

Quality Oversight in England— Findings, Observations, and Recommendations for a New Model

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QUALITY OVERSIGHT IN ENGLAND—FINDINGS, OBSERVATIONS, AND RECOMMENDATIONS FOR A NEW MODEL

EXECUTIVE SUMMARY

Joint Commission International (JCI) was invited to participate in a comprehensive review and reassessment of England's National Health Service (NHS). The focus of JCI's participation was on the current and future oversight mechanisms for health care quality in the NHS.

The findings and observations drawn from interviews with over 50 stakeholders address the pervasive culture of fear in the NHS and certain elements of the Department of Health; the significant flaws in the current quality oversight mechanisms; the weaknesses of current data collection, data quality monitoring, and data use processes; the regulatory context of performance improvement; the growing decentralization of responsibilities within the NHS and the resulting fragmentation and variation of quality oversight; the greater need for physician engagement and involvement in health care quality evaluation and oversight; issues relating to management of the trusts; and the proposed regulatory legislation, a component of which is the creation of a new, more empowered "regulator".

Two central themes emerge from the forenoted findings and observations:

1. The absence of an improvement imperative within the Department of Health and the NHS.
2. Unachievable expectations of the commissioning process as the driver for quality improvement at the provider and practitioner levels.

A number of systemic barriers have been identified in relation to these themes.

Finally, five recommendations are proposed to address the central themes and related barriers. These include (1) creation of an independent, private-sector, voluntary national accreditation programme; (2) immediate engagement of physicians and other health professionals in the design of quality oversight tools and activities; (3) immediate attention to development of standardized, evidence-based performance measures; (4) design and implementation of a data quality monitoring and evaluation methodology; and (5) provision of understandable quality-/safety-related data to primary care trusts, with the expectation that such data actually be used in the commissioning process.

INTRODUCTION

In November 2007 JCI was invited to submit a proposal to participate in a comprehensive review and reassessment of England's National Health Service. This project, led by Lord Ara Darzi, is expected to culminate in a final report which marks the 60th anniversary of the NHS this coming summer.

JCI, as respondent, was asked to specifically address the following Terms of Reference respecting health care quality oversight:

1. Systematically review the scientific literature in the area of inspection of health care quality.
2. Review the current inspection available to the United Kingdom's (England's) health care organizations and the history of previous initiatives.
3. Identify strengths and weaknesses of the current United Kingdom (England) model.
4. Carry out an assessment of international best practices for inspection of standards.
5. Use the knowledge from the international review to suggest models for improvement.
6. Conduct an exploration as to whether a model centered on accreditation, inspection, regulation, or an alternative approach would translate successfully in the United Kingdom (England).

JCI's consultants subsequently spent fifteen days in December 2007 and January 2008 conducting in-person and telephonic interviews of key public and private sector leaders and managers in England whose activities relate to the Department of Health's current and potential future quality oversight responsibilities. This report is based on those interviews, the experience and knowledge base of JCI generated from work with Ministries of Health in over 30 countries, and review of the international literature that relates to quality oversight.

FINDINGS AND OBSERVATIONS

The following summarizes the findings and observations drawn from over 50 stakeholder interviews, personal observations, and review of Department of Health and NHS documents and Web sites.

I. DEPARTMENT OF HEALTH/NHS CULTURE

- A. A “shame and blame” culture of fear appears to pervade the NHS and at least certain elements of the Department of Health.
 - 1. This culture generally stifles improvement and the kinds of chief executive officer (CEO) risk-taking behaviors that are necessary for creating organization cultures of quality and safety.
 - 2. This culture is affirmed by Healthcare Commission leaders who see public humiliation and CEO fear of job loss as the system’s major quality improvement drivers.
 - 3. This culture appears to be embedded in and expanded upon by the new regulatory legislation now in the House of Commons.

II. QUALITY OVERSIGHT

- A. The Department of Health’s current quality oversight mechanisms have certain significant flaws.
 - 1. Wherever undertaken, the standards development process is basically a “top down effort” that does not meaningfully engage physicians, other clinicians, and other parties of interest. Thus, there is a lack of ownership of the standards among all of these stakeholders.
 - 2. Standards development activities appear to exist at multiple points in the Department of Health. With the exception of the work being done by the Healthcare Commission and the Litigation Authority, it is unclear how or whether compliance with these various standards is being assessed.
 - 3. Standards compliance assessment by acute care trusts is judged primarily by annual self-assessments conducted under the aegis of the Healthcare Commission. Those outside of the Commission question the validity and integrity of the reported self-assessment findings. This concern appears to be validated by the selected Healthcare Commission follow-up on-site evaluations (see below). To mitigate this concern, the Healthcare Commission seeks to correlate self-assessment findings with performance data that it obtains from various sources. However, the quality and integrity of these data are also suspect for various reasons (see the Data Collection, Data Quality, and Data Use section below).
 - 4. The on-site evaluation of standards compliance is quite light-handed. The Healthcare Commission currently undertakes on-site evaluations of a 20% sample (10% judged to be at-risk, 10% random) of acute care trusts. During these on-site visits, organizations are evaluated against a 20% (approximate) sample of the Core *Standards for Better Health* that is felt to be particularly relevant to the individual trusts. This

means that the annual on-site review sample is approximately 4% (20% of 20%) of the potential standards compliance assessment opportunity. This is generally worrisome, but it is of even greater import in light of the fact that in the at-risk on-site evaluations, two-thirds of the assessments of standards compliance do not conform with the organization's self-assessment findings, and that in the random on-site evaluations, one-third of the assessments of standards compliance do not conform with the organization's self-assessment findings.

5. The Healthcare Commission's process is seen as regulatory rather than as an improvement strategy: It provides for inspection but not for advice to encourage and support improvement.
6. The only quality oversight activity that regularly involves standards-based, on-site evaluations of essentially all acute care trusts is that conducted by the Litigation Authority. This is also the only such activity that regularly provides improvement advice to these organizations. The principal limitation of the Litigation Authority review process regarding broad quality oversight is that, for sound reasons, these standards focus solely on the risk reduction priority.

III. DATA COLLECTION, DATA QUALITY, AND DATA USE

- A. Large amounts of quality- and safety-related data are collected at various levels within the Department of Health and the NHS. This appears to reflect a philosophy of gathering data before deciding the specific purposes for which it will be used.
 1. Not surprisingly, concerns exist about the substantial data collection burden, particularly because feedback loops with those who provide the data are rarely closed.
 2. Furthermore, and ironically, there are consistent complaints about the availability of relevant and usable (or sometimes any) data by key users, for example, acute care trusts, primary care trusts, and patient groups.
 3. In addition, the quality of available data is often suspect (for example, a 20% error rate in physician coding). This is a result of the following:
 - a. No consistent effort exists to standardize the measures that provide the basis for data collection through the specific delineation of component measure data elements which define precisely what data are to be collected. The absence of such standardization and definition makes apples-to-apples performance comparisons across provider organizations and practitioners impossible and substantially compromises any systematic data quality assessment.
 - b. There is no established, broadly applied data quality assessment process.
 4. Finally, the delays in implementing a modern, user-friendly health information technology platform across the NHS substantially limit the ability both to collect and access relevant performance data.
- B. The foregoing quality issues have significant implications for the validity of certain target measures and the Quality Outcomes Framework measures.

- C. Furthermore, the preponderance of the data regularly provided to the Department of Health by the acute care trusts is essentially “claims data” and generally lacks direct clinical relevance for health care professionals and other potential users. This creates a separate need (or opportunity) for others to mine this large database—such as the Dr. Foster data dissemination initiative—to identify meaningful information, particularly patient outcomes information.
 - 1. Because of this, individual acute care trusts—on a variable basis—often create their own measures and collect their own data to support their quality improvement efforts.
 - 2. Similarly, primary care trusts often devise their own measures and collect their own data to support the commissioning process.
- D. There appears to be no process for setting priorities for developing and using performance measures. Similarly, there appears to be no systematic effort to derive relevant clinical performance measures from National Institute for Health and Clinical Excellence (NICE) guidelines. In addition, there exists no standardized instrument for gathering patient experience of care data that could be shared to support the various quality oversight processes, the commissioning process, and Monitor, among others.
- E. The *Standards for Better Health*—at least those applied in the Healthcare Commission’s evaluation process (“core” standards)—create no expectation or guidance for using performance measure data to drive performance improvement.
- F. Although patient *Choice* is a stated goal of the NHS, there is insufficient data available about disease-specific care for patients to make informed choices.

IV. PERFORMANCE IMPROVEMENT

- A. Performance improvement is ostensibly driven by the setting of targets with which compliance is expected. This process is subject to gaming and has resulted in unintended consequences, leading to the apparent intent now to reduce or eliminate the use of targets.
- B. Both the NICE guidelines and the National Institute for Improvement and Innovation initiatives are significant improvement resources for the trusts and are generally viewed quite positively. However, implementation of the NICE guidelines is not regularly monitored, even though they are referenced in the *Standards for Better Health*.
- C. Performance improvement is not otherwise an expectation articulated in the *Standards for Better Health*, nor does the Healthcare Commission see itself as having any role in facilitating improvement in the acute care trusts or in independent sector organizations.
- D. Rather, performance improvement is left to the acute care trusts to pursue individually. No guidance or other resources, such as methodologies or analytic tools, are made available by the Department of Health to support this work. A specific example is the absence of a requirement to conduct a root cause analyses of serious untoward incidents. The overall process should facilitate the translation of data into actionable information and then into performance improvement plans and actions. There is today not even a regular way in which the acute care trusts can share best practices.
- E. Despite claims of equity, many observers report significant variation in care across the country. Sorting out reality from perception regarding this issue is difficult because variation in care across the NHS is not measured beyond the scope of the targets.

- F. Although there is an emerging aspirational tone across the Department of Health (“world class commissioning”, “clinical excellence pathways”), there are few indications of sufficient attention being paid to basic performance improvement efforts.
- G. The regulatory legislation now in the House of Commons is silent on any expectation for performance improvement in registered trusts, nor is there an intent to include a “duty to improve” in the associated registration requirements currently in development.

V. DECENTRALIZATION

- A. There is a strong emphasis on decentralization of responsibilities within the NHS.
- B. This decentralization is accompanied by lack of standardization in the performance measures applied and the data gathered.

VI. COMMISSIONING

- A. The lack of standardization is most evident in the commissioning process where each primary care trust appears to devise its own commissioning criteria, collect its own data, and set its own selection priorities. Absent access to relevant comparative clinical data—a stated concern of some primary care trusts—commissioning decisions appear to be made primarily on the basis of financial considerations. This creates little incentive for clinical performance improvement in the acute care trusts.
- B. Quality today does not drive or even influence commissioning decisions. In theory, the commissioning process could drive improvement, but that capability does not now exist and may take years to develop. To do this, the primary care trusts will need more clinical leadership than is currently available, as well as skill in using improvement tools and access to standardized, reliable performance data.
- C. The NHS currently has a substantial amount of data that could support quality-based commissioning, but the data are not accessible and are of questionable reliability.
- D. More effective oversight of the commissioning process in relation to quality, for example, by the strategic health authorities, is needed. There is support within the Department of Health for centrally-driven management of commissioning based on established clinical pathways.
- E. Public engagement in the commissioning process is lacking.

VII. OVERSIGHT FRAGMENTATION

- A. Multiple Department of Health and private sector entities engage in oversight activities directed to the acute care trusts and the primary care trusts. One primary care trust CEO estimated that 120 entities have the authority to undertake on-site reviews at trusts. Many of these entities have overlapping standards and/or responsibilities.
- B. These on-site review activities appear destined to increase over time, particularly as several of the Royal Colleges develop accreditation processes for specific trust services that are of interest to them.
- C. Oversight data and information gathered through oversight activities are not regularly shared among the entities. The exception to this rule is that the Litigation Authority regularly shares its findings with the Healthcare Commission and the National Patient Safety Agency.

However, neither the Healthcare Commission nor the Litigation Authority shares findings with the primary care trusts.

- D. Public and professional engagement in the formulation of health care policy is limited. The existing consultation process is not sufficiently interactive to foster a sense of joint ownership.

VIII. PHYSICIAN EVALUATION AND OVERSIGHT

- A. Physicians generally qualify for registration on the basis of their education and training.
- B. Several re-validation schemes for general practitioners (GPs) and consultants are presently being considered by the General Medical Council, but nothing has been finalized as yet.
- C. Oversight of physician performance is generally delegated to the local level.
 - 1. The *Standards for Better Health* do not contain provisions that would require the credentialing and privileging of physicians. However, some acute care trusts have created their own credentialing and privileging mechanisms.
 - 2. Physicians generally do not receive feedback on their performance.
 - 3. The General Medical Council is considering creation of the position of Responsible Officer in each trust to monitor physician “fitness to practice” at the local level.
- D. GPs are not overseen by the NHS.
 - 1. This is seen as a primary care trust commissioning responsibility; however, primary care trusts lack valid and reliable data upon which to base judgments about physician performance.
 - 2. The Royal College of General Practitioners is developing a program to accredit GP practices. This could provide a useful data source for the primary care trusts.

IX. PHYSICIAN ENGAGEMENT

- A. The physician community—primarily through the Royal Colleges—is not involved in the development of important quality oversight and improvement resources, such as the *Standards for Better Health*, targets, and performance measures. This generally translates into an insufficient clinical emphasis in these activities.
- B. The exception to the foregoing is the development of NICE guidelines in which physicians generally and Royal Colleges specifically are regularly involved in the guideline development process.
- C. Although the Royal Colleges are a potential important resource for the government, there are currently clear perceptions of estrangement between the physician community and the Department of Health. One observer stated that relations between physicians and the Department are at an all-time low.

X. TRUST MANAGEMENT

- A. Morale among trust CEOs and other managers is reported to be low because they live in constant fear of being sacked on the basis of a specific incident or outbreak.

- B. A number of CEOs, particularly those that have emerged from the nursing ranks, appear to have had minimal training for performing CEO duties.
- C. Although one observer suggested that there is constant churning of the same CEOs across the acute care trusts, the National Institute of Improvement and Innovation programs appear to be producing a steady stream of new CEO candidates. The Institute also sponsors various additional programs that focus on the re-training of mid-career individuals who find themselves in or transitioning into management positions.
- D. There appears to be significant estrangement between trust management and clinical leaders. Relatively few physicians aspire to be trust CEOs, and there is a perception that trust CEOs do not support clinical leaders.
- E. The importance of system/care process design and re-design is generally not recognized by trust managers. However, the National Institute for Health Research has a new Service Delivery and Organization Program which plans to develop and disseminate knowledge in this area.

XI. MANPOWER ISSUES

- A. There is a substantial excess of physicians in relation to available training posts. Concerns were not expressed about the adequacy of the numbers of physicians available to provide actual services.
- B. In the past, there appear to have been shortfalls both in the funding for nursing education and for nursing positions in the acute care trusts. These shortfalls have currently been resolved.
- C. There is a shortage of midwives that appears to be having adverse effects on maternal care.
- D. Generally speaking, health professional shortages may have direct impacts both on access to care and the safety of care being provided.

XII. PROPOSED REGULATORY LEGISLATION

- A. The proposed legislation is receiving mixed reviews at best.
- B. Like various licensure schemes, its focus appears to be on minimalist requirements whose fundamental intent is to reduce risks to patients. Or, as one observer stated, the new regulations should basically provide the grounds for prosecution in the courts.
- C. The legislation also has the stated intent of reducing regulatory costs, but some observers believe such potential savings are illusory.
- D. The legislation's punitive tone appears likely to further the existing fear-based culture of the Department of Health.
- E. As noted elsewhere, the legislation includes no expectation for a performance improvement function as part of the registration requirements.

CENTRAL THEMES EVIDENT FROM FINDINGS AND OBSERVATIONS

The findings and observations described above can be distilled into the following two central themes:

1. The absence of an improvement imperative.
2. Unachievable expectations of the commissioning process.

These two themes are further discussed below, with particular attention to the evident systemic barriers related to each.

I. THE ABSENCE OF AN IMPROVEMENT IMPERATIVE

A consistent performance improvement imperative does not exist despite the continuing attention of the Department of Health and the NHS to quality issues, as evidenced by public policy forums and debates, national quality strategies, a variety of quality-oriented publications, and engagement by several agencies whose name or charter reflects quality accountabilities. The absence of an improvement imperative within the Department of Health and the NHS thus undermines potential quality gains at the provider and practitioner levels.

The following four barriers to the creation of an improvement imperative have been identified:

1. The overall Department of Health “culture” is not conducive to ongoing, sustainable improvement initiatives and strategies. While Department of Health and NHS staff understand the influence of cultural issues on fostering improvement, there has been neither direction nor success in creating a blended culture that incorporates regulatory expectations into a broader continuous quality improvement framework. Such a blended culture will be difficult to achieve as long as the following conditions continue to exist:
 - The “stimulus” for positive change in quality is embedded in a regulatory context that emphasizes the use of punishment and humiliation to achieve change.
 - Quality oversight is dispersed among multiple agencies in a complex and unstable structure that is well intentioned but uncoordinated and unfocused.
 - Agencies responsible for quality oversight generally take a reactive posture in addressing untoward events and have no coordinated, proactive strategies for preventing such events in the first place and for fostering incremental improvement in provider performance.
 - Quality initiatives that hold promise are frequently top-down efforts and fail to achieve key stakeholder (especially provider and practitioner) buy in and ownership of the initiative, thus leaving these stakeholders on the sidelines.
2. Quality-related, standards-based assessments of performance are suboptimal, in large part because of the confusion over the purpose and use of standards, thresholds, and targets at the provider and practitioner level. In addition:
 - Key standards, such as the *Standards for Better Health*, appear only to focus on core or minimal expectations and do not stimulate or support aspiration to higher levels of performance that can be achieved only through a continuous journey of quality improvement.

- The standards compliance assessment process is limited in scope, reliability, and validity and is not considered a useful and actionable source of information respecting provider and practitioner performance.
3. The use of other performance measurement tools, such as indicators, has been ineffective in stimulating improvement because of the lack of standardization of measures, the lack of clinical focus and thus use, and inadequate IT infrastructural support. Thus, requests to providers to measure performance are viewed as part of the regulatory burden rather than potentially informative to improvement efforts.
 4. There is limited oversight of individual practitioner performance. Thus, improvements in the practitioner-patient interface are mostly left to local quality improvement initiatives. Meanwhile, the pressure to conform to Department of Health targets is more likely to shape behavior rather than practice. In addition:
 - There is an adversarial rather than collaborative relationship between practitioners and those who control the “system” within which they practice.
 - There is no consistent process for aligning the scope of an individual’s practice with his/her documented qualifications and competence. Those who could inform this process, such as the Royal Colleges, feel marginalized in this regard and pursue their own strategies for validating practitioner competency.

II. UNACHIEVABLE EXPECTATIONS OF THE COMMISSIONING PROCESS

In many minds, the commissioning process is seen as the “magic bullet” for addressing quality priorities in the NHS. Indeed, efforts are currently underway for making the commissioning process “World Class”.

For the promise of World Class Commissioning to materialize, the following two barriers must be attended to and eventually overcome:

1. There is an insufficient information base upon which to carry out quality-based commissioning. Although certain inputs to the commissioning process are available or obtainable (demographics of the population served and their health needs as well as the numbers and types of providers and their capabilities), there is no real basis for selecting among the providers and practitioners on the basis of quality. Thus, although some types of information are specific to the needs of the individual primary care trust, information on actual performance, especially the outputs of care, should be comparable across providers and practitioners at the primary care trust level and nationally. The latter is not presently possible for several reasons:
 - Nationally standardized measures are not available to permit determinations as to whether inequities of care, both with respect to access and outcomes, exist.
 - Information on individual practitioner performance is virtually non-existent.
 - There is similarly a basic lack of useful performance information at the provider organization level. The organization level data that arise from the Litigation Authority, Monitor, and Clinical Governance do not adequately profile the potential for clinical quality in individual provider organizations.

- There is no tested, structured instrument for assessing patient experience with care at the provider and practitioner level, and thus no way for primary care trusts to assess this important dimension of provider and practitioner performance.
2. Even if there were sufficient high quality clinical data and information to inform the commissioning process, there is insufficient clinical leadership and competence within the primary care trusts to use the information in the commissioning process, let alone to leverage improvements in provider and practitioner performance over time.

PREVIOUS AND CURRENT QUALITY OVERSIGHT ACTIVITIES AND STRUCTURES IN THE UNITED KINGDOM

Quality oversight in the United Kingdom has generally tracked the changing regulatory environment, as the control of quality has historically been viewed as a function of regulation. Within the NHS, there was remarkably scant interest in quality and standards until the 1980s. The principal initiative was the creation of the Hospital Advisory Service (HAS) in 1969. The general assumption seems to have been that the NHS's system of hierarchical control over the nation's hospitals made concerns about quality and standards compliance superfluous.¹

More recently, quality oversight has become an element of the decentralization of regulation and assignment of the management of quality to the strategic health authorities and primary care trusts. Clinical Audit was introduced into the United Kingdom in 1989 as a government-funded initiative. The clinical audit process was perceived to be within the control of health professionals and effective at the local level. Support for this process came from the National Centre for Clinical Audit. Reports in 1966 and 1999^{2,3} described the limited contribution of the audit process to clinical quality and noted the complexity of selecting audit criteria and the time-consuming nature of the process. Based on cost/time concerns, funding for the audit process was discontinued.

The current quality oversight schemes can be traced to 1997/1998 when the then newly-elected Labour government launched a comprehensive set of health care quality reforms aimed at putting “quality at the heart of the NHS”.⁴ One initiative led to the creation of the National Institute for Clinical Excellence in 1999. This agency transitioned to the current National Institute for Health and Clinical Excellence (NICE) in 2004, and subsequently absorbed the activities of the Health Development Agency in April 2005.

Also created during this regulatory reform period was a new system of clinical governance—a framework for improving clinical care quality supported by the Modernization Agency and a new Commission for Health Improvement (CHI) established to review clinical governance progress and investigate serious problems. CHI became the Healthcare Commission in 2003 and is currently the predominant agency that inspects and otherwise evaluates organizations against the *Standards for Better Health*. The Modernization Agency integrated into the Department of Health structure during this period.

Finally, the National Patient Safety Agency (NPSA) was established in 2001 to collect and analyze patient safety incident data and inform the NHS on patient safety issues. Similarly, the National Clinical Assessment Authority, a special statutory authority, was established to assist trusts in addressing individual physician performance issues.

A recent article that examines the problems of engaging hospital doctors in quality and safety activities notes that only 10% of reports to the NPSA have been made by doctors.⁵ More recently,

¹ Scrivens E, Klein R, Steiner A. Accreditation: what can we learn from the Anglophone model? *Health Policy* 1995;34:193-204.

² Millard AD: Scaling the quality of clinical audit projects: A pilot study. *Int J Qual Health Care* 1999;11:241-49.

³ National Centre for Clinical Audit. *Evidence to Support Criteria for Clinical Audit*. London, NCCA, 1996.

⁴ Freeman T, Walshe K. Achieving progress through clinical governance? A national study of health care managers' perceptions in the NHS in England. *Qual Saf Health Care* 2004;13:335-43.

⁵ Neale G, Vincent C, Darzi A. The problem of engaging hospital doctors in promoting safety and quality in clinical care. *J R Soc Health* 2007;127(2):87-94.

the NPSA was criticized by the Public Accounts Commission regarding the adequacy of its feedback processes and the sufficiency of its clinical involvement and leadership.⁶

A 2002 *British Medical Journal* editorial by Kieran Walshe described the rise of regulation in the NHS⁷ and noted that although not all the above agencies see themselves as regulators, they do all fit the regulatory mold and act like regulators even though they may have diverse missions. These are all essentially agents of the Department of Health.

Finally, there is a group of agencies—governmental and non-governmental—that have incorporated aspects of quality oversight into their processes and taken on deliberate roles as external reviewers of certain aspects of quality. The Litigation Agency has created a set of risk-focused standards and an on-site evaluation process and provides assistance to trusts in meeting the standards. Monitor has implemented measures and evaluation processes to support the oversight of Foundation Trusts. The Royal Colleges are beginning to create accreditation schemes that are consistent with the interests of their members. And private entities such as the Clinical Pathology Accreditation Ltd. (CPA) and United Kingdom Accreditation Service (UKAS) are growing and viable organizations.

However, what is lacking is a governmental or private sector organization that has taken the lead in setting the quality oversight agenda for England and is providing needed coordination and integration of activities across the quality oversight landscape.

⁶ Leigh E. Public Accounts Committee 51st Report 2005-6: A Safer Place for Patients. House of Commons papers 831. London: Stationery Office, 2006.

⁷ Walshe K. The rise of regulation in the NHS. *BMJ* 2002;324:967-70.

EXPERIENCES OF OTHERS

GENERAL CONSIDERATIONS

In recent years the strengthening of quality oversight has taken on new urgency as health care quality increasingly is viewed as essential to the sustenance of health system reforms and as the need to make patient care safer has become an imperative. The roles of governments as regulators, providers, and purchasers of health care have led to the creation of quality oversight mandates. Several examples of how these responsibilities and accountabilities have played out in various countries and regions are briefly described here.

A European Union project on external peer review techniques, termed 'ExPeRT', was funded by the European Commission in 1996.⁸ Four European models were described: *Visitatie*—professional performance review; accreditation—health service delivery capability review; EFQM—management system review; and ISO—quality system review. All four models use explicit criteria (standards) and external reviewers. The adoption and success of one or more of these quality oversight systems was closely linked to the social, political, and economic climate that determined incentives and disincentives for participation. In principle, and in reality, the delivery of health services and evaluation of quality remains the responsibility of individual EU states.

In 2005, a second project was funded by the European Commission to examine Methods for Assessing Response to Quality Improvement Strategies—"MARQuIS".^{9,10} The reports emerging from this project confirm that there is no consensus on the definition of quality nor on those aspects of health care that should be measured to make determinations about quality. The research described focuses on the cross-border trade in health services anticipated in the near future; the four European models described in the ExPeRT project are further described here. It can be concluded that although there is growing convergence among the four models, ISO and EFQM fail to address the clinical aspects of care delivery.¹¹ Performance measurement is increasingly becoming integral to all the models.

Reports on the use of external quality assessment^{12,13,14,15,16,17} all identify characteristics of effective external quality evaluation programs. The following are the most frequently identified characteristics:

⁸ Shaw CD. External quality mechanisms for health care: summary of the ExPeRT project on *visitatie*, accreditation, EFQM and ISO assessment in European Union countries. *Int J Health Care* 2000;12:169-75.

⁹ Spencer E, Walshe K. Quality Improvement Strategies in Healthcare systems of the European Union. *Methods for Assessing Response to Quality Improvement Strategies (MARQuIS)*. The University of Manchester, 2005.

¹⁰ Spencer E, Walshe K. Health Care Quality Strategies in Europe. *Methods for Assessing Response to Quality Improvement Strategies (MARQuIS)*. The University of Manchester, 2006.

¹¹ Klazinga N. Re-engineering trust: the adoption and adaption of four models for external quality assurance of health care services in western European health care systems. *Int J Health Care* 2000;12:183-89.

¹² Shaw D. External assessment of health care. *BMJ* 2001;322:851-54.

¹³ *Measuring hospital performance to improve the quality of care in Europe: A need for clarifying the concepts and defining the main dimensions*. World Health Organization, 2003.

¹⁴ Standing Committee of the Hospitals of the European Union: *The quality of hospital care in the European Union*. HOPE: September 2006.

¹⁵ Shaw CD. *Developing hospital accreditation in Europe*. World Health Organization, 2006.

¹⁶ Shaw CD. *Toolkit for Accreditation Programs: Some issues in the design and redesign of external health care assessment and improvement systems*. The International Society for Quality in Health Care: Australia, 2004.

- Legitimization of the program through recognition by a government agency or agencies and other key stakeholder groups, with identified incentives for participation when the system is voluntary
- Recognition of the organizations that participate in accreditation
- Published consensus standards that provide an objective basis for the evaluation
- Use of a combination of on-site evaluation by trained evaluators and self-assessment to determine performance against the standards
- The expectation that performance of reviewed organizations will continue to improve over time as the capability to measure, assess, and improve quality is established
- Transparency of the evaluation metrics and decision process

A 2003 review of accreditation and other external health care quality assessment systems¹⁸ concluded that accreditation programs are very effective when they combine the evaluation function with supportive efforts that help the organization improve quality. This report also found that of the programs reviewed, mandatory programs were less effective than voluntary programs. This is because the voluntary process is generally non-threatening and interactive, and the result is steady improvement in quality. In addition, mandatory accreditation programs are perceived as adding to the regulatory burden.

ORGANIZATIONAL STRUCTURE FOR QUALITY EVALUATION

In 2003, the World Health Organization published a report entitled “*Quality and Accreditation in Health Care Services: A Global Review*.”¹⁹ The report provides insight into the development of accreditation programs in 47 developed and developing countries. The findings are based on the results of a comprehensive survey. Respondents, who were requested to describe the relationship of accreditation to government in terms of their management, funding, or recognition, indicated the following:

- Half of the programs are funded, partially funded, or managed directly by government
- Long-established programs are independent of government
- Most programs established in the past five years are sponsored by government
- Accreditation is increasingly used by governments as a means of regulation and public accountability, rather than for voluntary self-development.

Some governments, for example, Denmark and Thailand, have chosen to organize accreditation in national “Institutes”, at arms-length from the government. In some countries, such as Italy, Poland, and Spain, general laws incorporate accreditation concepts, but leave the details of implementation to the regions, states, or other jurisdictions. This “regionalized” or “decentralized” approach has the inherent problem of lack of uniformity and ultimately comparability. For example, in Italy each

¹⁷ Rooney AL, vanOstenberg PR: *Licensure, Accreditation, and Certification: Approaches to Health Services Quality*. Center for Human Services (CHS), 1999.

¹⁸ Montagu D. *Accreditation and other external quality assessment systems for healthcare*. Health Systems Resource Center, May 2003.

¹⁹ *Quality and accreditation in health care services: a global review*. World Health Organization, 2003.

region selects its own quality oversight methodology and associated performance indicators. Thus, at a governmental level there is inconsistent quality data and information to adequately inform national policy.

It is generally acknowledged that even if the government does not ultimately operate the accreditation program, such a program needs to fit into the national strategy for quality oversight and usually requires “seed” money to carry the process through the three- to five-year development and implementation period. In 2007, the Australian Commission on Safety and Quality in Health Care began a study to explore greater integration of accreditation activities across Australia and define the separation of quality and safety issues and thus the respective authorities and accountabilities for oversight of these issues in the public and private sectors.²⁰

The decision to make accreditation a mandatory or a voluntary process is a critical one. Many believe that if accreditation is made voluntary, organizations will spontaneously participate.²¹ In general, voluntary programs are private sector programs. However, governments can provide the stimulus for participation in voluntary programs through reliance on the accreditation findings and decisions by various governmental agencies, with resulting reduction in the inspection burden. In general, the relationship between the accreditation body and government is considered a public-private sector partnership. This ensures sensitivity to government policy while also protecting the accreditation process from the political agenda and cycles of change common to governments.

ACCREDITATION METHODOLOGY

The internationally-recognized methodology for the accreditation process is described in the Principles of the International Society for Quality in Healthcare, ISQua, and used to accredit national and international agencies that provide accreditation services.²² These principles stress the involvement of all stakeholders in the standards development process, the use of peers in the evaluation process, and transparency to the public. Most new accreditation programs are designed with these principles in mind.

In this process, physicians are a primary stakeholder group and their participation is viewed as essential. The experiences of France and Germany regarding physician engagement are instructive. In 2004, the German government formally included physicians in quality management through the formation of the Federal Joint Committee, a legal entity under public law that replaced several former regulatory bodies. The Federal Joint Committee was established by the federal association of contracted physicians, the German Hospital Federation, and the federal associations of health insurance funds. This new entity is the highest decision-making body in a joint self-governing structure and has a range of responsibilities related to quality management in the health system.²³ In France, health care policy was characterized by the strong influence of the state and the weak

²⁰ *Consultation Paper: An alternative model for safety and quality accreditation of health care.* Australian Commission on Safety and Quality in Healthcare, August 2007.

²¹ ANAES. *Manuel d'accréditation des établissements de santé.* Paris: Agence Nationale d'Accréditation et d'Evaluation en Santé (ANAES), 1999.

²² International Society for Quality in Health Care. *International principles for standards for health care external evaluation bodies.* 2nd edition. Melbourne, ISQua, 2004 (available as PDF from www.isqua.org).

²³ Breckenkamp J, Wiskow C, Laaser U. Progress on quality management in the German health system—a long and winding road. *Health Res Policy Syst* 2007;5:7

bargaining power of a divided medical profession.²⁴ The formulation of France's first accreditation authority, ANAES, deliberately infused the various technical and scientific structures of ANAES with health professionals in order to gain legitimacy and credibility. Work is ongoing to achieve expected participation of physicians at the local levels of the quality evaluation continuum. Of the quality oversight models present in Europe, only the accreditation methodology deliberately engages the health professions at all levels of activity. This ensures clinical relevance and the more likely use of clinical practice guidelines and clinical outcome measures.

In addition to stakeholder involvement, especially in the development of standards, most accreditation bodies undertake evaluations of complete organizations using a combination of self-assessment and on-site evaluation processes. Re-review of organizations is usually accomplished on a three-year cycle.^{25,26,27}

POSITIONING ACCREDITATION IN THE QUALITY OVERSIGHT FRAMEWORK

Health system reform in many countries has led to decentralization of the delivery system and thus quality oversight. A tension clearly exists when governments seek to discharge their responsibilities for quality oversight in a decentralized system. In some countries—most notably Switzerland, Spain, Italy, and Canada—quality is viewed as a local, not a national, issue. For the most part, government-initiated quality oversight programs, such as national accreditation schemes, are viewed as necessary controls for decentralized and pluralistic delivery systems and counterweights to local, and variable, quality efforts.²⁸ National quality oversight schemes are usually flexible and evolving processes. Private-sector agencies, particularly accreditation bodies, generally have short cycle times for accomplishing standards revisions, can change evaluation methodologies through internal policy revisions, and have the ability to continuously raise the bar of standards expectation in line with the evolving quality capabilities of health care organizations.²⁹ Accreditation standards can also incorporate through reference the national norms of a society. For example, the standards of The Joint Commission in the United States require that health care organizations meet the relevant requirements of the National Fire Protection Association. Most other accreditation bodies likewise expect organizations they accredit to be in compliance with local law and regulations at all times; they also require documented processes for resolving compliance issues.

In addition, accreditation standards can incorporate the implementation and enforcement function respecting important performance expectations articulated by health professional groups, patient safety agencies, and others. For example, the standards of The Joint Commission and JCI require that health professionals maintain current board certification, be periodically re-certified according to national norms, and be formally appointed to the hospital staff through a criteria-based process and have their privileges delineated based on evidence of current competence. JCI's standards also require that organizations adopt and measure performance against clinical practice guidelines and clinical pathways.

²⁴ Wilsford D. The cohesion and fragmentation of organized medicine in France and the US. *J Health Politics Policy Law* 1987;12:481-503.

²⁵ Shaw CD. *Toolkit for Accreditation Programs: Some issues in the design and redesign of external health care assessment and improvement systems*. The International Society for Quality in Health Care: Australia, 2004.

²⁶ Rooney AL, vanOstenberg PR: *Licensure, Accreditation, and Certification: Approaches to Health Services Quality*. Center for Human Services (CHS), 1999.

²⁷ *Quality and accreditation in health care services: a global review*. World Health Organization, 2003.

²⁸ Scrivens E. International trends in accreditation. *Int J Health Plann Manage* 1995;10:165-181.

²⁹ *Quality and accreditation in health care services: a global review*. World Health Organization, 2003.

Finally, accreditation standards can set clear expectations for leadership functions such as collaborative management and oversight of health care quality and patient safety. Thus, in England, similar accreditation standards would have the potential to extend into practice worthy products of the Royal Colleges, the NICE, and the CEO training programs of the National Institute for Innovation and Improvement. This is another example of potential public-private sector partnerships to leverage greater accountability and health care quality improvement.

RECOMMENDATIONS

Based upon the foregoing observations, findings, literature review, and analysis, JCI sets forth the following recommendations:

- I. That an independent, private-sector entity be created to develop and carry out a voluntary accreditation programme for NHS acute care institutions and independent acute care hospitals. Such an accreditation programme would be funded, at least initially, by the Department of Health, and would enter into a mutually supportive public sector/private sector partnership with the Department of Health. This partnership would effectively provide a balance between basic government regulatory requirements and incented continuous improvement expectations in acute care institutions.
 - A. The accreditation programme would have the following characteristics:
 1. The programme would operate on the philosophical basis that a rigorous standards-based evaluation, upon which others might rely, is the most appropriate framework for guiding and leveraging continuous improvement in performance.
 2. The programme would be based on aspirational “optimum achievable” standards that address clinical care, clinical governance (for example, credentialing and privileging of physicians), and organization management. Patient safety and continuous quality improvement expectations would be emphasized across these domains.
 - a. The standards would be carefully selected to reflect the expectations that effective organization managers and clinicians should have of themselves in providing excellent patient care. Thus, the accreditation standards should not be seen as differing from expectations for excellence in the ongoing, day-to-day delivery of patient care.
 - b. For each standard, there would be clear evidence linking its stated expectation(s) to patient outcomes.
 - c. The standards would be developed with the active participation of health care professionals, organization managers, the Department of Health, and those who would eventually rely on the accreditation process (for example, patients and families, purchasers, the media).
 - d. The standards would be periodically updated (likely annually) to reflect the ongoing evolution of clinical care and organization management expectations.
 3. The accreditation programme would also develop, or participate in the development of, performance measures (indicators), and would utilize these measures and/or those standardized measures (see below) developed by the Department of Health/National Health Service.
 - a. The accreditation standards would articulate an expectation that performance measure data drive internal quality improvement efforts. Demonstrated improvement as a result of these efforts would be expected.

- b. Performance data would in some instances be used to judge compliance with specific accreditation standards.
 - c. Performance data would also be used to guide and focus the periodic on-site assessments of standards compliance (see below).
 - 4. Standards compliance assessment would be carried out on-site every 1-3 years for every organization participating in the accreditation process.
 - a. The on-site evaluation for a given organization would be guided by performance information from various sources, including previous accreditation findings and results, complaint data, reviews of untoward occurrences, and performance measure data, among others. Compliance with all standards would be assessed. The frequency with which on-site evaluations are conducted would also be determined by such data.
 - b. The on-site evaluation would be largely conducted through the use of patient tracers, which follow the experience of actual patients through their hospitalizations and use the information gathered in this process to judge standards compliance. The effectiveness of this methodology in evaluating standards compliance is now well-established, and has the added benefit of engaging clinicians in the process and convincingly demonstrating to them the relevance of the standards to excellence in patient care.
 - c. The on-site evaluation would also address common challenging problem areas, such as prevention of health care-associated infections, medication management, and emergency preparedness.
 - 5. Continuing standards compliance would be expected. This would best be assessed through conducting the on-site evaluations on an unannounced basis.
 - a. Organizations seeking to achieve or maintain accreditation would be encouraged to conduct periodic self-assessments that might include the use of patient tracers. Plans for resolution of identified deficiencies could be discussed with the accreditation programme as part of the organization's ongoing improvement strategy.
 - b. However, self-assessment findings would not be relied upon by the accreditation programme in making accreditation decisions.
- B. Full development of the accreditation programme would require 3-5 years. This would necessitate long-term Department of Health funding and political commitment to this initiative.
- C. Because the ultimate success of any voluntary accreditation programme depends on the reliance of others upon its findings and conclusions regarding provider organizations, the Department of Health itself and with others, such as the Royal Colleges, would need to devise a strategy that encourages and leverages such reliance by those who participate in or have a stake in the current quality oversight process. Such a strategy should include provision for the following:

1. Inclusion of accreditation findings and conclusions in commissioning determinations by primary care trusts.
 2. Eventual, if not immediate, acceptance—in whole or in part—of the accreditation programme findings and conclusions by the Healthcare Commission, the Litigation Authority, and other quality oversight bodies in lieu of the conduct of their own organization evaluations.
 3. Integration of the accreditation programme with other Department of Health quality oversight activities, toward the goal of simplifying existing structures and processes.
 4. Integration into the accreditation programme of existing and nascent accreditation initiatives of the Royal Colleges that focus on specific services within acute care trusts, for example, laboratories and radiology services, to simplify the College programmes and thereby reduce the oversight burden on accredited organizations.
 5. Development of perceptions of the value of accreditation among other key stakeholders, such as the Patient Board, to further leverage acute care institutions to seek accreditation.
- D. If the initial accreditation programme is successful, plans should be made to expand its reach to other types of health care entities, such as nursing homes and home care programmes.
- E. The foregoing recommendations should accomplish the following:
1. Effectively complement the risk-based registration process for acute care institutions contemplated by the legislation currently being considered in the House of Commons.
 2. Provide a framework for integrating and simplifying the current and planned array of quality oversight activities.
 3. Establish and drive an ongoing performance improvement programme that is essential to the continued progress of the NHS toward its goal of world leadership in health care quality and patient safety.
 4. Create an alternative mechanism for setting performance measurement priorities and formulating standardized performance measures and measure sets.
 5. Create motivation among acute care trusts to go beyond meeting minimum regulatory standards to achieve optimal performance, including an expectation that NICE guidelines at least be considered for use by individual acute care institutions.
 6. Actively engage physicians, other clinicians, and other stakeholders in the standards development process, and increase the clinical focus of the quality oversight process.
 7. Establish and leverage standardized requirements for the ongoing credentialing and privileging of physicians.

8. Provide for thorough, periodic, on-site, standards-based evaluations of all acute care institutions that are seeking accreditation or are already accredited.
 9. Provide an effective means of managing the tendency toward increased variation in quality and decreased equity in delivery of care that is an unintended consequence of the current decentralization initiative.
 10. Provide to the primary care trusts a rich source of quality- and safety-related information about acute care institutions for use in the commissioning process.
 11. Provide an effective vehicle for engaging all stakeholders, including the media, in the continuing improvement of the NHS.
- II. That immediate efforts be undertaken to actively and constructively engage the physician community and other health professionals in the design of current quality oversight tools and activities. The recently-launched initiative of the NHS Medical Director to develop standardized clinical performance measures represents an outstanding opportunity in this regard. Other similar opportunities should be actively sought.
- III. That immediate attention (as with Recommendation II) be directed to the systematic development of standardized, evidence-based performance measures that address both clinical care and organization management.
- A. Measure development should focus on the creation of measure sets that address specific clinical conditions or organization management issues. The data eventually gathered should then provide a meaningful overall portrayal of the performance in question.
 - B. The evidence base for each measure should be evaluated against the Cochrane criteria, and the results of these evaluations should be available to those who are asked/required to use these measures.
 - C. The data elements that make up each measure should be specifically defined to facilitate reliable data collection and eventually assure “apples-to-apples” comparisons of performance across organizations.
 - D. Once formulated, each measure/measure set should undergo field testing to assess the adequacy of its reliability and validity.
 - E. Adequate funding to support this effort is absolutely essential. Typical costs for development of a single measure set approximate \$1 Million USD over the 18-36 month development and testing time frame.
- IV. That a data quality evaluation methodology be developed and deployed at the acute care trust level on an ongoing basis. Data quality concerns, such as those that currently exist, can substantially undermine the credibility and use of data as part of the quality oversight process.
- V. That understandable distillations of quality-/safety-related data be made available to primary care trusts, and that the primary care trusts be expected to use this information in the commissioning process.

- A. Efforts should be undertaken to develop or assure primary care trust competency in the use of quality-/safety-related data in the commissioning process.
- B. Primary Care trust performance in utilizing quality-/safety-related data in the commissioning process should be overseen by the strategic health authorities.
- C. The foregoing expectations should also apply to Monitor in its oversight of Foundation Trusts.

END