The National Health Service in England considers on the Government’s plans to improve quality of health care

Commenting on another of its consultation papers, one notary recently gave the British Government “α for presentation, β minus for deliverability”. Early indications are that the Government’s consultation paper on quality in the English National Health Service (NHS) could edge up to a β plus or even an α minus, with some more thought about the practicalities of implementation.

The history of approaches to quality in the NHS has been of fragmented initiatives, with little sense of overall coherence. National complaints procedures resulting in pronouncements from the health service ombudsman, local consumer watchdogs, and external visiting bodies such as the Health Advisory Service have coexisted with variable internal and external use of voluntary performance indicators and patchy systems of medical audit. The most systematic approach to a national quality programme came from the previous government, when they introduced the medical (later clinical) audit programme to the service at the same time as the “purchaser-provider split”. This structural change was, itself, intended to produce improvements in quality, through the incentives anticipated by competition with other healthcare providers. Commitment to quality improvement was not always manifest in the priorities for performance monitoring, however, where measures—such as the efficiency index (essentially activity per £) and achievement of waiting list targets—overrode indicators of service quality. In its white paper setting out the dismantling of the former government’s internal market in health care, the Labour Government signalled that fundamental changes to the approach to quality in the NHS were afoot. A first class service: quality in the new NHS sets out their vision. The consultation paper introduces several measures which, taken together, are intended to produce a model of quality improvement which “marries clinical judgement with clear national standards”—that is, the Government is trying to harness national external approaches with local flexibility and responsibility. It proposes to achieve this by:

- Setting national standards (through a National Institute for Clinical Excellence, (NICE) and national service frameworks for selected disease or client group areas)
- Improving systems for local quality assurance and quality improvement (notably the new clinical governance proposals, but also including professional self regulation and lifelong learning)
- Monitoring the implementation of standards (by a new national body, the Commission for Health Improvement, along with routine performance monitoring of health authorities and trusts and a new national survey of patient and user experience).

The NICE will appraise therapeutic interventions and disseminate authoritative guidance throughout the NHS, including guidelines for the management of certain disease conditions and guidance on the appropriate use of new technologies. The NICE will also produce audit tools for use within the service. To achieve this, the Institute will take over a range of functions currently undertaken by different organisations—for example, the National Prescribing Centre, the National Centre for Clinical Audit, national guidelines programmes, and the systematic reviews (Effectiveness Bulletins) funded by the Department of Health.

National service frameworks are intended to be approaches to whole services, rather than simply dealing with clinical practice issues. They will set national standards and define service models for specific services or care groups. They will be modelled on the Calder-Hine framework for cancer services, which is already in place in England. Clinical governance will be a requirement of both healthcare trusts and primary care groups. How this will work in primary care is not yet clearly understood, as general practitioners will retain their independent contractor status. However, there is more clarity for trusts where the chief executive and board will, for the first time, have a statutory duty to account for the quality of their services.

They will be expected to have in place:

- A comprehensive programme of quality improvement activities (including clinical audit, evidence-based practice, and internal monitoring systems)
- Clear policies to manage risk
- Procedures to identify and remedy poor performance in all professional groups.

Professionals will be required to participate in national audit programmes where they exist. The Government also proposes to strengthen professional self regulation, with particular emphasis on the medical profession after recent high profile lapses in its public credibility. The document also introduces a new phrase to describe continuing professional development, “lifelong learning”, which intends to provide staff with the opportunities to update their skills and knowledge.

The Commission for Health Improvement will be a new statutory body, which will carry out a rolling review programme, assessing local clinical governance arrangements and the adequacy of implementation of NICE guidance and the national service frameworks. It will also be possible to call in the commission to tackle serious difficulties in the service. It is expected that the commission will link with the NHS complaints procedure, but details of how have not yet been worked out. The government is also consulting on a new national performance monitoring framework, which aims to take a broad overview of health and health services, rather than the past focus on service activity. Finally, an annual national survey of patient and user experience is proposed, to find out whether local services are meeting patients’ needs, and which could trigger the involvement of the commission.

The consultation paper sets out a highly ambitious agenda. In his introduction to the document, Frank Dobson (Secretary of State for Health), accepts that the “... changes will not happen overnight” and “are part of our 10 year programme of modernisation ...”.

Commentators,
although strongly welcoming the overall thrust of the paper, have picked out a series of potential problems in implementation. These range from the perverse incentives inherent in external monitoring, as embodied in the proposed Commission for Health Improvement and plans to publish indicator league tables; to the seemingly unrealistic expectations of the annual work programme for the NICE, and the methodological weaknesses in the planned national user survey. However, there is widespread support for the apparent coherence of the proposals, especially given indications that government health policy will be consistent across other relevant areas such as information technology.

For me, the crux will be how well the government walks the tightrope between “big brother” and local professional and organisational responsibility for quality improvement. The devil is, as always, in the detail: we need to ensure that the detail works out in favour of benefits for patients, rather than the lawyers’ pockets.

Comment

Defining appropriateness: the challenge of knowing the difference

In the forward to the consultation document *A First Class Service*, the Secretary of State proposes that “the unacceptable variations that have grown up in recent years must end”. I will make that statement the framework of a discussion on measuring and improving performance among healthcare providers, as it pertains to the English National Health Service (NHS) agenda for quality and health.

The Secretary of State’s pronunciation about variation contains all the essential elements for an agenda of ongoing amelioration of both services and the quality of life of the populations served. These essential elements are: (a) unacceptability; (b) variation; (c) increasing temporal trends; and (d) elimination of variation or halting the rate of its increase. Curiously, these also were the essential elements of many agendas for change in the United States encompassing government sponsored activities—for example, the Agency for Health Care Policy and Research (AHCPR)—and those on the private side—for example, small area variation analysis, and the National Committee for Quality Assurance (box 1). The similarity of these determinants certainly deserves attention.

Background

The first outcomes based standard of care was issued in Babylon nearly 4000 years ago, during the reign of Hammurabi, King of Babylonia. His code of laws, found on a column at Susa, is one of the greatest of the ancient codes. The penalty for surgeons who failed to meet the government’s standard of care was straightforward:

“If a physician shall make a severe wound with an operating knife and kill (the patient), or shall open an abscess with an operating knife and destroy the eye, the (surgeon’s) hand shall be cut off.”

The Agency for Health Care Policy and Research (AHCPR) was established in 1989 under Public Law. As a part of the United States Department of Health and Human Services, it is the lead agency charged with supporting research designed to improve quality of care, reduce its cost, and broaden access to essential services. The AHCPR’s broad programmes of research bring practical, science based information to medical practitioners, to consumers, and other healthcare purchasers.

The National Committee for Quality Assurance is a not for profit organisation that seeks to improve quality of patient care in partnership with and complementing managed care plans, purchasers, consumers, and the public sector. It evaluates the internal quality processes of health plans (through accreditation reviews) and developing performance measures.

From the Hammurabi code to the mapping of the genome, we have been interested in uniformity of our practice, its appropriateness, and in understanding the determinants of our behaviour. Fortunately many healthcare reform agendas around the world have embraced the logic of quality improvement, by contrast with the drastic recommendations of Hammurabi’s code.

In the United States an early 19th century maverick surgeon, Ernest Codman, set the tone for today’s agenda for change in health care. Codman, who died poor and rejected by his colleagues and the medical profession, also defined, perhaps most eloquently, the very core principles of quality improvement. During an address read before the Philadelphia County Medical Society, on 14 May 1913 he said:

“The object of this address is to stimulate thought on and discussion of the standardisation of a hospital. I take it that the word standardisation implies a general movement toward improving the quality of the products for which hospital funds are expended. As a rule, standards are raised by stimulating the best—not by whipping the laggards.”

I cannot think of another short quote that better describes the transition from quality assurance to quality improvement! And, I think that the NHS agenda for change is doing exactly that—looking at the entire system...
where patients, provider, and society cooperate toward a better healthcare environment. In the parlance of performance improvement strategies, the shift in the NHS agenda could be called one from quality assurance to quality improvement and monitoring. And, the NHS wants to do it first class.

The seminal work of Donabedian gave us the framework of structure, process, and outcome for systematic inquiry into the ethereal world of quality. Although he often recognised that there are situations when the ultimate decision is the provider’s, Donabedian’s curiosity in the matter of appropriateness resulted in a new field, now known as “health services research”, which as an intramural discipline considered the “sociology” of medicine as much as clinical decision making. Many of the structural components of the NHS agenda use the stepwise approaches of assessing a performance profile, understanding the magnitude of its occurrence, placing it within the realm of the group or society it is supposed to serve, evaluating its goodness, and monitoring it over time. That is the framework of health services research, based on the analysis of variation.

Indeed, variation analysis became most systematic in its inquiry with the work of Wennberg. He called this “small area variation analysis”. The purpose of the analysis was comparison of rates across geographical areas. The popularity of small area variation analysis was critical to health services research on quality of care in an obtuse way—with increasing emphasis on variation analysis researchers realised that high variation did not necessarily mean low appropriateness. Furthermore, and contrary to what policy makers had hoped, documentation of low variation did not reflect appropriateness of care. 3 In fact, there may be a higher proportion of inappropriateness within low rates or low variation profiles, than in high rates or high variation areas. Specifically, small area variation analysis was unable to show that variation was always related to bad care; and it was unable to fully adjust for characteristics of populations or patients (cultural, acuity of disease, expectations from the healthcare system.) Nevertheless, small area variation analysis, until recently, was the first agenda item on every United States agenda for change initiative! It was more than that: the AHCPR was created to curb variation through the centralised compilation of best practices, and their dissemination to the field. To close the circle, AHCPR, as a government agency, was also required to fund and finance research from the field that would further our understanding of best methods of care, which included clinical guidelines and analysis of service production efficiency.

Although variation analysis remains an important initial component of today’s performance improvement strategies, it may have lost its allure to policy makers. Whereas it was hoped that decreasing variation would increase quality and save unnecessarily spent resources, the findings to date have fallen short of these expectations. Today, we accept that variation will be found when looked for; that variation is indeed the underlying statistical logic of any distribution of events; and that variation is just that, neither good nor bad, until you evaluate the appropriateness of that variation. I would like to clarify what I mean by evaluation. In its most basic meaning, evaluation means putting a value upon some observation or act. Thus, when variation is measured, it is a value free measure. It becomes acceptable or not based on the value judgement, or evaluation, that one or a group of people will attribute to that variation. Who are these evaluators? Sometimes it is said that “where you stand on an issue depends on where you sit.” If true, then various groups—payers, patients, community representatives—may apply different values to the same observation of variation. The goal of sharing variation profiles with the various audiences or groups will be to reach consensus as to the ultimate good of the community, which is better health status, delivered through effective application of the state of the art biomedical knowledge. And that is just another definition of accountability.

The most recent developments in the United States are in search of accountability methods. Although the application of medical sciences and their evaluation have been historically the domains of medical professionals, at the eve of the 21st century, medicine’s accountability has become that of us all, recipients of care, payers for medical services, and managers of the resources needed to provide all the necessary care, in the best way. And, as in the Secretary of State remarks,1 we find ourselves needing to define what is appropriate care, and what is unacceptable variation. In both instances, the first requirement is to agree, through consensus, on the thresholds that would signal the inflection point on a curve when appropriateness and acceptable variation are on the axis. But firstly, we need to know why, through an evaluative process, an observed variation is valued as acceptable or not acceptable.

Why is variation unacceptable?

Although there may not be a direct answer to this question, in a first class service there are numerous attempts to define its dimensions. Indeed, under section 1.8 of A First Class Service it is referred to as “wasteful and unfair”, which brings economic and production efficiency variables in line with society’s issues of fairness. 1 If variation results from wasteful, irresponsible, and incorrect use of resources by providers, then variation analysis is a valid screening strategy. However, the evaluation of that variation will happen only after what is commonly referred to as “process analysis” is carried out, looking at the production of the total service or care, not only the clinical dimension. Thus, variation will remain a statistical observation until the evaluative analysis is conducted, taking into account the providers’ conformance to clinical guidelines, best management of resources, responsiveness to patient needs, and possibly the impact of all these on the outcome of the care. This is surely an ambitious agenda for the NHS, but also one that seems to be approached with extreme thoughtfulness and social responsibility, especially when the study of process, rather than outcome, is required to be evidence-based, wherever possible.

What is heartwarming to me is the explicit recommendation and the proposed structures to bring about the evaluation of variation, which will require, in the context of geographical and community boundaries, to that very local level. The devolution of responsibility to the local level for measuring performance, evaluating its appropriateness, and monitoring its temporal profiles is a remarkable characteristic of the NHS agenda. Specifically, accountability is imbedded in the local level of clinical governance which “...will be the process by which each part of the NHS quality assures its clinical decisions” (section 1.16) This statement I read more as a description of a partnership and not one of direct oversight. As such, the uniqueness of the decentralised approach to evaluation of appropriateness becomes even more laudable.

But the challenge of evaluating variation while striving toward uniformity remains. The consultation document recognises this conundrum.1 Section 1.11 reads:

“It must be for the individual clinician to decide what is the best interest of the individual patient. Each patient is different and treatment must be tailored made to their specific needs.”
The importance of this statement cannot be overlooked, as individual physicians deal with individual patients (the medical model), whereas variation analysis is the triggering strategy (the epidemiological model), towards the population improvement in health status (the public health model). The NHS agenda is interactive among these three models; and the NHS has to present to clinicians the methods of translating group observations into decisions at the individual patient level. Failure to achieve a valid translation of evidence-based processes of care may result in what epidemiologists call the “ecological fallacy”—interpreting the data from groups as valid for individual patients as well. This is neither a new issue nor one that can be resolved through a formula. It is the prologue to collaborative work, or partnership, as defined by the consultation document. It is one where the medical and public health models come together to discuss the continuum of care; to define outcomes as attributions to the care well after the patient is discharged; and to facilitate the evolution of this NHS strategy into a community focused service rather than predominantly a hospital or clinician centred endeavour. After all, medicine, in any society, is the ultimate good, and it is right that the government should facilitate the provision of good care by providing the resources and best knowledge. Thus, the government should centrally provide the parameters for defining good practices, and disseminate them through service frameworks and continuously updated evidence-based guidelines. Such a strategy will maximise the dissemination of timely and uniform knowledge. However, it seems to me also to be the responsibility of the government to place the onus of the proper implementation of these parameters on the local level. Thus, an attractive opportunity will be seized for a partnership between central government and local leadership to use national parameters while evaluating performance locally. I think that clinicians will welcome such a partnership.

**Accountability: the need to serve more than one master**

Accountability is synonymous with answerability. Thus, if there is an answer, I reason that there first needs to be a question. Immediately, it becomes apparent that with multiple questioners, there may be multiple answers.

In the United States, accountability is among the terms most often (and perhaps non-specifically) used in health care and policy. The practical translation of performance measures into accountability has been through report cards, a seemingly unique United States response to showing, to practically any audience, how an institution has performed clinically, administratively, or even from the point of view of education or prevention of disease. These cards, similar to those that students get from school, are expected to reflect how an institution performed in a certain type of clinical care or administration of care process. The report cards are a compilation of indicators, which are expressed as rates. So far, this is not a novel idea. For example, The National Committee for Quality Assurance, the counterpart to the JCAHO in accreditation of managed care organisations, has experimented with report cards by making publicly available a comparison across managed healthcare plans of various rates—such as immunisation rates and mammography rates, etc.

But the idea of making information available to the general public so that they can make better decisions is not new in the United States. In the past decade, the strategies for accountability have run the gauntlet from public release of mortalities by the federal government and private sector projects, to the design of comparative analysis of rates across institutions which voluntarily joined effort to learn more from each other and improve performance. The lesson is still not completely learned, but its message seems to be “if there are multiple audiences, there must be multiple report cards.” Why has such an obvious realisation taken so long to crystallise? Probably the difficulty of putting together a performance profile report (a definition I propose as a replacement to report cards) is at the core of the procrastination. Or perhaps it is because United States researchers and policy makers waited until it was inevitable that multiple approaches were necessary. Indeed, today there is much talk of integrated data systems in which financial, clinical and patient expectation, and management or organisational data are collected simultaneously as the main dimensions of performance. The correlation between these dimensions of the healthcare service subsequently establishes the needed understanding of how one dimension is affected by the variation in the others. For example, will cost really decrease if quality is increased? Will patients expect better outcomes if they are better educated by the healthcare professionals about their diseases or the type of intervention? Is there an optimal resource allocation to quality ratio?

No matter what the topic of inquiry, a framework for accountability is necessary. Perhaps we can define the three Ws of accountability as:

- **What is the question?**
- **Who is asking it?**
- **Why did they ask it?**

The NHS strategy recognises that there are multiple audiences in search of understanding how appropriate care should be delivered. That is a significant step forward which could prevent the growing pains still experienced in the United States, as many initiatives still yield one analysis, one type of report, which is often geared toward the providers of care rather than patients or communities. It remains to be seen if the multiple masters of accountability will work in tandem.

**The tangible results of the NHS agenda**

What will be the outcome of the partnership the NHS has so meticulously mapped? Firstly, there are structural entities (the National Institute for Clinical Excellance (NICE), The Commission for Health Improvement, the clinicians, and the patients) which may interrelate and interact in ways not always predicted or predictable. For example, whereas the Commission for Health Improvement “... will complement the introduction of clinical governance arrangements” (section 4.2), it is not clear to what extent it will also get involved in the direct judgement of performance profiles, rates, and outcomes. Patients, who are expected to contribute to the triggering process through their complaints (section 4.3), may not always participate in the evaluation of the very outcomes they experience, unless ad hoc initiatives are designed to allow a joint evaluation of outcomes by both providers and recipients of care. Knowing the caveats and limitations of patient surveys, it is not clear if the NHS strategy is simply to capture patient satisfaction, or also to interpret these satisfaction measures alongside measures of expectations. I would like to propose that there is a significant relation between what people appreciate and what they were expecting. And in health care the expectation by patients is a function of how the medical profession has educated them or their communities. Would a patient after a hip replacement be satisfied if he was told that he could play golf again, and then could not? Would a woman in labour go through 12 hours of back pain if she was told that there are easier ways of managing pain while managing labour?
Conclusions
A First Class Service has set forth a herculean agenda. The labours it will be required to complete are still not clear. It is, however, clear that taking the partnership between the government and providers to the communities that they all serve is a momentous decision and one that, I think, will bypass many identity and accountability crises the United States healthcare system has passed through since the first public release of hospital mortalities by the Health Care Financing Administration. However, whereas we know that evidence-based guidelines often assist physicians in reviewing their performance, patients should not be expected to base their evaluation of their care on these same guidelines. Thus, the ultimate success of the NHS agenda may not be to identify best practices or disseminate evidence-based guidelines. Rather, it will be in showing that the health status of communities and the quality of life of patients have improved. For that, the journey is long, the paths serpentine, but the rewards most comforting.

More than 1800 hospitals voluntarily participate in the Quality Indicator Project worldwide, including 20 British hospitals.

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