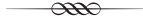


Still Demanding Medical Excellence



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Years before the Institute of Medicine began issuing health system quality alerts with nearly the same frequency as Microsoft warnings of rifts in software security, I painstakingly gathered much the same evidence the IOM used to such highly publicized effect.

I was a veteran journalist transformed by the magic wand of a Robert Wood Johnson Foundation Investigator Award into a health policy researcher. As I read and reread the articles, studies, and reports piled on every surface in my small academic office, I was appalled: years of research on important ways to make medical care safer and more effective had produced scarcely any effect on doctors and hospitals. I was also anxious. The trail of clues pointing to needless deaths and injuries seemed to me to be Poe's purloined letter—damning evidence hidden in plain sight. Naturally, I wondered why more seasoned researchers had not already sounded the alarm. Was I failing to detect some mitigating circumstance?

No matter how conservative I tried to be with the actual numbers, the grim bottom line remained. As I would eventually write in a book entitled *Demanding Medical Excellence: Doctors and Accountability in the Information Age*, “From ulcers to urinary tract infections, tonsils to organ transplants, back pain to breast cancer, asthma to arteriosclerosis, the evidence is irrefutable. Tens of thousands of patients have died or been injured year after year because readily available information was not used—and is not being used today—to guide their care. If one counts the lives lost to preventable medical mistakes, the toll reaches the hundreds of thousands” (Millenson 1997, 353).

Since I began my investigator work in early 1994, and since the words above appeared in late 1997, the movement to measure and manage the quality of medical care has gained significant clinical and political traction. Bits and pieces of the quality improvement (QI) ethos—and in some cases much more than bits and pieces—have become institutionally embedded in medical practice. What has not yet happened, however, is the kind of transformation that would signal a clinical, ethical, and economical clean break with the past. It is as if, in reaction to the thundering condemnation of medical education contained in the 1910 Flexner

report, a few schools had overhauled their curriculum while the rest had simply added a couple of biology courses and created an assistant dean for scientific affairs.

I believe the situation regarding medical excellence has changed so slowly because effective quality measurement and management does, in fact, demand true transformation. The IOM's ringing assertion that "systems of care"—which include organizational processes as well as information technology—can prove more important than training for individuals represents a radical departure (IOM 2001). Operationalizing the blueprint for change spelled out by the IOM requires a wholesale reexamination of deeply ingrained practices and beliefs.

As science historian Thomas Kuhn famously pointed out, the traumatic process of adopting a new paradigm does not occur until the defenders of the old ways "can no longer evade anomalies that subvert the existing tradition" (1970, 6). In a similar vein, quality pioneer W. Edwards Deming concluded that systematic quality improvement carries such a large burden of individual and organizational upheaval that it is embraced only when it offers the sole path "out of the crisis" (Deming 1986). Yet while health care pundits regularly and solemnly invoke the notion of "crisis," day-to-day reality belies this broad-brush characterization. In fact, the myriad payers, providers, insurers, and patients who comprise this \$1.6 trillion chunk of the U.S. economy remain quite comfortable with traditional approaches, both economically and culturally.

All of which reinforces the insight of Boston surgeon Ernest Amory Codman some ninety years ago. Contemplating the failure of his proposal to improve medical "efficiency" (his phrase for more reliable, high-quality care) by publicizing the outcomes of individual surgeons and hospitals, Codman wrote, "For whose *interest* is it to have the hospital efficient? Strangely enough, the answer is: No one. . . . There is a difference between interest and duty. You do your duty if the work comes to you, but you do not go out of your way to get the work unless it is for your interest" (1934, xviii).

Are the "interest" and "duty" to promote "efficiency" finally converging? I believe they are—not because I am convinced that widespread transformation is already under way, but because irreversible groundwork is now being laid for that transformation. Call it cautious optimism, but optimism nonetheless.

Diffusing Innovations

In his classic work *Diffusion of Innovations*, Everett Rogers wrote that five characteristics hold the key to an innovation's adoption. These include its relative advantage over what already exists; its compatibility with existing values and behaviors; its lack of complexity; its ability to undergo experiment ("trialability"); and its ability to produce results everyone can see ("observability") (Rogers 2003).

The first of Rogers's rules—that an innovation produces "relative advantage"—is roughly equivalent to Codman's rueful realization that those asked to change must believe it is in their interest to do so. The advantage must not only be real; it must be *perceived* as real. Surmounting this barrier can prove surprisingly difficult. Here outside pressure has played a key role in health care QI, as

contrasting tales of the patient safety movement and the effort to reduce inappropriate variation in medical practice reveal.

There was no patient safety movement in 1994 when I began my Investigator Award work; today, there is a strong one. No stunning new research emerged during the interim. In 1994 it was well documented that medical errors were common; that doctors and hospitals were in denial about their frequency; that system changes, not “punishing the perpetrators,” was needed to eliminate them; and that those changes, particularly when computerized, could be extraordinarily effective.

The 1991 Harvard Medical Practice Study, with its groundbreaking documentation of both the extent and impact of medical mistakes, had exerted virtually no impact on provider behavior. In December 1994 a frustrated Lucian Leape, one of the study’s authors, wrote in the *Journal of the American Medical Association (JAMA)* that the profession largely continued to ignore the preventability of medical mistakes, whose death toll equaled that of a crash of two 747s every three days (Leape 1994).

After Leape’s accusations (and his airline crash analogy) drew media attention, “hate mail began pouring in” to *JAMA* from AMA members outraged that the journal had printed the piece. Recalled then-editor George Lundberg, “I was accused of being on the side of the lawyers, a damned turncoat and traitor to the cause” (Lundberg 2000). Small wonder that when the *Boston Globe* in early 1995 broke the story of the painful death by chemotherapy drug overdose of its young medical columnist, Betsy Lehman, the American Medical Association’s official reaction was that “isolated and sometimes egregious mistakes” happen (McAfee 1995).

Changing Perceptions

So how did perceptions of the relative advantage of comprehensive patient safety reform finally change? To begin with, Lehman’s death at a nationally renowned cancer hospital convinced the intellectual leaders of American medicine to directly confront the inadequacy of the “people, not systems” approach. The “best and the brightest” had manifestly failed to protect someone much like themselves—an articulate and informed patient who complained about the drug’s effect but was ignored, someone who many medical leaders knew personally.

Lehman’s death represented a turning point for the news media as well. Investigations into medical mistakes became a staple of the health care beat, which, in turn, maintained public and political pressure (Millenson 2002). In Boston, physician and hospital organizations formed a coalition to prevent errors, and in Chicago the American Medical Association reversed course and established a National Patient Safety Foundation, which specifically rejected the idea that errors were “uncommon” and endorsed “systematic” efforts to prevent errors.

The 1999 IOM report *To Err Is Human* took the patient safety movement to the next level. The very first effort by the IOM’s Committee on the Quality of Health Care in America concluded that forty-four thousand to ninety-eight thousand Americans died in hospitals every year because of preventable medical errors.

Moreover, the report noted pointedly, “Silence surrounds this issue. For the most part, consumers believe they are protected” (IOM 2000, 3).

The research was not new, but the IOM report placed it in a radically different context. First, its statistics were in a simple form designed for maximum public impact: more deaths occurred yearly from medical errors than from breast cancer or AIDS, plus the ever-popular crashing 747 comparison. Moreover, researchers affiliated with the nation’s scientific elite had authored this indictment of American medicine for failing to act. Finally, the report linked abstract concepts to concrete consequences. The very first paragraph of *To Err Is Human* named three individual victims, all of whom (including Lehman) had been identified through local newspaper investigations. National television coverage of the IOM report turned those names into faces and families whose fate struck an instant chord with the American people.

A few weeks after *To Err Is Human* was released one poll found that an astonishing 51 percent of the public was aware of its conclusions (Kaiser Family Foundation 1999). Within a year, the U.S. General Accounting Office had produced a report on adverse drug events; members of Congress had introduced legislation requiring reporting of medical errors; and millions of dollars to fight medical mistakes had been channeled to the Agency for Healthcare Research and Quality. State legislators, usually deferential to hospitals and doctors, introduced a brace of error-prevention measures and passed some of them. Separately, a coalition of Fortune 500 employers known as the Leapfrog Group launched an initiative pushing hospitals to install computerized systems for physicians’ orders to prevent medication errors. All these moves helped change the perception among providers of the relative advantage of change.

Crucially, pressure for safety improvement has continued, manifested by national and local media attention and a variety of initiatives by legislators, accreditors, and payers at both national and local levels. In one potent symbol, Massachusetts announced in January 2004 the creation of the Betsy Lehman Center for Patient Safety and Medical Error Prevention. Its mission is to promote patient safety through work with governmental agencies, providers, and patients.

Putting Innovation into Practice

The IOM report, the AMA’s reversal of its stance on errors, and continuing public pressure also helped galvanize a broad spectrum of professional organizations to address safety, thereby signaling compatibility “with existing values and behaviors”—Rogers’s second requirement. One example is the aggressive effort to limit “wrong site” surgery, led by the American Academy of Orthopaedic Surgeons.

Professional support has also proven critical to Rogers’s third requirement: “trialability”—specific actions individuals can take to test an innovation. For example, the Boston-based Institute for Healthcare Improvement, a respected independent nonprofit founded by pediatrician and researcher Donald Berwick, has set up “best practice” collaboratives to help organizations handle the nitty-gritty details of instituting the IOM’s safety recommendations. Meanwhile the Pittsburgh

Regional Healthcare Initiative is involving the entire provider and payer community in its goal of implementing “zero tolerance” for preventable medication errors and hospital-caused infections. Many provider organizations have launched similar, if less ambitious, efforts.

All these initiatives not only make error-reduction “trialable,” but also reduce the complexity of innovation, Rogers’s fourth requirement. State-of-the-art safety improvement no longer requires a research infrastructure. Premier, Inc., an alliance of over two hundred hospitals and health care systems, offers a quality prize and says the best safety efforts are now coming from “frontline” hospitals rather than academic research centers. Fairview Hospital of Great Barrington, Massachusetts, with only twenty-four beds, implemented such sweeping safety improvements that it became a national finalist for the American Hospital Association’s 2002 Quest for Quality Prize. Meanwhile, efforts to reduce complexity continue. In early 2003, the federal Agency for Healthcare Research and Quality launched a Web-based patient safety and quality improvement forum that features interactive learning modules, online discussion, and expert analysis of medical errors reported anonymously (see www.webmm.ahrq.gov/).

Change over the past decade regarding the last item on Rogers’s list—observable results—has been striking. Stories of successful efforts to reduce errors have gone from invisible to ubiquitous in professional journals (including articles on impressive successes in reducing errors by the Veterans Health Administration and Boston’s Brigham and Women’s Hospital), the trade press, conference proceedings, and monthly listservs.

Creating a “Social Epidemic”

Both collectively and synergistically, these safety improvement efforts have begun creating what Malcolm Gladwell calls, in *The Tipping Point* (2000), a “social epidemic.” What an intervention needs to shift common practice, Gladwell writes, is not “an avalanche of new or additional information” but rather specific information that allows individuals to understand how the intervention fits “into their lives” (2000, 98). A staple of professional meetings on patient safety, for example, includes a slide with a scribbled prescription that seems to indicate one drug or dosage but actually prescribes something quite different. The same pointed message has also seeped into the public realm, as evidenced by a 2003 *Dilbert* cartoon where Dilbert asks his physician, “What if your bad handwriting causes the pharmacy to give me a harmful medication?” The doctor responds blithely, “That’s a little thing I call marketing.”

Still, while U.S. medical practice may have reached the tipping point on patient safety, the new paradigm is by no means universal. Safety efforts also remain inpatient focused; outpatient errors, not addressed in the 1999 IOM report, are only beginning to receive sustained attention. Finally, the speed of change sometimes suggests that what has been tipped over is a jar of molasses. In one not atypical example of lionizing the Lilliputian, the Ohio Department of Health related proudly how it was working with provider groups to stop the use of five dangerous abbreviations in prescriptions. The department characterized this effort, which

began in early 2003, as a response to the IOM report of 1999. The department said it is “hoping” to eliminate these dangerous and “very easy” to eliminate abbreviations by 2005. Not surprisingly, a 2002 survey by Blendon and colleagues found that practicing physicians do not share the same “sense of urgency expressed by many national organizations” regarding preventing errors (Blendon et al. 2002).

Unvarying Variation

Moreover, the patient safety story is the good news. At the other end of the spectrum is the battle against inappropriate variation in medical practice. In the early 1970s, John Wennberg published his first papers demonstrating high variation in surgical procedures performed on similar types of patients in different areas of the country and within individual states and counties (see Wennberg and Gittelsohn 1973). The road to publication was bumpy, and Dr. Wennberg faced significant resistance from editors at major journals before his papers were ultimately accepted. For his trouble, he was cursed by fellow doctors and lost his academic job.

In the early 1980s, as health care costs soared, Wennberg’s research received prominent attention professionally and through Senate hearings and media coverage. Yet efforts to address practice variation did not take hold. In the early 1990s Wennberg’s data on variation reemerged into the spotlight with efforts to reform the national health care system; but, once more, no sustained change in practice ensued. A decade later, in 2003, reports of variation in practice seemingly unjustified by better patient outcomes started appearing yet again in publications as diverse as *Self* and *Business Week*.

Viewed within a framework of diffusing innovation, the Wennbergian wheel-spinning is not surprising. While the patient safety movement raises sensitive issues, its basic goals are clearly consonant with the bedrock professional value of “first, do no harm.” For physicians, protecting patient safety is also financially neutral or positive, as it can help them avoid malpractice suits. Studies of variations in clinical practice, by contrast, can threaten physician income; the purchasers and policymakers who flocked to Wennberg’s work were attracted by the possibility of reducing the “high” outliers (surgeons who were likely to operate for a certain problem) to the lower norm, not by the intellectual challenge of discovering whether a higher rate of surgery or a lower rate was really better. In addition, doctors often view studies examining medical variation as clashing with “existing values and behaviors.” As medical sociologist Eliot Freidson has observed, “The model of the clinician . . . encourage[s] individual deviation from codified knowledge on the basis of personal, first-hand observation of concrete cases. This deviation is called ‘judgment’ or even ‘wisdom’” (1970, 347). Within that context, variation in medical practice is often seen as a legitimate response to patients’ individuality.

Moreover, while patients themselves intuitively understand and are disturbed by “mistakes,” variation is a far more elusive concept. Patients may believe that more care represents better care, or that the judgment of their doctors differs from that of their peers because the former are smarter.

Finally, even clinicians who want to reduce inappropriate variation have had

no reliable and “non-complex” means of doing so. As Harvard Medical School’s Barbara McNeil noted in her 2001 “Shattuck Lecture,” efforts to reduce uncertainty and rationalize care have suffered from both a lack of definitive data and delays in translating the information that does exist into usable clinical form.

Breaking the Deadlock

One might ask whether quality measurement and management in the early twenty-first century has dwindled to an effort to implement advice offered by Puritan preacher and physician Cotton Mather at the end of the seventeenth century: “Let this advice for the *sick* be principally attended to: *Don’t kill ’em.*” I believe the answer is no—which is where my cautious optimism comes in. For many years attempts to address variation in professional practice and, more broadly, improve outcomes have bogged down in “town-gown” arguments. Practicing physicians have worried that academics unfamiliar with real-world ambiguity were second-guessing their clinical reasoning, while researchers were equally suspicious that in-the-trenches docs respond more to peer pressure and self-interest than to science. Over the past few years, however, several factors have emerged to break this deadlock.

First is the quantity and quality of research linking quality defects to measurable financial and health outcomes. The IOM issued a call to arms in 1998 and then 2001 against the overuse, underuse, and misuse of care (Chassin, Galvin, and National Roundtable 1998). Patient safety efforts have focused on the human and financial costs of misuse; now overuse and underuse are coming in for a similarly focused examination that fits the facts into a specific social context. In the overuse category, for instance, two breakthrough articles by Elliott Fisher and colleagues in *Annals of Internal Medicine* examined how variations in Medicare spending affected measures of access, satisfaction, utilization, and outcomes (2003a and 2003b). The authors concluded that Medicare enrollees in higher-spending regions receive an extraordinary 60 percent more care “but do not have better health outcomes or satisfaction with care” (Fisher et al. 2003a, 286). Invited political, clinical, and economic commentaries highlighted the importance of the research given growing provider and social concern about health care affordability.

At the other end of the spectrum, a national review by Elizabeth McGlynn and colleagues in the *New England Journal of Medicine* found that physicians provide the preventive, acute, and chronic care called for by medical literature just 55 percent of the time. This failure poses “serious threats to the health of the American public,” the authors concluded. They linked specific procedures (such as replacement of broken hips and treatment of stomach ulcers) to specific failure rates (a compliance rate of less than a third with evidence-based recommendations) (McGlynn et al. 2003). Other reports have provided a steady stream of data on defects in care for specific conditions and series of conditions at individual institutions.

The Advent of Evidence-Based Medicine

A second important factor in breaking the town-gown deadlock is the way data on quality defects are being translated into actionable information. Recall that

a “tipping point” requires that individuals understand how an intervention fits “into their lives.” The evidence-based medicine (EBM) movement, with its focus on applied knowledge, is starting to provide that type of information. Moreover, it is doing so within a context compatible with existing clinical values. If studies of variations in medical practice seemed, to physicians, to invite statistics-based second-guessing, and “continuous quality improvement” could not shake the feel of the factory floor, EBM is dressed in the comfortable Flexnerian robes of scientific practice. Although some clinicians still fret about “cookbook medicine,” EBM has entered the medical mainstream. A Medline search of journal abstracts for 1993 found just six uses of the term “evidence-based medicine,” all but one of which were basic explanations of the concept. A similar 2003 Medline search found 2,315 citations, beginning with the clearly nonbasic “guidelines for the treatment of oligodendroglioma.” More important in terms of putting theory into practice, EBM has benefited from a decade of technological advances that have made QI innovations extraordinarily “trialable” and “observable.”

Computers allow clinicians, hospitals, and health plans to track adherence to well-established processes (for example, annual eye exams for diabetics) and even some outcomes. A host of organizations offer collaboratives, courses, and other educational interventions designed to help providers make specific changes that will improve these measures. At an even more sophisticated level, a handful of vendors have begun using neural network “artificial intelligence” techniques to integrate data from pharmacies and laboratories with data on health care utilization and diagnosis. The goal is to compare outpatient treatment of individual patients to the “best-care” standards, and to intervene to improve that care through “alerts” to the treating physician when clinically appropriate. In hospitals, informatics vendors are starting to provide similar actionable information to clinicians in real time. In both cases, the technology will only become more reliable, more usable, and less expensive. Finally, the growing movement toward networked medical records—spurred in part by government pressure—promises to make clinical analysis both cheaper and far more reliable.

To be sure, important analytical barriers remain, particularly concerning data at the individual clinician level (Landon et al. 2003). But the adoption of computer-enabled decision aids is sweeping through society; the move toward more timely and actionable EBM-based information in health care is unstoppable.

Pressure from Outside the System

A third important factor is breaking the town-gown gridlock. Reliable data and actionable data are not enough; there must be a compelling reason to use the information. Here health care transformation has long stalled in a quagmire of ego, financial self-interest, ignorance, and inertia—with substantial contributions from all parties. Frank Davidoff has written of a physician who stated he simply could not accept the findings of a new study on diabetes treatment because it meant admitting to patients that he had been wrong. Concluded Davidoff, “The experience of shame helps to explain why improvement—which ought to be a ‘no-brainer’—is generally such a slow and difficult process” (2002).

One way to persuade providers to use QI information is through peer pressure, a strategy that has produced modest success. The more effective method, as the literature on innovation diffusion makes clear, is to combine internal with external pressure. Economist Kenneth Arrow wrote in a seminal 1963 essay, “The social obligation for best practice is part of the commodity the physician sells, even though it is a part that is not subject to thorough inspection by the buyer” (1965). In the Information Age, the second part of that sentence is fast losing its validity.

For instance, the Internet has given patients easy access to “translated” versions of the same general evidence-based guidelines as their physicians. Patients with some conditions, such as cancer and heart disease, can now go to a Web site sponsored by a trusted patient advocacy group, answer a detailed clinical questionnaire, and receive a customized printout of the best medical evidence of care for individuals with similar conditions. This is truly the “abstract” (EBM) made concrete (“my care”), and it brings the issue of variation directly to the patient (see www.nexcura.com).

Once the for-profit affiliate of Wennberg’s Foundation for Informed Medical Decision Making peddled to doctors’ offices decision-making videodisc equipment, which sold poorly and was used infrequently. Now that affiliate has grown to a \$100 million business by coaching health plan members and corporate employees on “best practice” in helping patients talk with their doctors as decision-making equals. Other vendors now sell data that reveal procedure-specific outcomes by hospital.

Patients not motivated to act on their own may find their employer or health plan providing not-so-subtle pressure to become “empowered.” Disease management vendors now contact tens of millions of Americans on behalf of health plans as well as employers who are convinced that higher-quality care means lower cost—particularly if efforts focus on patients who are the most likely to pile up substantial expenditures. Clinical prediction rules and algorithms that were largely the playthings of theoreticians in 1994 are mass-produced in 2004 as desktop PC rules for nurses and software for doctors’ Palm Pilots. Codman’s “end-result idea”—which called for measuring and disclosing outcomes—is, in a sense, being reincarnated as computer code.

Kissing the Frog

The economic incentive for using information on quality improvement—the “interest” versus “duty” equation of Codman’s time—has also begun to change. The first pay-for-performance pilot programs are now being gingerly rolled out by both large private purchasers and, importantly, Medicare. I believe these programs will inevitably expand, particularly in the wake of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which links public reporting by hospitals of ten quality indicators to a modest increase in reimbursement. Similarly, the Federal Trade Commission in early 2004 was considering new rules that would ease prohibitions on presumed anti-competitive physician and

hospital collaborations if they included QI elements such as comprehensive safety improvements and measurement and reporting of outcomes.

On a parallel track, the “consumer-driven health care” movement—whose origins lie in the fervent desire of private payers to share the burden of rising medical costs with employees—is starting to understand that it cannot succeed unless it provides information to individuals on the quality of care as well as its cost. In 2003, an estimated 1.5 million Americans enrolled in these types of plans, which typically involve health spending accounts and customized network or benefit selection (Gabel, Lo Sasso, and Rice 2002).

Certainly, the economic fruits of “best care” must be shared. Too often, providers who have pioneered evidence-based practices that keep patients healthy have been economically penalized. Similarly, “consumer-driven” care must evolve from mantra to meaningful action; patients who suspect that “evidence-based medicine” is invoked only to eliminate overused services but not to support underused ones will respond by seeking the protection of regulators, legislators, and the courts.

Transformation is instantaneous only in fairy tales; alas, waving a magic wand or passionately kissing a frog accomplishes little in the real world. The Flexner report at the beginning of the twentieth century provoked a “crisis” in medical education that could be solved only by “subvert[ing] the existing tradition,” to use the terminology of Deming and Kuhn. At the beginning of the twenty-first century, I believe that an accumulation of social, economic, and clinical pressures is slowly but surely bringing the same transformation to everyday medical practice.

Fortunately, evidence-based medicine resonates with providers and the public in a way that the cerebral “practice variation” and cold-blooded “managed care” never did. After all, if there is anything Americans crave more than “more,” it is “best.” At the same time, transparency of information and a balancing of autonomy and accountability are secular trends, a “social epidemic,” if you will, to which medicine is not immune. Teachers now debate “outcomes-based” report cards, while law enforcement officials explore the merits of “evidence-based policing.”

Nonetheless, the pace with which QI innovations will be implemented still depends upon the persistence and sense of urgency of patients, of providers who are patient champions, and of those with the power to intervene on patients’ behalf. The price of inaction is painfully high by any yardstick—economic, clinical, and moral. At the beginning of the twenty-first century, as at the start of the last one, we must still demand medical excellence. Fortunately, signs are growing that we are.

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