Perspectives

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Quality and Safety Revolution in Health Care[1]

A number of publications by Brennan et al, Leape et al, Bates et al, Cullen et al, Thomas et al, and others alerted the health care establishment in the United States to the existence of widespread and disturbing deficiencies in the quality and safety of care being delivered in hospitals in this country (1–7). The proffered evidence of deficiencies in quality and safety is all-encompassing, with no stratum of the health care system being immune to problems, even highly regarded academic medical centers. The Institute of Medicine (IOM) called further attention to these investigations of health care quality and safety with two landmark publications, *To Err is Human: Building a Safer Health System*, published in 2000 (8), and *Crossing the Quality Chasm: A New Health System for the 21st Century*, published in 2001 (9). These books are products of the Committee on the Quality of Health Care in America, which was established by the IOM to study issues of quality and safety and to make recommendations for improvement.

A tsunami of change is taking place in the way patients, physicians, administrators, regulators, legislators, payers, employers, and society in general views health care, including its quality and safety and the accountability of all involved. The historic latitude accorded physicians and hospitals to keep data on quality and outcomes confidential or not collect it at all is now being systematically replaced; major efforts are being made by government agencies, employers, payers, and patient advocacy groups to force hospitals and physicians to collect and publish the important metrics of their performance and to improve quality and safety and other measurable outcomes of care. Contracts between providers and third-party payers, who have largely been silent on the issue of quality in the past, increasingly include pay-for-performance clauses that link total reimbursement to the achievement of quality objectives. In Massachusetts, insurance companies have established special Web sites that rank hospitals according to quality and cost of care (10). Hospitals are also scrambling to meet survey criteria established by organizations like the Leapfrog Group, which is a consortium of national employers who are dedicated to the improvement of health care quality and safety (11).

Two large studies of adverse events experienced by hospitalized patients have served as bookends to estimates of lives lost in the Untied States as a result of medical errors. Brennan et al (1) studied records of more than 30 000 patients who were admitted to 51 hospitals in the state of New York. Adverse events, broadly defined as injuries resulting from the care process, occurred in 3.7% of all patients who were hospitalized. Of these, 27.6% of events were judged to be caused by negligence (ie, medical errors representing deviations from accepted standards of care). Death was associated with adverse events in 13.6% of occurrences. Brennan and colleagues concluded, "There is a substantial amount of injury to patients from medical management, and many injuries are the result of substandard care."

In another study, Thomas and colleagues (7) used similar methods to estimate total adverse events and negligent adverse events in patients hospitalized in Utah and Colorado. In 15 000 patients who were discharged from hospitals, they found adverse event rates of 2.9% in each state. They further determined that negligent adverse events accounted for 32.6% of the total adverse events in Utah and 27.4% of the total adverse events in Colorado. The reported death rate in patients who sustained negligent adverse events was 8.8%.

From the data presented in these two reports, the IOM estimated that in 1997, at least 44 000 and possibly as many as 98 000 hospitalized Americans died as a result of negligent care (12). These estimates were obtained by applying death rates observed in patients with avoidable adverse events in the respective studies to the 33.6 million people who were hospitalized nationwide that year. These estimates have captured headlines across the country and are now routinely quoted as fact by the media and a wide spectrum of people and organizations seeking to promote improvements in health care quality and safety.

At first blush, the number of deaths caused by negligence in the care of hospitalized patients appears shocking and hard to believe. It is tempting to reject such high estimates out of hand as unreasonable and almost certainly methodologically flawed by their retrospective nature and lack of controls. Among the putative flaws in the IOM analysis, McDonald and colleagues (13) point out that no information was provided by the IOM or taken into account in its analysis on baseline risk of death in the study population. They note that many of the

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patients may have died because of any number of circumstances. McDonald et al reason that to ascribe a causal relationship between negligent adverse events and death in all associated cases, as the IOM did in reaching its estimates for excess deaths, implies that no patients in the adverse-event group would have died, if not for the observed medical mistakes. This is clearly unreasonable and means that the IOM estimates are undoubtedly overstated, perhaps substantially so. Moreover, the authors of the original reports qualified their findings and did not propose conclusions like those of the IOM (1,7,14).

However valid the reasoning of McDonald et al may be, it can only go so far. It certainly does not close the gap between current societal expectations for higher quality and safety in the health care system and widely held perceptions of the current problems. Even if the IOM estimates were off by 100%–200% or more, it would still leave an unacceptably high number of negligent adverse events for which to account—whether or not they resulted in death—and there would still be a disturbing pattern of substandard care of hospitalized patients. Public opinion has been mobilized, and the quality and safety revolution in health care is underway. The genie is out of the bottle.

Barriers to Improving Quality and Safety in Health Care

One of the ironies in addressing quality issues in health care is the high level of commitment and personal dedication that individual providers believe they already have for achieving high quality and safety. Physicians, nurses, and technologists all experience anguish when adverse events occur. No one wants to be the cause of unnecessary disability or death. How then do we explain the discordance between these feelings and the observed occurrence of avoidable adverse events due to negligence?

An obvious place to start is to consider the competence of medical personnel. There is no doubt that individual errors due to lack of knowledge, inadequate procedural skills, poor judgment, or inattentiveness are important sources of adverse events. In one study of adverse events in patients who underwent surgery, 53% of errors were attributed to inexperience or lack of competence on the part of the provider (15). Likewise, in a study (4) of adverse drug events in hospitalized patients, 56% occurred at the time of ordering; other mistakes occurred during transcription of orders or dispensing and/or administration of drugs, all of which are mistakes that were made by other individual providers.

Most observers of work in the areas of quality and safety point to system factors, not individual performance, as the most important root cause of the problems facing the health care system (3,4,16–19). The sheer complexity of medical practice, limited resources, poor communication, inability to share complete data between providers, decentralized decision making, and historically poor or nonexistent electronic medical information and management systems have been identified as more important barriers to achieving quality and safety goals than individual performance. The systems that support and underpin these and other important aspects of the care process are powerful determinants of quality. In this construct, documentation of training, demonstration of competence through board certification and continuing education, personal dedication, and licensure are still vitally important, but they are simply the necessary entry conditions for providers who obtain the credentials and privileges to practice medicine. Thereafter, every professional action occurs within the context of the different systems that support the care process.

The reasoning that stresses the importance of systems holds that good people will routinely be defeated by bad systems, no matter how well meaning or hard working they are. The airline industry came to this verity years ago. Historically, pilots were left to remember every step from takeoff to landing. As airplanes and flight conditions became more complex, this no longer worked at an acceptable level; therefore, pilots today use checklists, a systems approach that is far better than and fundamentally different from trying to memorize and recall each step in a complex process. No one doubts the skill, intelligence, or dedication of most pilots, but there is clear recognition that trying to memorize everything will ultimately lead to fatal errors. Perhaps an analogy in medicine might be physicians trying to memorize every medication, dosage regimen, and drug-drug interaction, which—in fact—has been the traditional approach. Too often this comes to a point of failure of one kind or another, no matter how good the training or dedication of the people involved, especially when the orders are written by hand. A transposed decimal point, mistaken dosing interval, or simple misunderstanding of a word can all lead to adverse events, as the literature so strongly attests.

Assigning individual blame is the cornerstone of the tort system in the United States and a defining feature of many hospital quality assurance programs. The potential for inflicting a higher risk of disciplinary action or legal liability on oneself through reporting of errors is a factor that has held providers and hospitals back from fully reporting and understanding adverse events. Underreporting of adverse events masks flaws in systems and is a formidable barrier to progress.

Charting Pathways to Improved Quality and Safety

There are now literally dozens of organizations, including professional societies, government agencies, industry consortia, and other public and private entities, seeking a role in improving the quality and safety of the health care system. A recent seminar for health care executives called "The Quality Colloquium" listed no fewer than 31 sponsoring organizations, including the *Journal for Health Care Quality* and the *Journal of Nursing Quality* (20).

The IOM is among the thought leaders in the quality and safety revolution because of its prestige, the shocking statistics it has promulgated, the wide publicity achieved by its publications, and the high level and global nature of its recommendations and agenda. The IOM Committee on the Quality of Health Care in America has postulated six overarching goals for the health care system (21): *(a) safe*—avoid injuries to patients from the care that is intended to help them; *(b) effective*—provide services based on scientific knowledge to all who could benefit and refrain from providing services to those who are unlikely to benefit (ie, avoid under- and overuse, respectively); *(c) patient centered*—provide care that is respectful of and responsive to individual patient preferences, needs, and values and ensure that patient values guide all clinical decisions; *(d) timely*—reduce waiting times and sometimes harmful delays for both those who receive and those who provide care; *(e) efficient*—avoid waste, including waste of equipment, supplies, ideas, and energy; and *(f) equitable*—provide care that does not vary in quality because of personal characteristics such as sex, ethnicity, geographic location, or socioeconomic status.

These goals go beyond simply addressing ways to reduce errors. Each of these high-level goals is associated with a fur-

ther series of recommendations on how to achieve them. For example, to the extent possible, effectiveness requires translation of medical knowledge and best practices into practice guidelines and evidence-based systems of care delivery. The IOM Committee on Health Care Quality in America provides a number of ideas for accomplishing this through collaborations between government agencies, professional societies, and other interested parties, including the National Quality Forum.

A singular point of emphasis in the work of the IOM Committee is the need for a major public and private collaboration to massively upgrade information technology systems used in health care (19). Arguably, the information technology systems used in health care have lagged behind virtually every commercial sector. It is routinely possible to access bank accounts electronically from anywhere in the world, but it is often impossible to access medical information from next door. Improved information systems would support progress toward all of the goals set forth by the IOM and may be the single-highest-impact systems factor because of the pervasive need to be able to access, record, and share information to provide high-quality medical care.

In 2001, the President's Information Technology Advisory Committee Panel on Transforming Health Care (22) reported that the United States does not have an "accepted national vision for information technology in health care." The Committee recommended that such a vision be developed through the Department of Health and Human Services, a recommendation very similar to one of the IOM recommendations. Legislation was introduced in Congress in 2003 to support building the National Health Information Infrastructure (H.R. 2915) and to provide funds to hospitals for acquiring information technologies designed to reduce medication errors (H.R. 3035, S. 1729) (23).

Other organizations have approached quality and safety improvement more concretely than the IOM by choosing a small number of specific issues associated with high risk of poor outcomes. The Leapfrog Group was founded by the Business Roundtable and represents more than 150 public and private organizations that are responsible for providing insurance for more than 34 million people throughout the United States. This organization started with just three specific issues: *(a)* computer physician order entry, *(b)* evidence-based hospital referral, and *(c)* intensive care unit physician staffing (11).

The Leapfrog Group has expanded its horizons to encompass 30 safe practices endorsed by the National Quality Forum, which is another private nonprofit entity dedicated to improving health care quality, and has initiated a self-reporting survey and scoring system that will enable hospitals to achieve these practices. The Leapfrog Group is encouraging its members to use the results of its surveys to reward hospitals that meet the safe practice standards. The Leapfrog Group (11) notes that "Purchasers can also contract for specific safety and quality improvements with their health care providers and health plans." This organization is vigorously promoting customer and patient advocacy as a means to pressure hospitals to perform better.

In some respects, the Joint Commission on Accreditation of Health care Organizations (JCAHO) is the odd man out, even though its accreditation program dates back over 50 years (24). After all, the JCAHO has doggedly accredited, year in and year out, the very institutions and their practices that are now under such scrutiny and criticism. In retrospect, the approach of the JCAHO was doomed to miss important issues because it focused too heavily on facilities, credentials, procedure protocols, and other inputs to the care process; only relatively recently has the JCAHO placed equal or greater emphasis on outcomes of care or adverse events. Moreover, the JCAHO has never been very successful in achieving compliance from hospitals on adverse events reporting (24–26), which is a cornerstone of research to improve quality and safety. Only 2552 sentinel events have been reported to the JCAHO since the inception of the program in 1995, which is a period of 9 years (26).

Most institutions probably regard the JCAHO as a necessary burden but not as an engine of change for the better. Many things are done at a pro forma level in hospitals simply to achieve accreditation; the interval between accreditation visits reduces the day-to-day influence of the JCAHO.

To the credit of the JCAHO, the organization is trying to regain currency and impact by implementing a new policy of unscheduled interim visits and undertaking its own substantial new initiatives to promote improved quality. In 2002, the JCAHO announced its Shared Vision-New Pathways program (27), which was designed to focus more of the accreditation process on the systems that are critical to quality and safety. In the same year, the JCAHO also initiated its first annual statement of National Patient Safety Goals. These goals are very specific and focus on hospital performance rather than on documentation of readiness to perform. The first goals are to *(a)* improve accuracy of patient identification, *(b)* improve effectiveness of communication among caregivers, *(c)* improve the safety of using high-alert medications, *(d)* eliminate wrong-site, wrong-patient, and wrong-procedure surgery, *(e)* improve the safety of infusion pumps, and *(f)* improve the effectiveness of clinical alarm systems (27).

The JCAHO is forging alliances with other organizations more than it has in the past. It has established a program called Speak Up, in collaboration with the Centers for Medicare and Medicaid Services, which is designed to solicit patient activism in reporting quality and safety problems.

A small sampling of the many other organizations now involved in defining the quality and safety agenda are the Agency for Health care Research and Quality of the Department of Health and Human Services, the Institute for Health care Improvement, the National Committee for Quality Assurance, and the National Patient Safety Foundation.

Radiology and the Quality and Safety Revolution

Most of the issues identified in studies of quality and safety in health care apply to radiology. Medication errors, wrong-site procedures, mistaken identification of patients, procedural complications, poor communications with other care givers, and myriad other shared problems all lurk in the practice of radiology to variable degrees.

The view that systems issues are critical to achieving high quality and safety also appears to be valid for radiology. Certainly, many of the well-known problems in radiology, such as lost or unavailable images and reports, delayed communication of results, and lack of patient information, have all been reduced with implementation of hospital and radiology information systems, voice recognition dictation systems, and picture archiving and communication systems. The quality of care and service has increased, and operational costs have decreased. The effect of these systems, especially when they are well integrated with other hospital information systems, has made a

number of radiology departments exemplars for the transformational power of a systems approach to improving quality. In many respects, radiology has taken a leadership role in systems improvement in health care, and hospitals would be well served to learn from the experience of radiology as motivation for making the necessary information technology investments throughout their enterprises.

The American College of Radiology, or ACR, has taken a lead role in developing programs to address quality issues unique to radiology, including practice guidelines, technical standards, appropriateness criteria for use of imaging examinations, and accreditation programs. The ACR Mammography Accreditation Program is deemed to accredit facilities under the Mammography Quality Standards Act, which allows Medicare billing. These are valuable programs, although most mainly focus on process issues and other inputs to imaging care and not on outcomes. An important exception is the ACR Rad Peer program, which is designed to allow practices to assess diagnostic accuracy of radiologists, a key requisite for high-quality care (28).

Last year through the ACR forum, the ACR convened a group of industry experts from both in- and outside radiology to examine important quality issues facing this specialty in the future (29). Many of the observations developed at the forum parallel those of the IOM. The observations address outcome issues and will be useful guides for directing future research and program development.

Radiation safety is a unique and chronically challenging safety issue in radiology that has been exacerbated by the increased use of computed tomography (CT). A number of investigations have now shown that it is possible to significantly curtail the radiation dose associated with CT while still preserving the diagnostic quality of images (30–32). What is unknown is how far this new knowledge has penetrated daily practice, a classic translational hurdle that limits the achievement of evidence-based medicine. Any comprehensive approach to quality and safety in radiology must address radiation safety.

Concluding Observations

Powerful forces have been unleashed that are fueling public expectations for improvements in health care quality and safety. These forces can be regarded as intrusive and misguided, or they can be used as leverage to obtain the resources and generate the momentum needed for progress. To the extent that the health care establishment resists change, eager cadres of new organizations will define the quality agenda, as they have begun to do already. Indeed, hospitals already find themselves being pushed to demonstrate compliance with new unofficial but powerful market-driven programs, such as those of the Leapfrog Group.

It is likely that in the age of heightened quality expectations, the most successful health care organizations will be those that see their own quality and safety programs as important and not simply as necessary to comply with the expectations of regulators and watchers. These organizations will benefit from substantial operational improvements and operating cost reductions, which will be secondary gains due to improvement of the basic systems that help secure quality and safety of care. By creating fundamentally better systems to support the care process versus placing undue burdens on the staff, these leading hospitals will become more attractive places for people to work, and associated morale will be higher. Patients will benefit through better outcomes and greater satisfaction with service.

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