Richard Shur
Norma Simons

Quality Issues in Health Care Research and Practice

Executive Summary

- The Institute of Medicine's comprehensive program for quality improvement is based on many years of data observation, collection, and analysis.
- This work was performed by practitioner-researchers and efficiency consultants from many disciplines.
- The resulting recommendations are striking in their straightforward practicality and in their insistence that process factors determine output.
- According to Leape and colleagues (1991) "most adverse events are preventable...particularly those due to error or negligence."
- Leape et al. (1991) note that in industry, "an error rate that exceeds defined norms is deemed unacceptable" and urge that similar norms apply in medicine.
- As knowledge and technology improve, the results of quality undertakings are certain to foster health care's development into an endeavor in which errors are becoming increasingly rare events.

The Institute of Medicine (IOM) report, "To Err is Human" (Kohn, Corrigan, & Donaldson, 1999), was produced as part of the Institute's "Quality of Health Care in America" project. The goal is ambitious: The IOM intends to develop a strategy capable of producing a "threshold improvement" in the quality of American health care. The massive collection of data that has been marshaled to document the project's rationale and the resources required to sustain its purpose clearly suggest a sense of unease with the health care status quo.

Kohn et al. (1999) define health care quality as "the degree to which health services...increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (p. 180). They cite remarkable progress made by industries that use systems approaches to enhance safety, reduce errors, and maximize quality and they note that health care "is decades behind... in terms of creating safer systems..." (p. 61). This critical assessment is consistent with, and to some degree is based upon, the classic studies of Brennan et al. (1991) and Leape et al. (1991), who used sampling statistics to estimate the number and types of iatrogenic injuries among patients discharged from New York hospitals in 1984.

According to Leape and colleagues (1991), "most adverse events are preventable...particularly those due to error or negligence" (p. 380). They note that in industry, "an error rate that exceeds defined norms is deemed unacceptable" (p. 382) and urge that similar norms apply in medicine. Once norms are established, hospitals can "target their quality-assurance activities to the areas most likely to respond to such efforts" (p. 382). These include attending to the "systemic causes and consequences" of errors, stipulating error rates that will automatically trigger process review, collecting and acting upon risk profile data, and targeting high-risk procedures and patients for quality interventions.

The Cost of Adverse Events

Johnson et al. (1992) interviewed a sample of individuals who had suffered medical injuries in New York hospitals in 1984.

RICHARD SHUR, PhD, was a Psychologist, Orchard Hills Psychiatric Center, Novi, MI, at the time this article was written.

NORMA SIMONS, MS, is Founder and Owner, Simons-White & Associates, Inc., Ann Arbor, MI.

They then estimated that the cost of all 1984 New York hospital medical injuries was $161,000,000 for medical care, $276,000,000 for lost wages, and $441,000,000 for lost household production. According to Thomas et al. (1999), these findings imply a total national cost of over $50 billion in 1984 for medical adverse events.

Bates et al. (1997) investigated the costs of adverse drug events in two tertiary-care hospitals. Their sample consisted of 190 patients with adverse drug events (ADEs) admitted to medical and surgical units. Each admission was matched with a control case. Of the 190 ADEs, 60 were preventable. The additional length of stay per preventable ADE was 4.6 days, while for non-preventable ADEs the additional length of stay was 2.2 days. The increased cost per preventable ADE was $4,685; for non-preventables it was $2,595. The total projected annual cost for a 700-bed teaching hospital was $8,400,000.

Malpractice-Related Costs

The 2004 report of the National Provider Data Bank indicates that the Data Bank received 17,696 malpractice payment reports during 2004. Cumulatively (since 1990), physicians were responsible for 210,647 malpractice payment reports (78.6%), dentists for 35,514 (13.3%), and all other practitioners for 21,787 reports (8.1%).

Obstetrics-related incidents, consisting of 9.5% of all physician reports, had the highest mean payment, $503,564. Diagnostic-related payments were the most frequently reported category for physicians during 2004, totaling 33.3% of physician reports. The mean physician malpractice payment in 2004 was $298,000.

About 1% of malpractice payment reports were for nurses in 2004. Over the history of the Data Bank, registered nurses were responsible for 3,139 payments (1.2% of all payments). In 2004, non-specialized RNs were responsible for 62.7% of payments made for nurses, nurse anesthetists were responsible for 20.7% of nurse payments, and nurse midwives were responsible for 9.2%. The mean malpractice payment for all types of nurses was $302,738.

Studdert et al. (2006) attempted to determine whether malpractice claims that lack evidence of injury and/or of substandard care are common and whether they tend to be paid or denied by courts and insurers. To address this question, physician-researchers reviewed a large sample of closed malpractice claims. Three percent showed no verifiable medical injuries and 37% did not involve errors. Most of the claims that were not associated with errors or injuries were not compensated. The 73% of claims that did involve injuries due to error were compensated. For cases involving injury due to medical error, 54 cents of every dollar in malpractice awards "went for lawyers, experts, and courts."

Studdert et al. (2005) examined the widespread perception that malpractice litigation and onerous insurance costs encourage defensive medicine, especially among practitioners in high-liability specialties. They surveyed physicians practicing emergency medicine, general surgery, orthopedic surgery, neurosurgery, obstetrics/gynecology, and radiology in Pennsylvania to determine whether the perception was supported by data. Among the 824 physicians who completed the survey, 93% reported practicing defensive medicine. These included practices meant to reassure patients such as ordering tests or other diagnostic procedures, referring patients for additional consultations, using unnecessary imaging technology, avoiding procedures and/or patients who might elevate litigation risks, and eliminating procedures prone to complications.

An economist or efficiency expert would probably describe the practice climate documented by Studdert and colleagues as one in which perverse incentives predictably produce inefficient care. In this regard, it should be noted that, according to the American Medical Association (AMA, 2007), Pennsylvania is one of 17 states in which patients are losing access to care due to high malpractice premium costs. An AMA medical liability crisis map may be seen at http://www.ama-assn.org/ama/noindex/category/11871.html

Crossing the Quality Chasm

By 2001, the IOM moved to the second phase of its massive quality initiative. Having provided extensive documentation of medical error and its human and material costs, Institute researchers and policymakers began focusing on remediation. This change of emphasis can be seen in "Crossing The Quality Chasm: A New System for the 21st Century" (IOM, 2001). As its title implies, much of "Crossing The Quality Chasm" is devoted to identifying and correcting the causes of inadequate care. These include the growing complexity of medical science, an aging population with chronic and/or multiple conditions, and a poorly organized and overly complex system of care delivery.

Information Technology

In September of 1999, the IOM Committee on the Quality of Health Care in America held a workshop during which participants identified key areas in which information technology could contribute to improved health care delivery systems (IOM, 2001):

1. Better access to clinical evidence via the Internet for providers and consumers.
2. Computer-aided support systems to facilitate the application of up-to-date scientific knowledge.
3. Improved coordination of care across clinicians and settings.

4. Standardizing and automating certain decisions.
5. Identifying potential errors before they occur.
6. Enhancing patient/clinician intercommunication via email.

The Case for Quality Management Science in Health Care

According to Laffel and Blumenthal (1989), the traditional medical approach "tends to focus on physician performance and to underemphasize the contributions of crucial nonphysician and organizational processes" (p. 2870). These writers define quality as "a continuous effort by all members of an organization to meet the needs and expectations of...patients and other customers" (p. 270). They maintain that in order to increase the proportion of satisfactory outcomes, it is imperative to measure actual outcomes and to study the organizational processes by which those outcomes are created.

Outcome variation is, in fact, ubiquitous in complex human actions and processes. In biology and medicine, it is taken for granted that individuals vary in physical, mental, and performance measures. In the world of industry and engineering, however, process and outcome variation are more likely to be systematically monitored and measured. The goal is to adjust the process in order to reduce variation, so that very few outcomes fall beyond prespecified limits. Those that do are, by definition, errors.

Chasin (1998) refers to a quality control procedure much in vogue in business and industry. A business or profession that produces goods or services with 3.4 or fewer defects per million opportunities (DPMO) is said to have achieved Six Sigma quality. Defects, however, exact a heavy cost. Chasin (1998) compiled data showing that ambulatory antibiotics are prescribed for colds in 210,000 cases PMO, that 580,000 depressed patients are not detected or treated adequately PMO, and that 790,000 eligible heart attack survivors fail to receive beta blockers PMO.

On the prevention of anesthesia accidents during surgery, Eichhorn (1989) illustrated how lack of close attention to process factors can contribute to serious and/or fatal errors. Eichhorn (1989) examined the records of over one million patients who received anesthesia during treatment at the hospitals of the Harvard Department of Anaesthesia from 1976 to mid-1988. Within this patient cohort, there were 11 "major intraoperative accidents solely attributable to anaesthesia..." These included five deaths, four cases of permanent CNS damage, and two cases of cardiac arrest with eventual recovery. Unrecognized hypoventilation was the cause of seven of these cases. These could likely have been prevented "by appropriate response to earlier warnings" generated by Harvard's safety monitoring standards. But the standards apparently were not fully implemented until the middle 1980s. Thus, from 1985 through mid-1988, there were 319,000 anesthesia cases without a major preventable intraoperative injury.

Eichhorn (1989) concluded that "nearly all the inevitable mishaps...that occur during anesthesia can be identified through safety monitoring early enough to prevent most major patient injuries" (p. 577). He suggested that "capnography... would be the best monitor of ventilation" during surgery. In fact, there is evidence that capnography, along with pulse oximetry, can prevent 93% of avoidable anaesthesia mishaps (Tinker, Dull, Caplan, Ward, & Cheney, 1989). In recognition of these findings, the American Society of Anesthesiologists (1999) now includes capnography as standard for "every patient receiving general anesthesia."

Underuse of Health Care Services

According to Chasin (1998), "failing to provide an effective service when it would have produced favorable outcomes constitutes underuse" (p. 5). Financial barriers, including lack of insurance, high co-pays, or lack of preventative care coverage may contribute to underuse.

The impact of co-pays on underuse was investigated by Goldman, Joyce, and Karaca-Mandic (2006). These researchers studied over 62,000 patients using cholesterol-lowering medication to determine if a relationship exists between insurance co-payments and medication compliance. The researchers determined that the number of fully compliant patients fell by 6% to 10% when co-payments doubled to $20. Among high-risk patients who fully complied, despite increased co-payments, there were 357 fewer hospitalizations annually per thousand. Based on a national population of 6.3 million adults on cholesterol-lowering medication, a policy of eliminating co-payments for high and medium-risk patients would avert almost 80,000 hospital admissions and 31,400 emergency room admissions, saving $1 billion annually (Goldman et al., 2006).

Another example of underuse can be seen in the failure of American health care practitioners to adequately diagnose and treat depression. Saver, Van-Nguyen, Keppel, and Doescher (2007) interviewed depressed patients who reported numerous visits to primary care practitioners during which questions assessing mental and emotional status were never raised. Wells et al. (1989) report data indicating that 58% of depressed patients fail to be diagnosed or treated properly during visits to medical clinicians, which is equivalent to 580,000 defects PMO. In contrast, 78% to 87% of depressed patients who visited mental health specialists were diagnosed accurately (Wells et al., 1989). Since brief, reliable, inexpensive, valid, and user-friendly

self-report inventories for depression are readily available (see, for example, Zimmerman et al. 2006), the failure of primary caregivers to use these measures is hard to fathom.

Medication and Lab Errors: Six Sigma Interventions

A study reported by Esimai (2005) documents the use of Lean Six Sigma methodology to reduce medication errors at a medium-size hospital. The intervention focused on the pharmacy's order entry process, since most errors were known to occur at that point in the process. Order entry errors among pharmacy employees ranged from 0 to 112 over 2 months. Errors often resulted from misunderstandings of guidelines and instructions. In response, the pharmacy department took steps to focus more effectively on educating and supervising of its employees.

Additional process factors soon became apparent, including technical problems with fax machines that caused delay or non-receipt of orders, poor legibility of orders, distractions and interruptions during order entry, and inadequate consultation between pharmacy staff and the nurses who administered medications. In response, monthly meetings between nurses and pharmacists were set up to enhance working relationships. Additional interventions included the institution of high-performance standards, increased instruction and supervision of staff, implementation of computerized physician order management, separation of fax and phone lines, and unit-based provision of medication.

During the initial 2 months following these process enhancements, the number of errors in dose, frequency, drug, failure to discontinue, duplicate orders, and orders not received each fell, and the total error rate fell from 0.33% to 0.14%. In addition, labor costs were reduced by $550,000.

Riebling, Condon, and Gopen (2004) reported Six Sigma intervention designed to reduce costly errors at a large regional clinical laboratory. The lab's quality team suspected that most errors occurred during "accessioning" (registering the sample and entering its identifying data into the lab's information system).

Using the step-by-step Six Sigma procedure of Define, Measure, Analyze, Improve, and Control (DMAIC), the quality team defined any lab requisitions with errors in one or more of its seven information fields as defective. A review of over 5,600 requisitions collected during a 1-week period revealed 283 defects, which translates to 7,210 defects per million opportunities or 3.9 sigma. The team then decided that all information fields would be entered from bar codes, which could be directly scanned into the lab's computer system. A new training program for staff was also initiated.

By the end of the improvement phase, the Sigma level increased from 3.9 to 4.2 and there was a 43% increase in specimen volume. These improvements resulted in a gain to the lab of $339,000 per year from increased revenues and cost reductions.

A National Agenda to Reduce Medication Errors

The IOM released a prepublication summary of a major new quality initiative, the purpose of which is to develop a national agenda for reducing medication errors based on estimates of the incidence of such errors and evidence on the efficacy of various prevention strategies (IOM, 2007). The IOM initiative rests on a detailed analysis of the data on medication errors, including differences in causation, impact, and prevention across multiple dimensions of health care delivery, including patient populations, care settings, clinicians, and institutional cultures. Researchers will be encouraged to evaluate approaches to reducing medication errors in terms of their efficacy, cost-effectiveness, appropriateness in different settings and circumstances, reliability, institutional barriers to implementation, associated risks, and quality of evidence supporting the approach.

The IOM safety initiative includes superbly practical recommendations for consumers and providers. Hospitalized patients, for example, are urged to ask doctors or nurses to identify each drug as it is provided, to be told the reason for the drug before taking it, and to have a surrogate present whenever they are unable to personally monitor medication intake. Providers are advised to discuss each medication and its purpose, especially during care transitions. They are also urged to discuss potential side effects, drug interactions, and what to do in response. In addition, electronic prescribing is strongly encouraged to support decision making, reduce the high error rates associated with paper prescriptions, anticipate drug interactions, and to automatically adjust dosage to each patient's renal function and age.

Conclusion

The Institute of Medicine's comprehensive program for quality improvement is based on many years of data observation, collection, and analysis. This work was performed by practitioner-researchers and efficiency consultants from many disciplines. The resulting recommendations are striking in their straightforward practicality and in their insistence that process factors determine output. Can it really be true that only now, at this particular moment in the history of scientific medicine, hospitalized patients are being authoritatively advised to request the name and purpose of each proffered medication before ingesting it? We will never know how many adverse medication events might have been avoided had this low-tech, low-

cost procedure been instituted years ago. However, it can now be said with some assurance that quality-oriented process redesigns are likely to become a major priority in American medicine and that these will command significant research and institutional resources. As knowledge and technology improve, the results of quality undertakings are certain to foster health care's development into an endeavor in which errors are becoming increasingly rare events. **$**

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