in overall performance within the system.

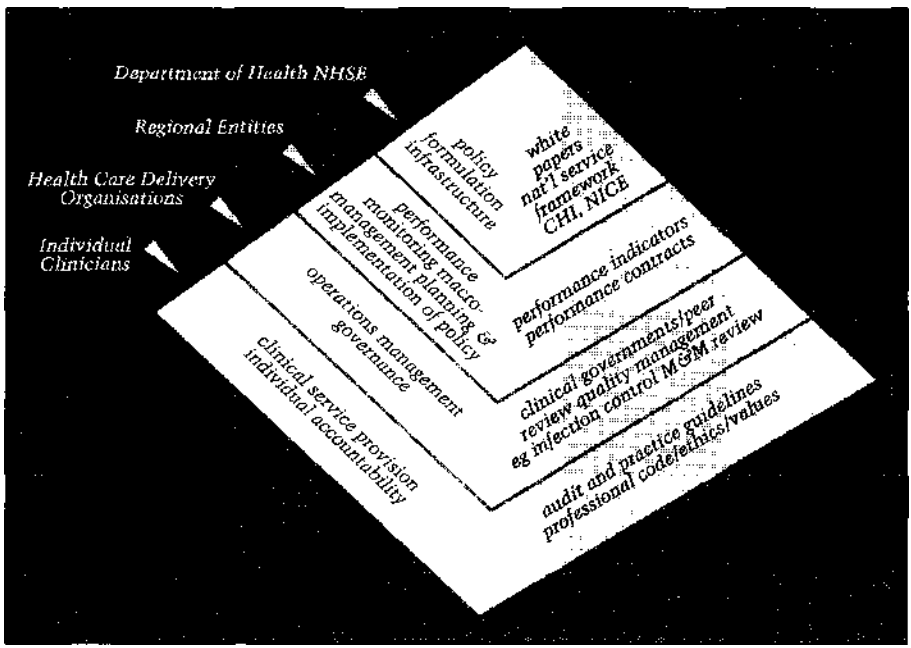

Figure 2 Organising and implementing quality.

It implies a context of centralisation to decentralisation (side 1) where certain key and critical processes are performed. Each stratum must explicitly be accorded both discrete responsibilities and

accountabilities related to quality of care. A national healthcare system, where standards, guidance, and definition of authority and accountability can be articulated and implemented with some consistency, may have inherent advantages for organising in such a framework.

There are certain general functions and responsibilities that must occur in a national strategy for quality (fig 2, side 2). Policy formulation is generally largly centralised, within a national healthcare system. Likewise, the government as sponsor of the health system retains most of the responsibility for infrastructure, both organisational and technological. Both are important in building for quality management. The second tier portrays the step down macro-management and monitoring functions at the regional level. In the NHS in England, this may be the regional health authority or health authority, and (at least historically) encompasses the implementation responsibilities of the NHS of Scotland, Wales, and Northern Ireland. The third tier applies to the level of the trusts, where governance is vested (in the past primarily for fiscal matters and throughput responsibilities) and operations management is performed. Finally, and forming the foundation for the hierarchy, are the clinical transactions of the healthcare system. The encounter between a clinician and patient fundamentally defines all inputs and outputs of a healthcare system. At this fundamental level, the responsibility and accountability for quality is individual and interpersonal. The challenge is to engender commitment among the clinicians, managers, and patients to initiatives originating from higher levels.

The essential nature of quality is abstruse, multidimensional, and multifactorial.

Disciplining a healthcare system - every level of it - to strive towards the realisation of quality - necessitates discrete processes and tools (fig *1*, side 3). In the United Kingdom it is essential to rationalise and integrate the many current but disparate and unlinked activities impinging on quality management and the equally many proposed initiatives for both policies and processes in the future. Figure 2 assigns processes and tools to the four organisation levels and functional responsibilities. A key issue in taking the quality agenda forward is determining how the various layers interrelate to deliver coherence across the entire system. It is insufficient to define structures and objectives for organisations at each level. Rather, there needs to be meaningful integration of the different structures, processes, and goals at the various levels.

EVOLVING QUALITY IN THE UNITED KINGDOM: THE FINDINGS

Looking across the Departments of Health in England, Scotland, Wales, and Northern Ireland, there are clear similarities and differences at both the macro-level and micro-level of quality evaluation and improvement. Philosophical congruence, shown through the individual White Papers, is evident.[1 19 20 21] Considerable differences exist in resources, priorities, and political issues influencing policy development. The evolution must appropriately reflect fundamental differences based on such factors as the homogeneity or heterogeneity of populations, the distribution of expertise, the state of the art for critical processes - such as guideline development-and essential issues of infrastructure - such as data and information technology. The following findings and recommendations, although intended to be generic, necessarily apply differently to the four regions.

There is general agreement about the principal challenges for quality improvement in health care. Unjustified variation in practice and the gap between evidence and performance are widely identified throughout the United Kingdom to be key areas of opportunity to secure considerable advances.[1 18 19 20 21 24] A well defined and commonly understood national approach to quality is needed, and by many indications is underway. We examine current directions of strategic concerns, the linking of strategy with operations and local responsibilities. From the pyramid (fig 2), although there is some fuzziness at the margins, strategic concerns are primarily within the apex; the linking of strategy with operations is carried out largely at a regionalised level; and local responsibilities fall within the remit of individual clinicians, their units, and the organisation to which they belong (level 3 and the base).

STRATEGIC ISSUES

At the most central level, the Department of Health and NHS Executive, certain tasks of policy setting and increasing organisational capacity are of paramount importance.

White Papers

The White Papers published in 1997-8 provide a policy for the evolution of measurement and management of quality in the United Kingdom. The mission, objectives, and vision are compelling. The short term value of the White Papers is articulating a vision and strategy for setting quality at the top of the NHS agenda and for providing balance to what is rather widely perceived to have been an unmodulated focus on cost and efficiency. Mid-term value lies in the most critical task, convincing many key constituencies that these White Papers are "for real" - that is, overcoming what is an obvious fatigue and scepticism with the constant announcements of new reforms and restructuring in the NHS over the past 20 years. The lasting value of these White Papers will be judged many years hence by their contribution to resetting the stage for realising health gains.

One of the new organising processes being delineated is the national service framework. The Calman-Hine framework for cancer services provides a template to be replicated for other areas. Wisely, it is envisioned that there will be some coordination between the health departments of England, Scotland, Wales, and Northern Ireland but that different priorities will be set based on the perceived needs of specific populations. For example, England has identified heart disease and mental health, and Wales has added a third priority of cervical screening. These national service frameworks should be designed to provide specific guidance to advance quality. This can be done by establishing explicit benchmarks for excellence, requiring the use of practice guidelines and protocols, thus defining good

clinical performance and creating an ongoing evaluation process for discrete clinical processes and outcomes.

National performance framework

A national performance framework has been delineated and will be refined. Again, the concept, as that of the White Papers, is clear and persuasive. The scope is arguably too ambitious for the current capacity for methodological development, the availability of requisite data, and analytical expertise. However, the new NHS quality agenda is clearly indicated to be a long term (10 year) strategy.[24]

The creation of two major new entities has been announced; The Commission For Health Improvement (CHI) and the National Institute for Clinical Excellence (NICE). Definition of these organisations is under consultation. If they are to advance quality, they should play complementary parts. The first, established at arm's length from Government, with power to influence and intervene in cases of poor performance and the second, ensuring that information and advice about what constitutes best practice is effectively disseminated. The National Institute for Clinical Excellence is positioned to play a much needed part in the convening, developing, endorsing, and promulgating of standards of practice. If it can develop its role to include the definition of such standards of indicators or measures of quality, it has the potential to rectify several of the most deficient aspects of quality evaluation in the United Kingdom - namely, the short supply of widely agreed and publicly available measures of clinical quality, the lack of interplay between the professions and the public in setting indicators, and the consequent deficit of comparable performance data in clinical quality. Three important questions for the National Institute for Clinical Excellence emerge: how to secure synergy with existing organisations who

perform a similar role - such as the NHS Centre for Reviews and Dissemination and the Cochrane Collaboration - how to implement recommendations and secure change in individual clinicians, and how to define what amount of customisation of guidelines and measures is justified at a local level.

There seems to be some controversy over whether the primary mission of the Commission for Health Improvement is one of inspection and regulation, or consultation and guidance. Recent and highly publicised cases of poor medical practice have created pressures on government to intervene in individual notorious situations where local controls have not prevailed. On the other hand, the possibility for the Commission for Health Improvement to play a larger strategic and visionary part in identifying the priorities for the health system and integrating the various players and processes is argued by some to be the most needed and potentially constructive contribution. There is, however, little policy documentation supporting this concept of the role of the Commission; rather its function is described as one which ensure that clinical governance processes are in place, and to carry out rolling inspections of NHS organisations.[24] There is for many a question about whether the Commission for Health Improvement can play both the interventionist, possibly even punitive, part and still be seen as the judicious arbiter of macro-level strategy.

LINKING STRATEGY WITH OPERATIONS

Derived from these policy and infrastructure activities are implementation issues. Three processes are critical to assure quality: planning and programming to achieve standards of quality, setting clear and measurable performance standards, and monitoring actual performance.

Performance indicators

Performance indicators can change behaviour. This has been shown in the NHS with the use of league tables and waiting lists.[25] It has likewise been shown in the United States through the use and public disclosure of certain clinical data.[26] Therefore, it is important to 'get it right', to identify which areas of performance are of the highest priority, to link performance indicators with accepted clinical guidelines, and make an informed selection of valid and reliable indicators to monitor and report. A thorny issue being debated is by whom, and how, will these selections be made. Certain pohtical considerations are necessary. There is always a natural tension between the arguments for a top down versus bottom up process. Effectiveness is delivered through a prudent blend of the two. Clinical and managerial expertise in combination with unique patient insights are needed to construct robust performance indicators; front line practitioners and the public should be involved alongside acknowledged experts.[22 27] However, aspirations for such an inclusive approach must be tempered by reality. Developing indicators is costly and complicated and therefore justifies a high degree of central activity for the definition, testing, and development of methods of performance indicators.[28] Central development allows for economies of scale and standardisation of content. Legitimate customisation and modification can be made through structured processes of review and ratification. Whether this central development activity is convened by government, professional organisations, or by the public is a

strategic consideration. A blended approach, although perhaps harder initially to organise and manage, may be necessary for political viability and content stability.

Performance contracts

A related issue is that of performance contracts. There is precedent in the NHS for performance stipulations related to quality of care and even with associated financial incentives. Certain primary preventions such as immunisation and cervical screening have historically had targets for achievement established and primary care payment made to reflect the standards met. Expanding this tradition in an incremental fashion, to judiciously selected additional areas of process and outcome measures, should be considered. Several pilot schemes could be designed to test those measures that seem most amenable to valid and fair monitoring and performance based payment. The areas for initial focus should be tied to the practice guidelines of the National Institute for Clinical Excellence and to the national service frameworks, thus showing the conceptual and operational integration of the initiatives. Extensive research into implementing the evidence into practice has shown us that there are 'no magic bullets' when it comes to securing comprehensive change in clinical practice. However, one underused lever for change is that of incentives.[23,29]

LOCAL RESPONSIBILITIES

In operations management and governance (fig 2), certain processes are essential; peer review, established ways of monitoring quality in hospitals - such as infection control and morbidity or mortality reviews - as well as the delineation of procedures for considering areas of compromised or poor performance.

Clinical governance

It is here that the new concept of clinical governance, introduced in the recent White Papers, will be instrumental.[1 19-21] Notable throughout our series of interviews was the frequency with which respondents identified clinical governance as the factor which would be most influential in effecting meaningful change to the culture and the delivery of quality improvement in the NHS. This is consistent with another major finding of the interviews,- the concern about the lack of clear and statutory responsibility on the part of any individual to answer for known problems of quality. Clinical governance is defined within the consultation document *A first class service (1998)* as *"a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish".*[14] It establishes a legal responsibility for the trust chief executives, commensurate with their current fiscal responsibility, for the quality of care in their organisations. Although this may in part rectify the vacuum of accountability and authority at an institution and specialty level of medical care, it is not clear how this will apply to primary care. This is an issue of pressing importance to be considered by policy makers in the professions, and consequently explained to the public.

For the front lines (the clinicians and practitioners of health care) two very different factors and processes for self regulation of conduct and

practices relating to quality improvement must be integrated. The first is external performance evaluation and monitoring. It is at the individual level of the practitioner that much of the previous quality evaluation has supposedly taken place, largely through the mechanism of audit. Audit remains a highly controversial subject throughout the United Kingdom. It is widely recognised by physicians and managers to have played a constructive part in raising the issue of evaluation of clinical practice but not delivering great systemic, or even local, impact.[30] As implemented, audit had many problems. It was viewed, as least initially, as the private domain of the medical profession. This history compromised more recent attempts to adopt a more inclusive multidisciplinary approach of so-called clinical audit. Also, it was often performed on a 'one off' basis as a project or clinical research activity as opposed to a deliberate attempt to gather objective data on a problem within the context of an organised system of evaluation and intervention. Is audit an obsolete process? Not necessarily. However, the potential to realise any benefits from audit, commensurate with direct and indirect costs, argues that it be used selectively within systematic evaluation.

The second key determinant at the individual level is that of professional code and ethics. A striking theme from our interviews was the faith placed in professional values as a means to secure quality in health care. Despite being a fundamentally important aspect, the professional ethos is unlikely to be sufficient to support the ambitious quality agenda of the new NHS. Strong values have long been a feature of professional life and despite them there are, albeit rarely, episodes of poor or dangerous clinical performance. Relying solely on professional values does not seem to be an adequate or prudent means of predictably advancing the cause of quality.

EVOLVING QUALITY IN THE UNITED KINGDOM: PRIORITY TASKS

On the political side to effect an orderly and constructive evolution for quality improvement, we see several issues as essential. Firstly, it is imperative to capitalise on the opportunities presented by the current high level of interest in quality. Secondly, there is a need to establish conceptual coherence in the quality agenda, bringing together the disparate pieces and ensuring that the people within each level of responsibility or accountability understand and have regard for other levels of the quality pyramid. Policy objectives and goals related to defining, monitoring, evaluating, and improving quality of care should be made explicit. Thirdly, there are several particular aspects of the quality agenda which need attention or clarification. These have been explored throughout the paper and are summarised in box 2.

- Clarification about the underlying assumption sregarding professional self regulation versus government regulation
- Attention to the issue of incentives defining the importance (or lack of) and what currently exists or needs to be designed
- Definition of clinical governance in operational terms
- Inclusion of primary care in all of the quality initiatives
- Prioritising and design of a strategy to increase capacity, including data and information technology, human resources, and analytical expertise
- Engagement with the public through new communication and education capabilities

Box 2 Defining priorities for the quality agenda.

CONCLUSION

How do we see the state of quality in the NHS? Many of the ingredients are there: there is recognition, although often tacit, of the three key constituencies, the individual patient, the population, the system, to which quality must be delivered; there is an appreciatior of the factors which contribute to quality - staff, technology, strategy, resources, and environment; and there is a healthy respect for the values and culture in which the health service is grounded. What is required is a unifying approach for all of these elements which together make up the NHS, taking into account the disparate concepts of quality and areas of interest.

Several dynamics found in the current NHS environment augur well for efforts to evolve the mission of and capacity for quality measurement and improvement. First and foremost may simply be the confidence of the population in the NHS.[18] This is not trivial. When looking for levers of change and incentives for improving performance, positive regard and trust for the institution is noteworthy. Collective goodwill and the desire to protect and preserve the health system is a force that should be harnessed. Secondly, by contrast with the fragmented and disparate United States health sector, in the United Kingdom it is at least conceivable to align politics, policy, and resources within the NHS to advance a deliberate and directional strategy for quality improvement. Again, this is no trivial advantage.

The overriding message is one which urges coherence in approach; recognition of quality as a concept with multiple stakeholders and the difficulties that this implies; regard for the many processes of quality necessitating coordination and integration, and acknowledgement of the values, attitudes, and commitment that make the NHS a unique entity.

INTERVIEWEE LIST

Dr Sheila Adam, Deputy Director of Health Services, NHS Executive

Dr Jonathan Boyce, Director of Health Studies, Audit Commission

Liz Bracken, The Welsh Office Department of Health

David Brackenridge, The Scottish Office Department of Health

Tessa Brooks, Director, Chief Executive Development Programme, NHS Executive

Dr Robert Broughton, Secretary, BMA Wales

Sir Kenneth Caiman, Former Chief Medical Officer, Department of Health

Dr Doreen Campbell, Medical Officer, The Scottish Office Department of Health

Dr Henrietta Campbell, Chief Medical Officer, Department of Health &. Social Services, Northern Ireland

Sir David Carter, Chief Medical Officer, The Scottish Office Department of Health

Peter Coe, Chief Executive, East London & City Health Authority

Dr Angela Coulter, Director of Policy & Development, The King's Fund

Nigel Crisp, Regional Director, NHS Executive, South Thames

Professor Sandra Dawson, Director, Judge Institute of Management Studies.

William Farquhar Director, Chnical Review and Audit Group, The Scottish Office Department of Health

INTERVIEWEE LIST

Dr Bernadette Fuge, Principal Medical Officer, The Welsh Office Department of Health

Pamela Garside, Independent Consultant to the NHS

Brian Grzymek, Director of Performance Review, Northern Ireland Belfast Health &. Social Services Executive

Juliette Harlen, Scottish Intercollegiate Guidelines Network

Sir Graham Hart, Former Permanent Secretary, Department of Health

Dr Felicity Harvey, NHS Executive.

Lord Hunt of Kings Heath, House of Lords

Baroness fay of Paddington, Minister of State for Health

Professor Alison Kitson, Director, RCN Institute, Royal College of Nursing

Sir Alan Langlands, Chief Executive, NHS Executive

Dr Alasdair Liddell, Director of Planning, NHS Executive

Dr Phillip McClemence, Deputy Medical Officer, Department of Health & Social Services, Northern Ireland

Professor Martin McKee, Health Services Research Unit, London School of Hygiene &. Tropical Medicine

Dr Hugh McKenna, Department of Health Science, University of Ulster

Yvonne Moores, Chief Nursing Officer, Department of Health

Dr Fiona Moss, Editor, Quality in Health Care

Maggie Parker Nursing, Officer, The Welsh Office Department of Health

Sir Naren Patel, President, Royal College of Obstetricians and Gynaecologists

Professor Tames Petrie, President, Royal College of Physicians, Edinburgh

Dr Gina Radford, NHS Executive

Colin Reeves, Director of Finance & Performance, NHS Executive

Dr Charles Shaw, Director, Audit & Quality in Health Care, CASPE Research

Clive Smee, Chief Economic Adviser, Department of Health

Dr Richard Smith, Editor, British Medical Journal

Professor Robert Stout, Dean, Faculty of Medicine, Queen's University of Belfast

Sir Rodney Sweetnam, President, Royal College of Surgeons of England

Stephen Thornton, Chief Executive, NHS Confederation

Dr Dorothy Whittington, University of Ulster

Dr Kevin Woods, Executive Office, Scottish Health Service Management Executive

John Wyn Owen, Secretary, The Nuffield Trust

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