Implementing health reforms

Clinical governance: bridging the gap between managerial and clinical approaches to quality of care

Stephen A Buetow, Martin Roland

Department of General Practice and Primary Health Care, University of Auckland, New Zealand
S A Buetow, *repatriation fellow of the Health Research Council of New Zealand*

National Primary Care Research and Development Centre, University of Manchester, UK
M Roland, *director*

Correspondence to:
Dr M Roland, National Primary Care Research and Development Centre, University of Manchester, Oxford Road, Manchester M13 9PL, UK.

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Abstract
Clinical governance has been introduced as a new approach to quality improvement in the UK national health service. This article maps clinical governance against a discussion of the four main approaches to measuring and improving quality of care: quality assessment, quality assurance, clinical audit, and quality improvement (including continuous quality improvement). Quality assessment underpins each approach. Whereas clinical audit has, in general, been professionally led, managers have driven quality improvement initiatives. Quality assurance approaches have been perceived to be externally driven by managers or to involve professional inspection.

It is discussed how clinical governance seeks to bridge these approaches. Clinical governance allows clinicians in the UK to lead a comprehensive strategy to improve quality within provider organisations, although with an expectation of greatly increased external accountability. Clinical governance aims to bring together managerial, organisational, and clinical approaches to improving quality of care. If successful, it will define a new type of professionalism for the next century. Failure by the professions to seize the opportunity is likely to result in increasingly detailed external control of clinical activity in the UK, as has occurred in some other countries.
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Keywords: quality assessment; quality assurance; clinical audit; continuous quality improvement; clinical governance

Introduction

Having been defined in many different ways, approaches to measuring and improving the quality of health care have become confusing, leading to misunderstandings and hindering efforts to improve care.[1–3] Now, yet another term has been introduced. The UK government has determined that "clinical governance" will be the framework within which healthcare organisations at every level of its national health service (NHS) will be "accountable for monitoring and improving the quality of their services". Clinical governance is intended to "safeguard high standards of care by creating an environment in which excellence in clinical care will flourish".[4]

Past approaches can be described under the headings of quality assessment, quality assurance, clinical audit, and quality improvement, including continuous quality improvement (table 1). There has been little consensus on how these should be defined or used. In the NHS, they have been interpreted, and their implementation controlled territorially, by managers and professionals who have vied for centre stage in activities relating to quality of care. Whereas quality assessment and clinical audit have been professionally led, quality improvement approaches have involved a shift towards managerial ownership, and quality assurance has been perceived to be either externally driven by managers or to include internal inspection by professionals. This paper

Table 1   Approaches to measuring and improving quality of care

	Quality assessment	*Quality assurance*	*Clinical audit*	*Continuous quality improvement*
Aim	Identify discrepancies between desired and actual performance	Reach and maintain an acceptable standard of care	Raise performance in one area to meet local needs	Continue to improve the whole system as part of normal daily activity
Philosophy	Through daily activity, professionals can identify and remedy gaps in performance	Outliers can be identified, to indicate potentially inappropriate care, and corrected when necessary	Self evaluation and professional improvement can achieve best practice	What is good can be made better through continuous process improvement
Method	Performance measurement against standards, and investment in selection and training of professionals	Detection of outliers through external or internal inspection, and their correction, when necessary, through systematic activity	Peer review by professionals	Prevention of problems and control of unintended variation in process through total quality management
Principal responsibility of:	Professionals at an individual, implicit level	Payers (US) or managers responsible for purchasing health care (UK)	Clinical teams involved in care delivery	Clinical services managers

describes these four approaches to provide a clear understanding of what each entails and an informed basis for their respective use. We examine how the new concept of clinical governance maps to the previous approaches, and identify threats and opportunities associated with its adoption.

Quality assessment

Quality assessment compares performance with expectations, standards, or goals,[5] and is often assumed to be the responsibility of professionals. Quality assessment has sometimes been described as an approach to identifying defects or deficiencies, which are inherent in any system.[6] Quality assessment does no more than identify opportunities to improve quality. As such, it is a necessary component of other approaches to improving quality. Quality assessment can permit "quality control" or rejection of services that do not meet standards.[7] However, it does not seek to impose solutions. Nor does it require any declared intention or ability to take corrective action or action for improvement. Instead, healthcare professionals involved in quality assessment are assumed to have an implicit concern for quality and to be able, and trusted, to make changes when problems or needs become apparent.

The most influential formulation of quality assessment is Donabedian's application of a systems based framework of structure, process, and outcome.[8] According to Donabedian,[9] the relations between these components of care must be known before any particular one can be used to assess quality. Berwick and Knapp state that "this prerequisite for measuring quality is probably a formula for paralysis" because so little is known about the relation between process and outcome.[10] The categories of structure, process, and outcome, however, describe categories of care, not actual quality of care. Maxwell identified six dimensions of quality—relevance, accessibility, effectiveness, acceptability, efficiency, and equity[11]—and combined them with the Donabedian trilogy.[12] However, Joss and Kogan reported difficulty in using this framework.[13] Neither Donabedian's nor Maxwell's model focuses unequivocally on the needs of patients, and each neglects how the whole organisation, rather than merely the professional, relates to the patient and contributes to improved healthcare outcomes.[14]

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The limitations of quality assessment relate first to the limitations of measurement. The temptation is to focus on the easily measurable, thus potentially neglecting important aspects of care. Moreover, because quality is multidimensional, it is rarely possible simultaneously to measure all aspects of care as defined, for example, by Maxwell. Choices therefore need to be made. So, in the example of cardiac surgery, mortality after surgery may be a key aspect of care to measure, whereas in primary care, mortality may relate more to characteristics of the population served than characteristics of the care provided. Secondly, quality assessment makes no attempt to ensure that changes indicated as necessary are either made or appropriately managed, even though the recognition of problems or needs cannot be relied on to change management.

Quality assurance

Quality assurance begins with an assessment of quality to identify outlying results which may indicate inappropriate care.[15] Although outliers might not represent poor care—for example, they may point to a lack of consensus about the appropriateness of healthcare provision[16]—the identification of outliers can identify the need for systematic further investigation to ensure that minimum or acceptable standards of care are being provided. These stages describe the quality assurance cycle, which has been depicted as a spiral rising upwards in an ongoing quest for quality.[17] The aim of quality assurance is not to achieve error free care but rather to rectify what is grossly aberrant by improving the inputs and processes by which services are delivered.[15] Advantages of quality assurance generally include its reliability, strategic orientation, and independent scrutiny of services.

Quality assurance has its origins, and has found prominence, in the United States (US) where pressures for cost containment and accountability have emphasised the need to assess appropriateness of care, especially in a system where there is believed to be significant overprovision of care. Since the 1950s in the US, external monitoring agencies have undertaken quality assurance as a review activity with accreditation, mainly involving payers. In the UK, by contrast, perceived underprovision of services has favoured a wider, population perspective[18] of quality assurance. This perspective highlights the contested nature of quality assurance as a reactive activity as against a regular and systematic one, and as the responsibility of managers as against an approach that professionals can drive internally.[18] European approaches for quality assurance have tended "to be based on the premise that the medical profession undertakes its own quality assurance".[19]

When identified by external inspection, topics for quality assurance have generally been hospital based outcomes, such as maternal or perioperative deaths, considered important by regulatory agencies or accreditation organisations. Professionals have been expected to meet the standards set by these groups. External checks on quality have been uncommon in the UK but include the Health Advisory Service, which inspects services for long stay elderly and mentally ill patients.[20] A new Commission for Health Improvement is proposed by the government as an external monitoring agency.[4]

Formal and explicit methods of assessment used in quality assurance include the growing use of indicators to assess clinical, managerial, or organisational performance. By identifying areas in need of further investigation and comparing areas sharing common characteristics, performance indicators are quantitative tools for raising questions about health care. They can be used to set targets, monitor perform-

ance, and describe variations in medical practice, including the identification of areas of excellence and areas where everyday practice appears to depart significantly from expectations or some other standard. The popularity of indicators reflects interest across the public sector in strengthening management, accounting for resources, and improving performance. There has also been global interest in assessing both the management and outcomes of care,[21] [22] due, for example, to concerns that escalating costs of health care are not yielding health improvements.

In the UK, indicators have been developed by health authorities and the NHS Executive for use in primary care. Hospital based clinical indicators have become commonplace and, like non-clinical *Patient's Charter* indicators, are now being published. The publication of indicators for external evaluation is in line with developments in countries including Scotland and Italy.[23] [24] In contrast, "the largest comparative quality indicator database in the United States, the Maryland Quality Indicator Project . . . feeds back comparative data in an anonymised fashion for internal use" and has "supportive and educational components".[24] This project now involves countries including the UK, the Netherlands, Belgium, Austria, and Japan.

> *"Quality assurance is a misnomer…quality can be protected and enhanced but cannot be ensured."*

LIMITATIONS

Quality assurance is a misnomer. It is an ideal too often promised in health care because quality can be protected and enhanced but cannot be ensured.[25] Moreover, evidence is frequently not provided for the validity of external quality criteria and standards. Indicators tend to lack specificity and measure limited aspects of performance without necessarily being relevant to individual patient populations. Observational data collected, especially on outcomes, are beset by methodological problems.[26] [27] Where league tables are produced, they invite comparison of relative rather than absolute levels of performance, so improvements by some providers may be undetected. Concern has been expressed that league tables do not take into account the circumstances under which different providers operate and the needs of their patients, for example by failing to account for variation in patients' socioeconomic circumstances. This tends to minimise clinical and patient perspectives on quality. Professionals also fear that league tables may be used to "punish poor performers" rather than to improve performance.

Indicators used in quality assurance contain value judgments about what is important to measure. The myth of "value free" science was exploded during the 1970s, and Suchman[28]

had previously noted that the cycle should begin and end with value statements because personal and organisational values influence the setting of goals or standards and decisions about performance after implementation of change.[13] Moreover, valuations of different outcomes may vary among the different stakeholders and in different localities.[29] The values that govern the selection, measurement, and assurance of aspects of care therefore need to be explicit before quality measures are chosen. Most often this is not done, and the indicators used are those for which data are available.

Quality assurance is frequently based on a culture of external inspection that seeks to respond to demands for public accountability and patient choice. However, this culture assumes the need to deter "poor intentions"[30] and to detect errors rather than to build in quality prospectively. The inspections can also focus on individuals, augmenting concerns that quality assurance can be misused to seek out, blame, and impose punitive sanctions on poor performers. These concerns discourage commitment by professionals to quality assurance, so the data they collect may be of variable quality.

Quality assurance can also invoke defensive responses including acceptance of minimum standards of care rather than excellence, eschewal of new methods of practice, and poor performance one year to secure easily achievable targets in subsequent years. Perverse changes may result, for example in prescribing or referral patterns. For example, pressure to reduce prescribing costs may result in reduced use of expensive but effective treatments such as statins and inhaled corticosteroids. Davies and Lampel note that the private sector, which has given legitimacy to the public escalation of performance measures, is increasingly abandoning its dependence on process control.[27]

Clinical audit

Clinical audit has sometimes been defined narrowly as a part of quality assurance.[31] This is most easily justified in the US where, compared with the UK, audit has a longer history and is more advanced as a management tool. In the UK, however, clinical audit is led and done by professionals themselves, usually through structured peer review.[32] As with quality assurance, clinical audit compares service provision against agreed clinical standards to identify whether individual standards have been met and, where they have not been, why not. Clinical audit is frequently concerned with making and sustaining changes to achieve acceptable care and can be presented as a cycle.[17]

In the UK, the purpose of most clinical audit is to improve performance in one area and, funded through general financial allocations to individual health authorities, to meet local needs for the development of clinical practice.[33] As part of continuing professional development, clinical audit may be multiprofessional and undertaken by the healthcare team, or uniprofessional and undertaken by staff in one clinical discipline. In European systems of primary care where many general practitioners work single handed—for example the Netherlands,

Germany, Switzerland, and France—clinical audit is more likely to be done by small peer audit groups or quality circles than through multidisciplinary audit. Topics for audit can be selected collaboratively by professionals, managers, and patients. To undertake clinical audit, professionals may, for example, apply review criteria to medical records. Allowing for clinical judgment, this can indicate whether key, past actions meet minimum thresholds of care for individual patients.[34]

Clinical audits are an integral part of clinical practice in the UK. Since 1990, widespread support has been provided for clinical audit in general practice, and audit has become part of the contractual commitment for hospital doctors.[20] The popularity of clinical audit has grown in the UK for two main reasons. Firstly, review by external agencies has been unsuccessful, although external monitoring has been successfully used in areas such as prescribing costs.[35] Secondly, and more importantly, healthcare professionals have preserved a large degree of control over the clinical audit process. They have been encouraged and frequently supported by health authorities to choose their own topics to audit, to agree criteria with which to assess performance, and to set standards.[35] Their clinical audits have been locally controlled and implemented, and any consistent failure to meet standards is viewed as a clinical rather than a managerial problem. Consequently, the use of clinical audit has become widespread and is, for example, a mandatory part of summative assessment of training for general practice.

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Professionals may lack the skills to undertake clinical audit, and audit is frequently regarded by individual professionals as an expensive addition to clinical practice rather than an intrinsic and effective part of it.[36] They apply it periodically and perceive it to be tedious, compromising to routine clinical practice, lacking in strategic orientation, and too time consuming to be operationally useful.[37] The action needed to improve practice is frequently unclear to professionals, many of whom lack the resources needed to act for improvement and complete the audit cycle.[12 38] As a consequence, it is not uncommon for peer review groups to resist collecting the data that they require to determine whether improvements are continuing to take place.[39] A lack of consensus also exists among professionals about the systematic involvement of service users in the audit process.[40 41] The effectiveness of clinical audit is unknown therefore despite the continuing major investment of clinical time[42] and money from the UK government,[31] and concern about the cost effectiveness of clinical audit has been widely expressed.[37]

Audit has led, however, to a cultural change in the attitude of clinicians towards quality of care in the UK. These professionals are now much more aware of the need to monitor and improve quality of care than they were in the early days of audit in the late 1980s. Moreover, by giving them "the rudiments of a common language" in the UK,[43] clinical audit has increased their ability to articulate issues about, and achieve, quality improvement. It is difficult to specify how audit has led to improvements in the quality of care but, compared with a decade ago, there is a much greater appreciation by healthcare professionals that improving the quality of care is of great importance.

Quality improvement
The term "quality improvement" is poorly defined. In general, it suggests that what is good can be better. It does not guarantee that improvements to quality will be maintained,[32 35] although in Europe the terms "quality assurance" and "quality improvement" have often been used synonymously. In the US, it has come to mean continuous quality improvement,[44] which is the meaning that table 1 conveys. Continuous quality improvement has its origins in private sector manufacturing and the industrial recovery of Japan after the second world war. American theorists including Shewart,[45] Deming,[46] and Juran[47] have led this concept, which seeks to "design quality in" rather than "inspect errors out", and to improve the whole system as part of normal daily activity.

Continuous quality improvement values empowerment of individuals, for example by trusting in their abilities and commitment to improving quality, and organisational learning, awareness, and responsiveness to patient needs. Opportunities are taken for continuing improvement, and prevention, rather than detection, of difficulties is encouraged. So too are innovation, serial experimentation, and the identification, redesign, and testing of processes to control unintended variation. Continuous quality improvement is management driven and controlled, and total quality management is an overall organisational strategy for engendering and sustaining its culture or philosophy.

Using total quality management, leaders define the strategy but implementation is decentralised. They devolve responsibility for problem solving and decision making to teams that are actively committed to continuous quality improvement and supported from the top. Leaders produce a corporate plan and a strategic vision that challenge the status quo, suggest promising options, break down barriers between disciplines or functional areas, and put quality on the managerial agenda. Leaders also invest substantial time and capital in continuous quality improvement, in particular through continuous education, so that all staff learn new skills including teamworking and cooperation with patients, managers, and other professionals. Proponents of these initiatives believe that staff feel valued and respected as they continue to learn, search for, and act on opportunities to raise quality.

Organisations committed to total quality management and continuous quality improvement are responsive to components of quality assessment, as exemplified by the need for

measurement[20] and cycles such as plan-do-study-act.[48] This cycle requires staff to set aims, define measurements for learning, identify promising ideas for change, and test changes in real work settings. A similar conceptualisation involves project definition and organisation, problem identification (diagnostic journey), evaluation of an intervention (remedial journey), and holding the gains.[49]

Quality improvement may be described alternatively by process re-engineering. Since its introduction in 1990 by Hammer[50] and Davenport and Short,[51] process re-engineering has been widely applied in business and has recently spread to the service sector, including hospitals.[52][53] Driven by the desire to achieve major and rapid gains in performance and to boost competitiveness, this top-down approach to quality improvement requires organisational leaders to scrutinise, question, redefine, and radically redesign from first principles core processes of production and service delivery. To these ends, process re-engineering may require complete restructuring of the organisation.[54][55] Unlike continuous quality improvement and total quality management, which operate within the current framework of the organisation to improve existing processes incrementally, re-engineering invents new approaches to essential healthcare processes in an attempt to achieve dramatic results. Nevertheless, both re-engineering and continuous quality improvement emphasise process, and work backwards from the needs of customers.

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Whereas continuous quality improvement and total quality management have generally demonstrated concern for, and responsiveness to, the needs of workers, applications of process re-engineering have tended to neglect the human dimensions of managing and organising change.[56] The managerial accent of both sets of approaches is anathema to many healthcare professionals for whom the terms these approaches use are jargon and subjugate professional autonomy. The warning of Donabedian that the approaches may emphasise efficiency at the neglect of clinical effectiveness reflects such concerns,[57] which are compounded by little advice on how to achieve organisation-wide culture change. Joss and Kogan have identified the additional difficulty of applying to the NHS the principles of approaches based in commercial practice.[13] Evidence is lacking that these approaches improve patient outcomes and thus scepticism about them may not simply reflect a lack of understanding by professionals. Joss and Kogan also suggest a mixed model that can harness professional expertise.

Nevertheless, successes have been claimed for quality improvement initiatives,[13] and Shortell and colleagues identify three preconditions for continuous quality improvements in clinical practice[58]: firstly, the continuous quality improvement initiative is focused on areas of real importance to the organisation, with clearly formulated interventions; secondly, the

organisation is ready for change and has prepared itself by appointing able leadership, creating relationships of trust with clinicians, and developing adequate information systems; and thirdly, the external environment is conducive to continuous quality improvement in regulatory, payment, and competitive factors.

Clinical governance

The UK government has developed the new framework of clinical governance for improving quality of care in the NHS. This framework can be seen as an attempt to bridge the professional approaches of quality assessment and clinical audit with previous managerial approaches of quality assurance and quality improvement. Following on from a history of these often fragmented approaches to quality, the white paper in 1997 set out the dismantling of the internal market in health care and signalled changes to the approach to improving quality.[59] The consultation document, *A First Class Service: Quality in the New NHS*,[60] outlined this vision by describing a systematic model of quality improvement that "marries clinical judgment with clear national standards". In March 1999, *Clinical Governance: Quality in the NHS*,[61] set out in some detail this model for consolidating previous approaches.

Clinical governance will be set in the context of a nationally coordinated programme of clinical guideline development (National Institute for Clinical Excellence) and national service standards for priority areas. Box 1 lists key features of clinical governance, which will require clinicians in healthcare trusts and primary care groups to lead the development of systems for local quality assurance and quality improvement. A nominated individual in each provider organisation will be responsible for clinical governance.

- A management and organisational framework for clinical quality improvement
- A "duty of quality" which relates to the organisation, not just individuals within the organisation
- A comprehensive strategy to be developed by each organisation, including a range of quality improvement methods, for example audit and risk management, linked closely to professional development programmes
- A named individual appointed within each provider organisation who has responsibility for improving quality of care
- A focus on clinical leadership, though with greater external accountability
- A focus on processes of care, including clinical decision making, and on concepts of appropriateness, clinical effectiveness, and evidence-based care
- Set in the context of a nationally coordinated programme of clinical guideline development including service standards for priority areas.

Box 1   Key features of clinical governance

Although it builds on previous experience in the UK, especially with clinical audit, clinical governance incorporates a clear shift of emphasis, for example from competition to collaboration but with the professions nominally in charge. In other UK public services, such as teaching, social work, and the probation service, there has been a consistent and increasing emphasis on external standards and external inspection. It seems perhaps surprising therefore that responsibility is being given to the professions to lead on quality improvement in health care. However, there are strings attached.

The previous approach to clinical audit was largely process driven, with little monitoring or assessment of the effectiveness of audit activity. The new approach places on the professions an expectation of, and statutory duty for, increased accountability for care provided[62 63] So, for example, government policy priorities for the NHS for 1999–2002 state that "by 2002, all primary care groups and trusts will be delivering measurable improvements against their locally agreed milestones and targets for each function (improving health, reducing health inequalities, commissioning services, and developing primary and community care services)".[64]

Clinicians are likely to find that the only way they can achieve what is expected of them is to borrow from the managerial approaches described above. It remains to be seen whether they are up to the task. Those accepting the role of clinical governance lead will carry a heavy responsibility. In primary care they will be responsible for developing quality improvement initiatives for about 50 independent primary care practitioners, most of whom have had no need to communicate with each other before, let alone share information about the quality of care they provide.

Clinical governance is therefore a bold experiment. In countries such as the US, where health care is heavily dominated by powerful external regulation, healthcare professionals have long since lost control over the quality agenda. The UK's approach offers the professions an opportunity to show that they can self regulate in a manner consistent with current notions of public service accountability. Donaldson and Muir Gray[63] describe clinical governance as "the means by which the clinical professions can maintain the positive liberty they have enjoyed for so long without, until recently, serious challenge". If the professions succeed, they will have defined a new role for professionalism. If they fail, and the government's patience looks to be short, they will find themselves subjected to increasingly tight and detailed external control of clinical activity.

Conclusions
In this article, we have described and evaluated key approaches to measuring and improving the quality of health care. These approaches represent a menu of options sharing certain characteristics such as the need to set goals and relate them to performance to identify opportunities for improvement. Quality assessment underpins all the approaches, but each approach has different aims and methods that reflect disciplinary needs and tensions that have led to a perceived divide between managerial and professional activity.

The approaches have distinctive strengths. None is likely to suit all purposes, but each represents a step forward, for example by seeking to design quality into service delivery and increase comprehensiveness, as exemplified by the shift from medical audit to clinical audit. Recent steps to bring managerial and organisational aspects of care together with clinical care would not have been possible without clinical audit which, despite its limitations, has been associated with a shift in the attitudes of healthcare professionals in the UK towards quality improvement.

Clinical governance draws on each approach in giving professionals the lead in the development of quality improvement strategies, albeit with increased external accountability. In the UK NHS, structures have been put in place to drive this change at considerable speed within a nationally defined strategic framework. It remains to be seen how this will work. If successful, clinical governance will define a new type of professionalism for the next century. If it fails, clinicians in the UK will find themselves under the tight managerial control found in some other countries.

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