

Policy Challenges in Modern Health Care



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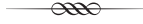
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PART III



*Improving Quality
of Care*

Still Demanding Medical Excellence



MICHAEL L. MILLENSON

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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Preventing Medical Errors



LUCIAN L. LEAPE

Most people first became aware of the problem of medical errors in late 1999, when the National Academy of Sciences' Institute of Medicine (IOM) released *To Err Is Human*, which announced that up to ninety-eight thousand people die each year from medical errors (IOM 2000). Although the shocking mortality figures came from studies published up to eight years previously (Leape et al. 1991; Brennan et al. 1991; Thomas et al. 2000), they were new to most readers and came now from an impeccable source. Congress promptly scheduled hearings, and shortly thereafter the president called on all federal health agencies to implement the IOM recommendations (Quality Interagency Coordination Task Force 2000).

The IOM brought to public attention a slow-growing safety movement that began in 1995 with the coincidence of disaster and opportunity. The disaster was a series of highly publicized serious medical errors, most notoriously, the death of Betsy Lehman, a health reporter for the *Boston Globe*, from a massive overdose of chemotherapy at the respected Dana Farber Cancer Institute. That such a tragic error could happen at such a prestigious medical institution shook both public and professional confidence. The opportunity was the discovery by health care leaders of the potential for preventing errors by using industrial human factors approaches, particularly the recognition that the cause of most human errors is neither carelessness nor incompetence, but defects in the systems in which people work (Leape 1994). For example, system characteristics such as look-alike labels and sound-alike names, conditions of work (long hours and heavy work loads), and managerial style (diffused responsibility and lack of teamwork) make it more likely that an individual will make a mistake. Errors can be reduced by redesigning the systems.

The implications of this concept for medicine are profound because it runs counter to classical medical training that focuses on faultless individual performance, reinforced by shaming and blaming. However, the systems approach is based on a wealth of studies in cognitive psychology and human factors engineering, as well as substantial experience in industries such as aviation, which have

found that achieving safety requires much more than training individuals to be careful (Reason 1990, 1997; Helmreich 2000).

Also in 1995 studies began to appear indicating the feasibility of applying the systems analysis approach in health care (Bates et al. 1995; Leape et al. 1995). Several leaders turned this opportunity into action. At the American Medical Association (AMA), legal counsel Martin Hatlie, long frustrated with attempts at tort reform, quickly recognized the potential of these new insights. He and James Todd, executive vice president, persuaded the AMA Board of Regents that it would be more productive to focus on reducing errors and that they could take the lead by establishing a foundation of stakeholders to promote patient safety. At the same time, Dennis O’Leary, president of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), recognized the need for that organization to change its approaches to safety. Within the year, the AMA and the JCAHO joined the American Association for the Advancement of Science and the Annenberg Foundation in organizing the first multidisciplinary conference on medical errors. At this meeting, which was held in 1996, the AMA announced the formation of the National Patient Safety Foundation, with Hatlie as its executive director, and O’Leary announced that the JCAHO was making its reporting system nonpunitive.

During the mid-1990s, a small number of hospitals began to take actions to better protect patients from medical errors. The Dana Farber Cancer Institute, badly shaken by the Lehman tragedy, underwent a major reorganization. New leaders, particularly James Conway, chief operating officer, undertook a major transformation of institutional culture to drive out blaming and to redesign systems. At the Veterans Health Administration, Kenneth Kizer, then under secretary for health, decided to make safety a system priority. Both Conway and Kizer spoke of their experiences and plans at the Annenberg Conference.

Yet continued research on medical errors, the application of systems theory to making changes in hospital systems, and experiments by some hospitals to improve care systems did not create much of a groundswell for greater focus on patient safety. Indeed, patient safety was not a major concern of most hospitals, doctors, or the general public until the IOM report made this “insider” information public (Leape et al. 2000). Release of the report triggered a media blitz and captured the attention of President Clinton and members of Congress. Overnight, public and professional awareness of the seriousness of the medical error problem spread from hundreds to millions.

Since the IOM Report

In the previous chapter, Michael Millenson describes the acceleration of activity in patient safety since the IOM report, which he presents as an encouraging example of the diffusion of innovation. While one might dispute that rosy scenario, a fair assessment would conclude that a remarkable amount of progress has been made in a relatively short period of time. Almost everyone is now aware that we have a serious problem—the public, Congress, government bureaucrats, payers, hospital managers, hospital boards, professional societies, and frontline workers.

TABLE 11.1 *NQF-Endorsed Set of Safe Practices*

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1. Create a healthcare culture of safety.
 2. For designated high-risk, elective surgical procedures or other specified care, patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that have demonstrated superior outcomes and should be referred to such facilities in accordance with the patient's stated preference.
 3. Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix and the experience and training of its nursing staff.
 4. All patients in general intensive care units (both adult and pediatric) should be managed by physicians having specific training and certification in critical care medicine ("critical care certified").
 5. Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications.
 6. Verbal orders should be recorded whenever possible and immediately read back to the prescriber—i.e., a health care provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard.
 7. Use only standardized abbreviations and dose designations.
 8. Patient care summaries or other similar records should not be prepared from memory.
 9. Ensure that care information, especially changes in orders and new diagnostic information, is transmitted in a timely and clearly understandable form to all of the patient's current health care providers who need that information to provide care.
 10. Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.
 11. Ensure that written documentation of the patient's preference for life-sustaining treatments is prominently displayed in his or her chart.
 12. Implement a computerized prescriber order-entry system.
 13. Implement a standardized protocol to prevent the mislabeling of radiographs.
 14. Implement standardized protocols to prevent the occurrence of wrong-site procedures or wrong-patient procedures.
 15. Evaluate each patient undergoing elective surgery for risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment of high-risk patients with beta blockers.
 16. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.
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(continued)

As envisioned by the IOM, the Agency for Healthcare Research and Quality (AHRQ) has become a national focus for safety, funding safety research, convening policy groups to set agendas, disseminating safety information, and supporting the development of standards for reporting and safe practices. Under the forceful direction of Kenneth Kizer, the National Quality Forum (NQF), a public-private partnership of purchasers, providers, payers, accrediting organizations, government agencies, and consumer groups, has convened expert panels to work on improving patient safety in the hospital setting. These panels produced a standardized list of serious reportable events for states to use in their mandatory re-

TABLE 11.1 *NQF-Endorsed Set of Safe Practices (continued)*

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17. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.
 18. Utilize dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.
 19. Upon admission, and regularly thereafter, evaluate each patient for the risk of aspiration.
 20. Adhere to effective methods of preventing central venous catheter-associated blood stream infections.
 21. Evaluate each pre-operative patient in light of his or her planned surgical procedure for the risk of surgical site infection, and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.
 22. Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.
 23. Evaluate each patient upon admission, and regularly thereafter, for risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.
 24. Whenever a pneumatic tourniquet is used, evaluate the patient for the risk of an ischemic and/or thrombotic complication, and utilize appropriate prophylactic measures.
 25. Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to and after direct contact with the patient or objects immediately around the patient.
 26. Vaccinate health care workers against influenza to protect both them and patients from influenza.
 27. Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
 28. Standardize the methods for labeling, packaging, and storing medications.
 29. Identify all "high alert" drugs (e.g., intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics and opiates).
 30. Dispense medications in unit-dose or, when appropriate, unit-of-use form whenever possible.

Source: National Quality Forum 2003. See the full report for applicable care settings for each practice, detailed specifications, background, and references.

porting systems and identified thirty proven safe practices that JCAHO and others can require hospitals to implement (see table 11.1) (National Quality Forum 2002, 2003).

JCAHO has toughened its stance on safety. Accreditation surveys are no longer scheduled months in advance: JCAHO auditors now arrive without warning to conduct audits of health care facilities. In 2002, the accrediting organization required that hospitals implement eleven specific safe practices, with promise of more to follow. These include methods to ensure proper identification of surgical patient identity and operative site, standardization of abbreviations, and removal of hazardous chemicals from nursing units. The National Patient Safety Foundation (NPSF) has also been a strong advocate, funding safety research and convening many regional and national conferences to inform, motivate, and instruct safety leaders.

A number of other organizations are focusing on patient safety. Professional organizations, such as the American College of Physicians, have begun to make patient safety a priority in their meetings and journals. The American Hospital Association (AHA) disseminated to all member hospitals a set of recommended medication safety practices, tools for systems analysis of medication systems, and survey instruments and safety leadership recommendations for hospital executives. The Accreditation Council for Graduate Medical Education (ACGME) recently established limits on the number of hours residents can work. With the American Board of Medical Specialties (ABMS), it is leading specialty societies to develop standards and measures of competency, including safe practices and systems analysis.

Safety coalitions have developed in fifteen states (Rosenthal et al. 2001). In response to programs initiated by these groups, many hospitals have made changes in their medications systems (Massachusetts Coalition for the Prevention of Medical Errors 2001; Shapiro 2000; Delaware Valley Healthcare Council 2001). In addition to peer pressure, coalitions provide technical support, public visibility, and positive publicity for participating hospitals.

Purchasers brought their power to quality and safety in 2000, when the Leapfrog Group, the health care purchasing coalition of the Business Roundtable, announced that it would only pay for care in institutions that met certain standards. These included the use of computerized physician order entry and the presence of an intensivist to monitor the care provided in intensive care units. The Leapfrog Group established volume minimums for certain complex operations and other procedures and pays for these procedures only when performed in hospitals that meet the volume standards (Milstein et al. 2000). Other payers have recently endorsed similar measures.

Since the IOM report, safety activities in hospitals have increased. Virtually every hospital now has launched some sort of a safety program, and many are trying to create a nonpunitive environment that encourages workers to report errors and to identify systems failures. Several large health care systems, including HCA (formerly known as Hospital Corporation of America), Premier, VHA (formerly known as Voluntary Hospitals of America), and Allina, have recommended various safe practices (mostly in the medication realm) to their member hospitals (VHA 2000). However, the outstanding leader is the Veterans Health Administration, which has implemented nonpunitive reporting, use of computerized order entry systems, bar coding, team training, and other initiatives.

Patients have also become significantly more involved in their own care in response to the explosion of information available about illnesses, treatments, and patient experiences as well as entreaties by consumer advocacy groups (Ponte et al. 2003). A variety of national and regional organizations, such as NPSF and the AHA, state and regional coalitions, and AHRQ have published safety tips for consumers and have encouraged hospitals to establish full disclosure programs and partner with patients.

A few hospitals have implemented an impressive number of new practices. Luther-Midelfort Hospital in Eau Claire, Wisconsin, for example, has implemented more than twenty new practices and policies, such as nonpunitive error reporting,

leadership training, protocols for managing hazardous drugs such as insulin and anticoagulants, and methods to ensure that prescribed medications match those taken prior to hospitalization (Rozich and Resar 2001; Pronovost et al. 2002; Randolph and Pronovost 2002).

Yet despite fairly widespread activity since the IOM report, actual implementation of changes to prevent accidental injury of hospitalized patients has been incredibly slow. Instead, what we see in most hospitals can be most charitably labeled marginal: the implementation of a few changes in the medication system or the announcement of a new policy for surgical site identification, but often not much more. Most health care institutions have not made safety a priority nor devoted significant resources to preventing errors. Even public tragedies often result in “damage control” and cover-up, rather than reassessment of policies and practices and major changes.

Overall, there is no evidence that the rate of accidental injury is falling. In its first annual report, AHRQ analyzed changes in its patient safety indicators as measured by ICD-9 discharge codes in a random sample of hospitalized patients. There was no significant change from 1994 to 2000 (AHRQ 2003).

Why Has Progress Been So Slow?

Given the magnitude of the problem—a million preventable injuries each year and one hundred thousand preventable deaths—and extensive knowledge about how to reduce them, one might reasonably have expected a huge national effort—a “moon shot” type of governmental commitment. Instead, the only major action for patient safety taken by Congress in four years was to appropriate, starting in 2001, approximately \$50 million annually to AHRQ for research on patient safety. While this order-of-magnitude increase in research support is welcome, it pales in comparison to funding for research in any of the conditions (heart disease, AIDS, arthritis, etc.) addressed by individual National Institutes of Health.

Why hasn't patient safety become a national priority, commanding the resources, leadership, talent, and effort that it seems so obviously to require? One reason for political inertia is that there is not sufficient public pressure to overcome the powerful forces to maintain the status quo. The initial public furor that sparked presidential and congressional responses at the time of the IOM report has subsided, and with it any sense of political urgency. Media accounts of individual outrageous cases of preventable deaths or injuries still appear as before, but, as before, seldom lead to systemic changes.

Loss of public concern is dramatically evident in an opinion poll taken in 2002. Despite widespread dissemination in late 1999 of the IOM's alarming figure of ninety-eight thousand preventable deaths annually, three years later more than 60 percent of the public believed that the number of preventable deaths was five thousand or less. Yet 10 percent also reported a family experience with a preventable death (Blendon et al. 2002). Adjusting for the time span of recall and possible double counting, this yields a national estimate of approximately five hundred thousand preventable deaths annually—five times the shocking IOM estimate!

(Presumably the low estimates of risk came from the other 90 percent of those who were polled.)

A second reason that safety has not become a burning political issue is that its advocates have not succeeded in making the case that specific policy changes will result in significantly safer care. A case in point is reporting of adverse events and errors. Congress has tried unsuccessfully each year since the IOM report to pass legislation protecting from legal discovery information about medical errors and adverse events when they are reported to a central agency (such as AHRQ or JCAHO). However, there is little evidence that enhanced reporting would improve safety, or how it would do so in the absence of intensive (and expensive) investigation of underlying causes. No cost-benefit analysis has been done.

Another example is the lack of federal support and funding for information technology, particularly the standardized electronic medical record (EMR). No one questions the value of an EMR. It would vastly improve communication between all parties, including doctors and patients, and it would greatly facilitate measurement of all aspects of quality. It would permit aggregation of national data to quickly detect complications of a new drug, for example. However, advocates have only recently succeeded, via the IOM, in convincing government officials of the need to address issues related to the standardization of information and formats and the compatibility of existing technology so that commercial EMR systems will be able to communicate with one another.

Third, in the current political climate, there is a great reluctance to expand government's regulatory powers. Given the immensity of the problem of medical errors and accidents, one might think a first step would be to create a federal agency with the power, scope, and funding of the Federal Aviation Agency. Not so. Such a proposal would be strongly opposed by the pharmaceutical and device industries, the AMA, and the hospital industry. In fact, even the relatively small support for AHRQ, a non-regulatory agency which has done a superb job of providing advice to policymakers and funding research, is shaky.

Culture Change Is Needed

Progress would be slow even if safety were a national priority, because making health care safe is much more complicated than launching a moon shot. What is needed is not just new techniques or rules. Nor is the challenge just to adopt an innovation, such as a new hybrid strain of peas, or even one as complex as the automobile or implementing national health insurance. It is to change the medical culture (Weeks and Bagian 2000; Hatlie and Wagner 1999). Culture change of this magnitude is not an innovation; it requires a host of innovations at multiple levels—personal, professional, organizational, and societal.

An oft-cited model for a culture of safety is high reliability organizations (HROs), companies in highly hazardous industries such as commercial aviation, nuclear power, aluminum production, and aircraft carrier operations, that have succeeded in becoming highly safe. The distinguishing characteristic of HROs is their culture of mindfulness, accountability, and commitment to safety (Roberts, Stout,

and Halpern 1994; Grabowski and Roberts 1997). Safety is not just an organizational priority, it is *the* priority, articulated at the highest level and translated into shared values and beliefs throughout the organization. Safety is an explicit goal, supported by a host of policies and practices that are carefully, even compulsively, followed.

HROs value organizational learning. They do not just respond to accidents, but constantly and proactively search for hazards. They have created open cultures characterized by easy and frequent communication both between workers and across organizational levels. Most work occurs in multidisciplinary teams, yet every individual has a sense of personal responsibility to practice safely, to identify hazards, and to take action to reduce them. Because errors are recognized as indicators of systems failures, the response to individuals who make mistakes is nonpunitive. At the same time, misconduct or reckless behavior is not tolerated. There is no ambiguity about who is responsible for implementing safe practices, who monitors compliance, and who is responsible for taking action when performance fails. Safety is not a program; it is a way of life (Weick, Sutcliffe, and Obstfeld 1999).

By contrast, most modern health care organizations are very dysfunctional. They are more inclined to cover up problems than to solve them, to be concerned about reputation over substance, and to adopt a blaming, fix-the-problem-and-don't-let-it-happen-again approach when things go wrong. The peculiar administrative arrangements in hospitals whereby the dominant professionals, physicians, consider themselves independent contractors makes establishing accountability and organizational coherence difficult.

The Hospital Safety Agenda

The safety agenda for hospitals is huge. To begin to approach the high levels of safety seen in HROs, hospitals must implement a broad array of new policies and practices (see table 11.2). These include prohibiting punishment for errors, while still holding personnel accountable for poor performance or misconduct; demonstrating respect for workers through humane hours and work loads; and demonstrating respect for patients by requiring full, honest, and prompt disclosure of errors.

All health care organizations need to give higher priority to implementing known safe practices, such as checking patient identity prior to starting procedures or administering medication, and proper hand disinfection. The NQF list of thirty proven safe practices is a good place to start (see table 11.1). These practices also need to be enforced. For example, a hospital that is serious about safety would revoke the privileges of a physician who refuses to disinfect his hands between patients. All these, and more, are part of a culture of safety.

Barriers to Culture Change

There are many barriers to achieving a safe culture in health care. One of the most challenging is the specialization and isolation of workers, many of whom

TABLE 11.2 *The Hospital Safety Agenda*

Create a nonpunitive learning environment where practitioners feel free to report and talk about their mistakes without fear of punishment while also feeling personally responsible to identify and remedy unsafe conditions that they encounter in their work.

Respond promptly to reports of accidental injuries to patients using a systems approach to find and remedy underlying failures.

Proactively seek out hazards (“accidents waiting to happen”) and correct faulty systems. Create safety by design.

Break down hierarchical barriers and prohibit demeaning behavior in order to develop strong multidisciplinary teams in which the contributions of all members to patient care are valued.

Establish clear lines of accountability for implementing, monitoring, and enforcing compliance with safe practices.

Implement all known safe practices (such as computerized order entry, various medication safety practices, surgical site verification, etc.). These include, at a minimum, those recommended by the National Quality Forum, American Hospital Association, and the Joint Commission on Accreditation of Health Care Organizations.

Implement a full-disclosure policy whereby patients are promptly and compassionately informed of errors in their care and are provided with appropriate support.

Provide humane and reasonable working conditions, including appropriate staffing ratios for nurses, reasonable work loads for physicians, and strictly enforced limits on working hours for both nurses and physicians.

Take responsibility for physicians with behavioral or competency problems by developing programs to promptly identify them and deal with them by providing remediation, retraining, or, if necessary, restriction of practice.

are locked into outdated paradigms of individual performance and expertise and organized in so-called “silos.” Physicians in one specialty, for example, often have little understanding of the practice of those in another, or even when to call on them. Clinic nurses lack expertise to work in the intensive care unit, and vice versa.

Modern health care is also extraordinarily complex. The variety of devices, operations, types of imaging, and expertise required are mind-boggling. Physicians must choose from among more than nine thousand prescription drugs, for example. The diversity of the workforce reflects the myriad specialized skills that are required to make it work.

Another barrier is the lack of meaningful accountability in most institutions. Because no single person is responsible for major systems such as medication, no one has the authority to make needed changes. Most physicians don’t feel that they work for anyone, least of all the hospital administrator. They feel entitled to flaunt rules that they don’t agree with—such as disinfecting hands between patients. Financial incentives in this fragmented system are often antithetical to changing

systems to improve quality. For example, a program that reduces complications in diabetic patients so that fewer require hospitalization reduces the income of both hospitals and physicians.

Ironically, physicians are often a barrier to progress. Although the leaders of the safety movement are mostly physicians, the vast majority of doctors have been remarkably passive—many don't choose to believe there is a serious problem. In a blaming culture, it is shameful to admit that patients are injured by our mistakes (Davidoff 2002; Hilfiker 1984). But, in fairness, it is also true that most physicians don't see mistakes very often in their own practices, however numerous they are in the aggregate. The IOM figure of ninety-eight thousand preventable deaths per year, for example, averages out to only one every six years per physician. Since typically fewer than half of errors are recognized by the person making them, an average physician might perceive himself as responsible for at most one preventable death every ten to twelve years—hardly a cause for alarm in a profession where death is a common occurrence. They don't perceive a need to change.

Doctors also tend to be skeptical about the concept of systems causes of errors. It runs against everything they were taught and have believed: that if you are well prepared and careful, you will not make mistakes. The systems approach smacks of irresponsibility for those who do not understand it (Casarett and Helms 1999). It also implies—correctly—some loss of autonomy as individual preference defers to required safe practice.

Often, hospital chief executive officers also don't perceive a need to change because they receive few reports of errors. In the typical hospital blaming culture, most errors are not reported, and even fewer make their way to the front office. Thus, the CEO really doesn't see a problem. In the absence of pressure from either their physicians or the public, there is little incentive for major change. Pressure from regulators or the JCAHO can be responded to by implementing the prescribed practices rather than revamping systems.

Culture Change from the Bottom Up

Conventional wisdom and historical evidence indicate that a culture change of the magnitude needed in health care requires both a major crisis and strong leadership. But individuals dying from medical errors one by one, however many there may be in a year, are not perceived as a crisis; and, so far, a national leader has not emerged. When customs and practices are strongly entrenched as they are in medicine, change is even harder to accomplish.

Yet the culture is changing. We are witnessing culture change in the absence of national leadership or perceived crisis. It is change from the bottom up: piecemeal, spotty, and slow, but enduring and spreading. It is driven by a relatively small number of individuals who believe passionately in what they are trying to do, a belief that gets reinforced with each success.

The “transforming concept,” that errors are caused not by bad people, but by bad systems, has struck a profound chord in many health professionals, not

just physicians, but also nurses and pharmacists who are at the “sharp end,” making errors that hurt patients. In our blaming culture, many—perhaps most—nurses live in constant fear of making a serious mistake and are burdened with guilt when they do. Systems theory, almost like a new religion, offers a way out, lifting the burden of guilt while offering a path to prevention. Not surprisingly, many nurses embraced it enthusiastically. They are changing the systems, bit by bit, unit by unit—not just implementing new medication practices, but also experimenting with working better in teams, fuller disclosure to patients, adjustment of work loads and hours, and building a variety of other aspects of a safe culture. They are doing it because it is the right thing to do.

The recognition of the intrinsic validity of this transforming concept has also motivated leaders of government and accrediting and professional organizations, as described earlier. While it was the IOM report that galvanized many to action, they have been sustained by a vision of what needs to be done. No grand plan, no national program, no national leadership exists, yet these leaders are moving ahead in hundreds of ways because it is the right thing to do.

Will It Do the Job?

A central policy question is how to facilitate this progress in the absence of a major commitment by the federal government. Clearly, one course is to continue pressing for incremental change. The IOM report, *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*, would be a good place to start (IOM 2002). The report calls for the federal government to support bold regional demonstration projects in five critical areas, two of which, information and communications technology and malpractice liability, are critical to patient safety. These recommendations should be accepted and funded.

But much more than demonstration projects are needed. The government has finally moved on setting standards for computerized patient records and has committed to making a model patient record available in 2004. However, the costs of purchasing and implementing these computer systems are substantial. Without government subsidies, hospitals and practitioners are unlikely to adopt them. Major federal funding, on the order of \$20–40 billion over five years, should be actively sought for the rapid implementation of computerized medical records and order entry systems in every hospital, office, and patient care facility in the nation. Politically, such an appropriation could be achieved if all major health organizations (the AMA, AHA, professional societies, and JCAHO) were to focus on that single goal.

AHRQ’s research initiative on patient safety should be further expanded with a target of doubling expenditures every five years. This effort builds both the knowledge base and the expertise needed for hospitals to improve patient safety. Within AHRQ, the Center for Quality Improvement and Patient Safety’s role as sponsor of safe practice development and validation is crucial to progress and should be fully funded. The agency should also receive adequate funding to meet its mandate to monitor progress in safety by annually collecting and analyzing hospital data on safety indicators.

The Food and Drug Administration (FDA) must also play a more active role in reducing medication errors. Insufficient attention to packaging, labeling, naming, and standardizing medications has made it too easy for patients to make mistakes when taking prescription drugs. Errors could be reduced if the FDA required manufacturers to provide all drugs in unit of use and to modify labels so that the names of drugs are clearly displayed in large print.

Policymakers, politicians, and all who are concerned about safe health care should support the continuing efforts of health-related organizations to advance safe practices and policies. ACGME and ABMS need to complete their project to define performance standards and indicators and promote implementation of these measures within hospitals to monitor and improve physician performance. The moment of truth is at hand for ACGME: Will it enforce restrictions on residents' hours that went into effect in July 2003? If so, it can move onto other tough issues, including methods and standards for training residents to respond to adverse events, carry out systems analysis, and respond to patients with honesty and sensitivity.

Specialty societies, such as the American College of Physicians and the American College of Surgeons, should be encouraged to expand their efforts in safety at all levels by:

- Scheduling presentations and courses in such safety issues as systems analysis, teamwork, leadership, and disclosure at their annual and regional meetings;
- Showcasing safety studies at research forums;
- Featuring safety topics in their journals; and
- Establishing expert panels to identify, validate, and disseminate safe practices unique to each specialty.

All payers should adopt the model advanced by the Leapfrog Group, and the model should be broadened each year to include additional safe practices. Payers, in turn, should expand the use of indicators, such as those pioneered by the National Committee for Quality Assurance and NQF, and publish annual report cards of each hospital's compliance with safe practices and policies, as determined by independent audits. Health plans should play the primary role in the dissemination of tools and instruction for implementation of safe policies and practices.

Of all organizations, the JCAHO has the most potential to motivate hospitals to change their cultures and make safety a true priority. With the recent shift to unannounced inspections, the commission has the opportunity to demonstrate to hospitals and to the public that it is serious about safety. It must do so. It would not be unreasonable for the JCAHO to expect every hospital to implement all of the NQF safe practices within two or three years, and to begin to levy sanctions against those that are laggards. It is also time for the JCAHO to issue meaningful public reports of all hospital evaluations. Safety is too important to be kept a secret.

How much more consumers can do is unclear. While patient advocacy groups have had an impact on safety organizations such as NPSF and the Institute for Healthcare Improvement (an organization in Boston that is working with

stakeholders on quality improvement initiatives), their impact on public policy and funding is less apparent. Certainly, keeping public pressure on for safer health care is important, however.

Medical Errors are Symptoms of a Dysfunctional Health System

Although pressure from all stakeholders will continue the push to adopt safer practices, if we are to achieve the culture change necessary to raise safety to a level comparable to that in high reliability industries, it will be necessary to address fundamental deficiencies in the organization and delivery of health care to Americans. As the IOM report pointed out, the challenges of patient safety are but one aspect of the much larger problems of access, financing, and coordination of care that confront the American health care system (IOM 2001). The IOM called for a complete overhaul of the health care system.

The Physicians' Working Group for Single-Payer National Health Insurance provided additional pressure by proposing a universal health care system, supported by taxes that would effectively expand Medicare to all Americans (Woolhandler et al. 2003). An essential feature of their proposal is that basic health care should be non-commercial and not-for-profit. While that seems unlikely to happen, some realignment of financial incentives will be necessary to achieve safe health care. Payment systems must be devised that reward, not punish, safe practices. For example, serious errors in the management of patients taking anticoagulants (blood-thinning drugs) such as warfarin are much less common when the process is managed by a nurse-run clinic. Yet some payers will not provide reimbursement unless the service is provided by a physician.

Finally, to create a culture of safety we must deal with the problems posed by the tort system. More than any factor, the threat of malpractice suits inhibits physician participation in safety programs and poisons their relationships with patients. To solve this problem, we must address the issues that the tort system is supposed to address: compensation and negligence. No-fault compensation offers a promising alternative for compensating injured patients and has been implemented in Sweden and New Zealand. The IOM recently called for federal funding of state demonstration projects to test the feasibility of that approach here in the United States (IOM 2002).

However, it seems unlikely that state legislatures will adopt no-fault compensation plans without substantial improvement in the methods for dealing with the other objective of tort law—detering negligence. Prevention of negligent acts must occur within the hospital or physician practice, for that is where the precursors of negligence— incompetence, disruptive behavior, substance abuse, and mental and physical illness—first manifest themselves. Hospitals need to develop more effective programs for doctors with problems, to identify unsafe behavior before it results in patient injury, and to retrain and rehabilitate as many physicians as possible. To do this, they need support and direction from state licensing boards, health departments, and the JCAHO.

Making the changes necessary for safe health care requires a major change

in our thinking: not just about what we do, but about what we are. Achieving safe health care requires much more than changing some practices, developing some new systems, and putting some new rules in place. It requires that all health professionals fundamentally reassess their concepts of professional autonomy (Can physicians learn to share authority in teams?), responsibility (for *all* patients and systems, not just our individual work), and how to improve, how to move from perfecting individuals to perfecting systems.

No other industry has succeeded in achieving a high level of safety without heavy regulation. But health care is very different from other industries: medical professionals have a strong sense of duty and responsibility to patients. It is possible that voluntary effort at the front line and pressure from many stakeholders will be sufficient to change hospital cultures. We should all hope so.

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Improving Quality through Nursing



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Both the public and physicians rank nurse understaffing of hospitals as one of the most serious threats to patient safety (Blendon et al. 2002). Two-thirds of hospital bedside nurses concur that there are not enough nurses in their hospitals to provide high-quality care, and close to half score in the high-burnout range on standardized tests. Almost one in four intends to leave his or her job in the hospital within a year (Aiken et al. 2001). Federal estimates suggest that the shortfall of nurses could approach 275,000 by 2010 and 800,000 by 2020 (U.S. DHHS 2002). Until very recently, policymakers and health care leaders have not associated hospital nurse understaffing and burnout with medical errors and adverse patient outcomes, as evidenced by the few references to nursing in the Institute of Medicine's first two major quality reports (Institute of Medicine 2000, 2001). This chapter explicates the link between nursing and quality and discusses the implications for the nation's quality improvement agenda.

The Role of Nurses in Promoting Quality of Care

Nursing is the care of the sick (and those who may become sick) and the maintenance of the environment in which care occurs (Diers 2004). Nurses are responsible for fulfilling those aspects of the medical regimen delegated to them by physicians, such as administering medication, but they are legally and professionally responsible for their own actions when fulfilling delegated tasks. In the case of administering medications, nurses are responsible for ascertaining that the dose is correct for the age of the patient and that the route of administration is proper. Nurses have a professional and legal scope of practice that is complementary to that of physicians and includes assessing and intervening within their areas of expertise, such as skin and wound care, managing pain and providing comfort, and teaching patients and their families how to manage their care after hospital discharge, among myriad other responsibilities. Nurses are also responsible for maintaining a safe and patient-centered care environment. Thus, nurses routinely step in when non-nursing support services are not available or are inadequate to maintain a clean environment. They ensure that patients receive adequate nourishment, enforce infection control practices, and prevent hazards such as

improper disposal of needles and sharps that could transmit blood-borne pathogens to unsuspecting staff and visitors.

Two of nurses' most important functions associated with patient safety, quality of care, and patient outcomes are providing surveillance for early detection of adverse events, complications, and medical errors and mobilizing institutional resources for timely intervention and rescue. A number of factors influence the effectiveness of nurse surveillance, including patient-to-registered-nurse ratios, the education of registered nurses at the bedside, and the numbers of licensed practical nurses and aides relative to registered nurses (often referred to as the skill mix of nursing personnel). Once a nurse detects potentially hazardous clinical signs, the work environment and institutional culture can promote or impede timely and successful resolution of the problem.

Nurses' relationships with physicians are particularly important in ensuring that patients receive the help they need. Since U.S. physicians typically combine office-based medical practice with caring for hospitalized patients, nurses are often physicians' eyes and ears at the hospital bedside. This arrangement works best in organizations that employ enough well-qualified staff, where nurses and physicians have a high degree of mutual respect and trust, and where top administrators facilitate patient-centered services throughout the institution (Aiken, Clarke, and Sloane 2002). Increasingly, nurses, particularly nurse practitioners, have assumed the same important roles in primary care and ambulatory settings.

Patients have high regard for nurses. For many years Gallop polls have reported that nurses top the list of occupations that the public most trusts and respects; indeed, nurses rank considerably higher than physicians, pharmacists, health care executives, and all others who work in health care. Nurses interact with the public in a variety of roles across the life span from birth to death, providing support in labor, consultations on breastfeeding and infant care, well-child care in medical offices and schools, occupational health in the workplace, care for the chronically ill and elderly, and care for the dying and support for their families. Patients and families often seek out nurses to translate information imparted by physicians, perhaps because there is less social distance between nurses and their patients than between doctors and patients. Nurses have been the key advocates for some of the innovations that have made modern health care more humane and patient-centered, such as demedicalizing normal births, liberalizing visiting hours and family participation in hospital care, and providing alternatives to invasive medical interventions at the end of life, such as hospice care. The high regard in which the public holds nurses is a source of personal gratification for them and the basis, along with their close interface with physicians, for their influence and authority in health care.

The Adequacy of Nurse Staffing

The adequacy of nurse staffing in hospitals and other health care settings is a matter of considerable debate, largely because of concerns about costs. Registered nurses constitute the largest group of health professionals in hospitals and

account for a significant share of their operating expenses. Using a conservative total compensation estimate of \$60,000 a year for a registered nurse, hospitals that add 50 nurses a year would have to pay out a total of \$3 million. At present the nation's hospitals employ some 1.2 million nurses. It is generally easier for hospitals to base nurse staffing levels on budgetary resources than to use objective case-mix standards which would require additional financial resources.

An underappreciated aspect of the debate over the adequacy of nurse staffing concerns the impact of understaffing on annual nurse turnover rates, which are estimated to average about 13 percent nationally and over 20 percent at some hospitals. Aiken and associates examined the hypothesis that a minimum level of staffing is required to retain nurses and minimize turnover (Aiken et al. 2002). They found that each patient added to the workload of a hospital bedside nurse was associated with a 23 percent increase in burnout and a 15 percent rise in job dissatisfaction—both precursors to voluntary job resignation. Forty percent of nurses who were dissatisfied and burnt out intended to leave their jobs, compared with only 10 percent who were satisfied and not burnt out.

Assessing Nurse Staffing Adequacy

Two different perspectives dominate perceptions of hospital nurse shortages. One focuses on vacant budgeted positions and the influence of vacancies on costs and revenues. The other—often held by clinical nurses and physicians—evaluates the extent to which existing staff can provide needed services, taking into account the illness burden and intensity of care their patients require. Measuring shortages by vacancy rates has led to the widely held belief that nurse shortages are cyclical and self-correcting in response to changing market conditions (Aiken and Mullinix 1987; Buerhaus et al. 2002). The expectation that nurse shortages will not last long has tempered efforts to address nurses' dissatisfaction and claims that inadequate investment in nursing is undermining quality of care. However, the factors associated with predictions of greater national need for nurses are not cyclical. They include population aging, prevalence of chronic illness, rising per capita use of health services, and greater use of nurse-intensive technologies. These factors have prompted federal workforce planners to forecast a growing gap between nurse supply and demand (U.S. DHHS 2002).

Hospitals have experienced substantial increases in the intensity of services and case-mix complexity and shorter lengths of stay since the advent of prospective payment in 1980. This new payment system reimbursed hospitals based on patient diagnosis rather than length of stay. Since hospitals received the same amount regardless of whether patients with hip replacements remained in the hospital for three days or two weeks, prospective payment drove many hospitals to shorten patient stays. As large numbers of patients were discharged before they fully recuperated from surgery or illnesses, the condition of patients remaining in hospitals became more serious, requiring more intensive services and care.

Before the 1980s, hospitals commonly admitted preoperative patients several days before surgery for tests and evaluation. Nurses used that preoperative time to develop a trusting relationship, prepare patients and their families for what

to expect following surgery, and assess the patient's usual physical and mental state, to be able to evaluate abnormalities and detect complications postoperatively. Today few patients are admitted to the hospital before the day of their scheduled surgery, and nurses see most patients for the first time when they are leaving the recovery room still groggy from anesthesia. They do not know the extent to which a patient can see, hear, or communicate under normal circumstances, or the patient's normal color, breathing patterns, and blood pressure. Patients may have more than one surgical site, multiple monitors, an artificial respirator, and an intravenous line administering powerful drugs that can result in death if the infusion rate is not correct. On average, nurses care for five to six postoperative patients at a time. Every day about a third of nurses' patients arrive directly from the operating room or have been admitted in an acute medical crisis; a third are in the early stages of recovery or stabilization, with many requirements for nursing time; and a third are being discharged, often with complicated home care requirements.

Hospitals have not added enough new registered nurse positions to offset the substantial rise in case-mix complexity. Between 1981 and 1993, the total percentage change in full-time-equivalent nursing personnel—adjusted for patient days and case-mix complexity—declined by more than 7 percent nationally and by over 20 percent in some states, including Massachusetts, New York, and California (Aiken, Sochalski, and Anderson 1996). Pennsylvania hospitals experienced a 21 percent increase in patient acuity between 1991 and 1996, and no change in the number of employed licensed nurses (RNs and LPNs). The result was a 14 percent decrease in the ratio of licensed nurses to case-mix-adjusted patient days of care (Unruh 2002).

Because increases in case-mix complexity and faster admission/discharge cycles have placed a burden on nurses that hospitals have not adequately recognized, about 85 percent of nurses work longer on a daily basis than their scheduled hours. Recent research has documented a substantial increase in the rate of errors associated with nurses working more than twelve consecutive hours, and close to half of hospital staff nurses commonly work longer than twelve hours (Rogers 2004). Presently no policies govern safe working hours for nurses, in contrast to other occupations in which vigilance is a matter of life and death. Lack of understanding by institutional managers and public policymakers of how shortened stays and greater case-mix complexity have adversely affected the work of nurses and the safety of patients—and failure to add enough nurse positions to ensure high-quality care—lie at the heart of the nurse shortage and perceptions that hospitals are unsafe.

Nurse Staffing and Patient Outcomes

Many research studies have now linked nurse staffing and patient outcomes. One of the first such contemporary studies was the national halothane study, which documented a twelve-fold variation in surgical mortality from this form of anesthesia across the nation. The study found nurse staffing among the significant determinants of mortality (Moses and Mosteller 1968). Public availability of Medicare data for U.S. hospitals also generated a series of studies on the factors underlying

variations in mortality; these studies focused primarily on non-nursing correlates such as for-profit versus nonprofit hospital ownership (Shortell and Hughes 1988; Hartz, Krakauer, and Kuhn 1989; Silber et al. 2000). Each study reported in passing that nurse staffing was significantly related to mortality, but no one took much notice of these collective findings until nurse investigators began designing studies to examine the effects of nurse staffing on patient outcomes.

In 1996 the Institute of Medicine published the results of its study on the adequacy of hospital nurse staffing, acknowledging the evidence from health services research suggesting a link between nurse staffing and patient outcomes, but concluding that insufficient evidence existed for recommending safe staffing levels (Institute of Medicine 1996). The IOM's call for funding more research spawned new studies reinforcing the link between nurse staffing and patient outcomes.

In a study of outcomes following common surgical procedures for over 230,000 patients in 168 hospitals, Aiken and colleagues documented a strong association between staff nurse workloads and surgical mortality and failure to rescue patients who had developed complications (Aiken et al. 2002). Hospital staffing ranged from about 4 to 8 patients per nurse; 50 percent of hospitals had a patient-to-nurse ratio of 5 to 1 or lower. After adjusting for over 130 patient and hospital factors, the results suggested that each additional patient in a nurse's workload raised the odds of mortality by 7 percent. Thus the risk of death and failure to rescue patients with complications was nearly 30 percent higher in hospitals where nurses' average workload was 8 patients than in hospitals where nurses cared for 4 patients. The effect was linear, so reducing nurses' workloads from 8 to 7 patients produced the same 7 percent decline in mortality risk as cutting the workload from 5 patients to 4. (The sample included too few hospitals to reliably estimate the effect beyond 8 patients per nurse.)

There is a growing literature of well-designed studies demonstrating a variety of better patient outcomes associated with more favorable staffing of registered nurses (Kovner and Gergen 1998; Blegen, Goode, and Reed 1998; Cho et al. 2003). For example, Needleman and associates documented a significant relationship between nurse staffing and urinary tract infections, pneumonia, shock, hemorrhage in the upper gastrointestinal tract, and length of stay in medical patients, as well as failure to rescue in surgical patients (2002). Person and associates showed that the odds of dying from first-time acute myocardial infarction were significantly lower in hospitals with more favorable nurse-to-patient ratios (2004). Studies have also linked better nurse staffing to lower rates of medication errors and reduced needle-stick injuries to nurses (Blegen, Goode, and Reed 1998; Clarke, Sloane, and Aiken 2002).

Nursing Skill Mix and Patient Outcomes

Nursing skill mix varies substantially, with some hospitals employing predominantly registered nurses (RNs) and others a mix of RNs, licensed practical nurses (LPNs), and aides. The organization of nurses' work and the deployment of non-RNs have changed over time. In the 1960s division of labor within hospital

nursing commonly occurred in a team structure, where RNs provided assessments, medications, and treatments to all patients while directing LPNs and aides who attended to personal hygiene, ambulation, and other routine patient care. As the number of registered nurses employed by hospitals grew, RNs saw the value of maintaining a closer relationship with patients than team nursing allowed and the opportunity to shed the unwanted responsibility for supervising LPNs and aides. Nurses advocated returning the care of all patients to RNs under a model referred to as primary nursing, and hospital managers supported the transition from team to primary nursing. The result was a substantial decline in the employment of LPNs in hospitals nationally and a skill mix in which RNs represented the majority of nursing personnel.

During the hospital restructuring movement to contain costs in the 1990s, many hospitals once again substituted LPNs and aides for RNs (Brannon 1996; Norrish and Rundall 2001). However, research findings consistently support the conclusion that the most important factor in improving patient outcomes is the number of registered nurses. Aiken and associates found no relationship between patient-to-LPN ratios or patient-to-aide ratios and variation in mortality, but they did find a substantial effect of patient-to-RN ratios on surgical mortality and failure to rescue (Aiken et al. 2002). Jarman and associates found the higher the proportion of the least-trained auxiliary nursing personnel in English hospitals, the higher the mortality (1999). The weight of evidence suggests that lesser-trained nursing personnel are not substitutes for RNs in ensuring quality of care and patient safety.

Nurses' Education and Patient Outcomes

Registered nurses in the United States receive their basic education in one of three types of programs, all of which qualify graduates to take the registered nurse licensing examination. These programs include three-year hospital-sponsored diploma programs, two-year associate degree programs in community colleges, and four-year baccalaureate nursing programs in colleges and universities. Freidson described nursing as an incompletely closed profession because of its inability to establish minimum education requirements for entry (1970).

In 2001 hospital diploma programs—which had educated almost all nurses in the 1960s—graduated just 3 percent of new nurses. Associate degree programs replaced diploma programs, accounting for over 60 percent of new entrants to nursing in 2001, while about 36 percent of new nurses were baccalaureate graduates (National Council of State Boards of Nursing 2001). Close to 45 percent of nurses nationally had a baccalaureate or higher degree in 2000, and almost one in four obtained the degree following basic education in a diploma or associate degree program (Spratley et al. 2001). Many other countries, including Canada, Australia, New Zealand, Ireland, Iceland, and Cuba, have eliminated multiple educational pathways into nursing by establishing the baccalaureate as the entry-level degree for new nurses. The United Kingdom has moved nursing education within higher education but has not yet completed the full transition to a baccalaureate degree.

Research is surprisingly scanty on variations in nurses' education across institutions and health care settings and on the impact of nurses' educational levels on clinical practice and patient outcomes. A few studies have suggested that baccalaureate-prepared nurses are more likely to demonstrate professional behaviors important to patient safety, such as problem solving, performance of complex functions, and effective interdisciplinary communication (Hickam et al. 2003; Blegen, Vaughn, and Goode 2001). Nurse executives in teaching hospitals prefer baccalaureate-prepared nurses and aim to have at least 70 percent of their staff nurses trained at the baccalaureate level, while community hospital nurse executives reportedly prefer that 50 percent of nurses have BSNs (Goode et al. 2001). With only about 43 percent of hospital staff nurses holding a baccalaureate degree, not enough are available to meet these targets.

Aiken and colleagues observed that the proportion of hospital staff nurses holding a baccalaureate degree ranged from none to 77 percent across Pennsylvania hospitals, and they designed a study to find out if variation of that magnitude was associated with differences in patient outcomes (2003). The answer was yes. The researchers found that hospitals with a larger proportion of baccalaureate-prepared nurses had significantly lower surgical mortality rates, after adjusting for patient and hospital characteristics (such as size, teaching status, and technology) as well as patient-to-nurse staffing ratios, nurse experience, and whether the patient's surgeon was board certified. Every 10 percent increase in the proportion of nurses holding a baccalaureate degree was associated with a 5 percent decrease in both the likelihood that patients would die within thirty days of admission and the odds of failure to rescue patients with complications.

Moreover, the effects of nurse staffing and education were found to be additive. The best outcomes occurred in hospitals where nurses took care of four or fewer patients each and 60 percent of staff nurses were educated at the baccalaureate level or higher. The worst outcomes occurred in hospitals where nurses cared for eight or more patients each and only 20 percent had baccalaureate degrees. The effect on mortality of a 20 percent rise in the percentage of baccalaureate-prepared nurses was roughly equivalent to adding enough nurses to reduce the mean workload by two patients. Thus, hospitals might be able to stem the growing need for more nurses per one hundred inpatient days by moving to a more highly educated RN workforce.

Nursing faces special challenges in raising educational requirements commensurate with trends in other health professions because of modern hospitals' dependence on large numbers of nurses. Hospital employers seem to prefer training nurses quickly and inexpensively and inculcating interchangeable skills and modest career expectations. However, this scenario clashes with the aspirations of many people attracted to nursing with hopes of upward mobility and opportunities for personally gratifying careers and reasonably remunerated work. The number of applicants to nursing schools who already have college degrees is growing rapidly, and universities have responded with programs as short as one year for college graduates who wish to earn a BSN.

Nurse Practice Environments

Flood and Scott describe hospitals as having dual bureaucratic and professional structures that represent opposing approaches to managing complex tasks (1987). Conventional bureaucracies subdivide work among many participants and control their activities through externally imposed rules and hierarchies. Organizations with professional structures support the efforts of self-regulating individuals who exercise considerable discretion in carrying out their work (Freidson 1970). Hospital nurses are agents of a bureaucracy but hold professional values and seek peer relationships and professional modes of organizing their work. Etzioni described professional-bureaucratic conflict as a major concern for complex health care organizations such as hospitals, suggesting that “the authority of knowledge and the authority of administrative hierarchy are basically incompatible” (1969, viii). Indeed, research on hospital nurse burnout is consistent with this view, showing that organizational conflict far outweighs the psychological and physical stress associated with caring for ill and dying patients (Aiken and Sloane 1997).

Studies have devoted relatively little attention to the impact of organizational context and culture on patient outcomes, focusing instead on the effects of staffing. One of the first studies of nursing to integrate a sociological perspective with outcomes such as mortality examined the performance of magnet hospitals (Aiken, Smith, and Lake 1994). Such hospitals were originally designated in the early 1980s based on their success in attracting and retaining nurses when other local hospitals were experiencing nurse shortages (McClure and Hinshaw 2002). Compared with other institutions, magnet hospitals had higher nurse satisfaction, and their nurses reported more autonomy, greater control over resources required for high-quality care, and better relations with physicians.

As a first step in exploring the effects of organizational features common to magnet hospitals, Aiken and colleagues matched the 39 original magnet hospitals with 195 control hospitals selected from all non-magnet U.S. hospitals. Using a multivariate matched sampling procedure—propensity scoring—that controlled for twelve hospital characteristics including size, teaching status, technology, and proportion of board-certified physicians, the investigators found that magnet hospitals had a 4.5 percent lower Medicare mortality rate than matched hospitals (Aiken, Smith, and Lake 1994). Nurse staffing alone did not explain this outcome: organizational cultures that devolved greater autonomy and control to nurses and promoted good relations between nurses and physicians were also associated with better patient outcomes.

Aiken and colleagues further explored the relationship between nurse practice environments and patient and nurse outcomes in a subsequent study making use of a natural experiment in the organization of care associated with the AIDS epidemic. A multiple-site study was designed that included forty units in twenty hospitals. Ten of these hospitals had dedicated AIDS units and were matched with comparable hospitals without such units. The study included two magnet hospitals without AIDS units for comparison. The investigators found that risk-adjusted AIDS mortality within thirty days of admission was substantially lower and patient satisfaction was significantly higher in dedicated AIDS units and magnet hos-

pitals than in conventionally organized general medical units (Aiken et al. 1999). More favorable nurse staffing and practice environments were among the important explanations for these better patient and nurse outcomes.

Aiken and colleagues have since studied nurse practice environments in a large representative group of hospitals to determine the extent to which features are associated with nurse retention and patient outcomes. That study—which included over seven hundred hospitals in five countries—found that nurses in hospitals in the United States, Canada, the United Kingdom, Germany, and New Zealand face common challenges regarding nurse understaffing and high levels of burnout and job dissatisfaction. Nurses in all these countries also associate deficiencies in quality of care with inadequate staffing and poor nurse work environments (Aiken et al. 2001; Aiken, Clarke, and Sloane 2002). Germany is the only country with substantially lower nurse burnout, which may reflect its significantly longer average length of stay.

Remarkably, given the many differences in culture and nurses' education across countries, at least some hospitals in every country have organizational features similar to those of U.S. magnet hospitals. Nurse and patient outcomes are better in magnet-like hospitals, which devolve greater autonomy and control to nurses and provide a more supportive environment for professional practice. For example, the frequency of patient falls with injuries, medication errors, and hospital-acquired infections is lower in hospitals across the five countries where nurse staffing is more favorable, the administration supports high-quality nursing, nurses have career development opportunities, and physicians and nurses have good relations.

Nursing and Quality Improvement

There is one area of potential discordance between the research evidence documenting better outcomes when hospitals devolve more authority to nurses and ongoing efforts to protect patients from medical errors. Much of the evolving thinking about how to reduce medical errors suggests developing systems that standardize medical decision-making and minimize professional discretion. Do the aims of patient safety systems conflict with evidence that organizations that devolve more authority and autonomy to nurses have better outcomes?

Nurses have long been responsible for many of the safeguards in hospital care, such as counting sponges and instruments in the operating room to ensure that they are not left inside patients, storing dangerous drugs in locked cabinets, having two nurses check the compatibility of blood before transfusion, and notifying physicians when a medication order seems out of the ordinary before administering it. Nurses have been the *de facto* safety system in hospitals for over a hundred years. Indeed, recent studies confirm that nurses find most of the medication errors that are detected in hospitals. However, nurses understand the vulnerabilities of the people-dependent safety provisions on which hospitals rely. Indeed, a common fear of nurses—and one that contributes to their high levels of burnout—is that with their increasingly heavy workloads they will fail to detect

an error committed by someone else or commit an error themselves that will hurt a patient. Hence, more effective safety systems that minimize the opportunity for human error would improve the work environment and mental health for nurses more than for any other hospital workers.

However, minimizing errors is only one strategy for improving quality of care in hospitals. Good nurse-patient relationships are at the heart of safe and effective hospital care. A myriad of situations still require expert clinical judgment, including recognizing early signs that a patient may not be doing well and mobilizing a timely institutional response, and determining when and under what circumstances a patient can be safely discharged. Moreover, in addition to caring for patients, nurses are responsible for maintaining the environment in which care takes place, which requires authority as well as status within an organization. Nurses must have some control over the resources required for meeting patients' needs, such as safe nurse staffing levels, timely responses from physicians, accessible supplies and equipment, and support departments, such as housekeeping, pharmacy, central supply, and blood bank, that run efficiently and effectively around the clock.

The international hospital outcomes study aimed to show that nurse autonomy was consistent with—rather than antithetical to—effective interdisciplinary team functioning. Researchers documented that hospitals in which nurses had greater autonomy and more control over resources were more, not less, likely to have well-developed and effective interdisciplinary teams (Rafferty, Ball, and Aiken 2001). Research by Aiken and associates suggests that hospitals that promote the full exercise of the professional nurse role and devolve authority to nurses in their areas of expertise also create effective interdisciplinary care cultures, patient-centered environments, and better patient outcomes. Such institutions will probably be at the forefront of establishing new and better systems to reduce human error because their professional culture values clinical excellence informed by evidence-based practice.

Both new systems that reduce human error and an organizational context that enables the best performance from each health professional are essential in ensuring safe and effective care for hospitalized patients. The IOM reports on quality, which initially gave little attention to nursing, have now focused explicitly on the need to transform the nurse work environment to keep patients safe. This suggests a merging of two previously separate areas of concern—nurse shortages and patient safety—into a more unified approach to quality that is likely to yield important new initiatives to ameliorate both problems.

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Improving Medicare for Beneficiaries with Disabilities



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A few lines caught my eye near the end of a lengthy *New York Times* article on June 11, 2003. The article recounted the growing likelihood that Congress would add prescription drug benefits to Medicare and itemized the trade-offs required to trim projected expenses (Pear 2003a, A21). After describing various components of proposed Senate legislation, the article concluded, “To help offset the costs, Medicare would freeze payments for home medical equipment, like wheelchairs and oxygen, for seven years.”

Of course, the legislation signed by George W. Bush in December 2003 bore little resemblance to this June proposal. In particular, Congress did not overturn Medicare’s central tenet: coverage of only those services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (42 C.F.R. Sec. 402.3), services that fit snugly within the standard medical armamentarium. Although policymakers have strayed occasionally, such as adding coverage for selected screening tests and palliative care, Medicare’s guiding mandate remains inviolate.

Given this context, the acceptability of freezing Medicare payments for wheelchairs and home-based oxygen comes as little surprise—although limiting oxygen payments carries a mischievous symbolism (certainly, oxygen should meet Medicare’s reasonable and necessary standard). This proposal exemplifies a more basic and vexing reality that extends well beyond Medicare: The American health care system fails to meet the daily health and function-related needs of many people with chronic, disabling medical conditions. Although technologies and therapies exist to maintain, restore, or maximize function, they often fall outside health insurance coverage boundaries. Such gaps in coverage prevent people from obtaining services and equipment that are costly to purchase out-of-pocket, needlessly compromising lives.

This observation draws upon long historical roots. Achieving passage of the Medicare program required years of political maneuvering, compromises, and reduced expectations. The Medicare program did cover more non-acute care, including limited stays in skilled nursing homes and home-based rehabilitation, than any

other governmental, nonprofit, or commercial insurer at the time (Fox 1993). Nonetheless, in the end, “Left out were provisions that addressed the particular problems of the chronically sick elderly: medical conditions that would not dramatically improve and the need to maintain independent function rather than triumph over discrete illness and injury” (Marmor 2000, 153). Forty years later, little has changed.

Although these problems wend throughout the health care delivery system, I concentrate on Medicare policies for several reasons. Medicare is huge. In 2002, Medicare insured roughly 40.6 million persons, including 6.0 million individuals under age 65 with disabilities (Centers for Medicare and Medicaid Services [CMS] 2003b). Of an estimated \$236.5 billion expenditures in 2001, Medicare spent \$31.9 billion on beneficiaries with disabilities (CMS 2002). Furthermore, unlike Medicaid programs and private health plans, Medicare’s rules extend nationwide, although specific implementation decisions can vary across regions. Over the years, Medicare policies have frequently infiltrated the rest of the health care system. Therefore, Medicare offers an excellent starting point to examine health care policies for persons with disabilities.

Demographic Trends Breed Urgency

Countless persons with disabilities daily slip through the fault lines crisscrossing the health care delivery system. Why is this issue so pressing now? Numbers offer a clear answer.

Almost one-fifth of U.S. residents—19.3 percent of people age 5 years and older, or 49.7 million—report disabilities (U.S. Census Bureau 2003b). As table

TABLE 13.1 *Estimates of Disability from the 2000 U.S. Census*
(population in millions)

Disability ^a	Age 16 to 64 years					Age 65 years and older						
	Total	(%)	Males	(%)	Females	(%)	Total	(%)	Males	(%)	Females	(%)
Population	178.9	(100.0)	87.6	(100.0)	91.1	(100.0)	33.3	(100.0)	13.9	(100.0)	19.4	(100.0)
With any disability	33.1	(18.6)	17.1	(19.6)	16.0	(17.6)	14.0	(41.9)	5.6	(40.4)	8.3	(43.0)
Sensory	4.1	(2.3)	2.4	(2.7)	1.7	(1.9)	4.7	(14.2)	2.2	(15.6)	2.6	(13.2)
Physical	11.2	(6.2)	5.3	(6.0)	5.9	(6.4)	9.5	(28.6)	3.6	(25.8)	6.0	(30.7)
Mental	6.8	(3.8)	3.4	(3.9)	3.3	(3.7)	3.6	(10.8)	1.4	(9.9)	2.2	(11.4)
Self-care	3.1	(1.8)	1.5	(1.7)	1.7	(1.9)	3.2	(9.5)	1.0	(7.5)	2.1	(11.0)
Ability to leave the home	11.4	(6.4)	5.7	(6.4)	5.8	(6.4)	6.8	(20.4)	2.3	(16.8)	4.5	(23.0)
Employment	21.3	(11.9)	11.4	(13.0)	9.9	(10.9)	—	—	—	—	—	—

Source: adapted from the U.S. Census Bureau 2003b.

^aItems 16 and 17 on the 2000 long-form census questionnaire addressed disability. The questions and the definition of disability are described elsewhere (U.S. Census Bureau 2003a).

13.1 shows, persons age 65 and older report any disability at higher rates than younger people—41.9 percent compared with 18.6. At younger ages, males generally have higher rates of disability than females, while the reverse occurs over age 64 years. Physical disabilities are more common than sensory or mental health disabilities. Racial and ethnic minority populations have higher disability rates than do whites (see table 13.2).

Even more compelling numbers come from looking ahead. By 2030, the number of people age 65 years and older will rise to 69.4 million (20 percent of the population) from 34.7 million (12.6 percent) in 2000 (Day 1996). Persons age 85 years and older will become the most rapidly growing segment of the population, rising from 4.3 million (1.6 percent) in 2000 to 18.2 million (4.6 percent) in 2050.

This growth reflects lengthening life expectancies, even in recent decades. The average male born in the United States in 1970 could anticipate living to roughly 67 years of age compared with over 74 years for those born 30 years later (Arias 2002). Life expectancy for females rose from 75 years in 1970 to almost 80 years in 2000. Declining death rates from heart disease substantially prolonged longevity, expanding the numbers living with chronic, nonfatal, but disabling conditions. Persons with significant physical disabilities are also living longer, largely because of fundamental medical breakthroughs like advances in antibiotics. According to the National Spinal Cord Injury Statistical Center (2001), persons who become paraplegic at age 40 and survive 1 year following injury can expect to live another 29 years, compared with 38 years for persons without spinal cord injury.

Aging does not invariably produce disability, at least not until near death. Centenarians often remain reasonably healthy until shortly before dying. Recent reports suggest that rates of serious functional deficits are declining among older

TABLE 13.2 *Disability by Race and Ethnicity Groups, 2000 U.S. Census*

Racial/ethnic groups ^a	Age	
	16 to 64 years (%)	65+ years (%)
Total	18.6	41.9
White alone	16.8	40.6
Black or African American alone	26.4	52.8
Asian alone	16.9	40.8
American Indian or Alaskan Native alone	27.0	57.6
Native Hawaiian, other Pacific Islander alone	21.0	48.5
Some other race alone	23.5	50.4
Two or more races	25.1	51.8
Hispanic or Latino (of any race)	24.0	48.5

Source: adapted from the U.S. Census Bureau 2003c.

^aFor the first time, during the 2000 census respondents could indicate membership in more than one race or ethnicity group.

individuals, although evidence about the most severe disabilities is contradictory (Freedman, Martin, and Schoeni 2002). Multiple factors likely underlie improvements in functional abilities among older persons, including new medical therapies and healthier lifestyle. Nevertheless, “disability is not something that happens only to a minority of humanity, it is a common (indeed natural) feature of the human condition. . . . Over the lifespan, [disability is] a universal phenomena” (Üstün et al. 2003, 82).

With the aging population, the absolute number of Americans with functional limitations will rise by over 300 percent by 2049 if the age-specific prevalence of major chronic conditions remains unchanged (Boult et al. 1996). Arthritis, the leading cause of disability among adults, affected 70 million adults in 2001, including 60 percent of people age 65 and older (Centers for Disease Control and Prevention 2003). If current rates remain unchanged, the number of persons over age 65 with arthritis will double by 2030, causing more physical impairments than ischemic heart disease, cancer, and dementia combined. Obesity among adult Americans is also rising, growing from 12 percent in 1991 to 20.9 percent—or 44.3 million persons—in 2001 (Mokdad et al. 2003). Apart from causing disability itself, obesity contributes to other debilitating conditions, including diabetes, arthritis, high blood pressure, and asthma. Many more persons will therefore have multiple coexisting, chronic, disabling conditions in coming years.

Medicare covers more than just people age 65 and older. Rising numbers of disabled workers receive Medicare through qualifying for Social Security disability insurance (SSDI). The average annual rate of growth in Medicare enrollment between 1973, when SSDI recipients could first get Medicare, and 1999 was 4.3 percent for disabled beneficiaries compared with 1.7 percent for aged enrollees (CMS 2003a). In 2002, 5.5 million disabled workers received benefits from the Social Security Administration (SSA). Today’s SSDI recipients look different than those of prior years (IOM 2002b). In 1960, when persons younger than 50 years of age could first receive SSDI benefits, the average disabled worker was 57.2 years old; by 2002, the average age fell to 51.0 years. In 1957, when SSDI benefits first became available, only 20 percent of disabled workers were women, compared with 45 percent in 2002. Disabled women workers receive lower monthly payments than men: \$709 compared with \$936 in December 2002 (SSA 2003). Thus, on average, those receiving SSDI today will likely stay on the rolls longer and have less disposable income than former beneficiaries.

One final demographic issue involves social, economic, and health disadvantages experienced by many persons with physical, sensory, and psychiatric disabilities. Compared with others, persons with disabilities have less education and higher rates of poverty, unemployment, tobacco use, obesity, and fair or poor health. They are also more likely to live alone and report feeling frequently depressed, anxious, fearful, or under stress. Even with insurance, persons with disabilities could still risk poor health outcomes because of complex underlying medical conditions that need to be treated by diverse clinical specialists, poor coordination of care, inadequate communication or discordant expectations between physicians and patients, physically inaccessible care sites, insufficient health literacy, and finan-

cial barriers. Medicare beneficiaries with disabilities spend \$1,532 out-of-pocket annually for health care services; this amount rises to \$2,175 for persons with two or more limitations of activities of daily living (Foote and Hogan 2001).

Targets for Policy Changes

As the Disability Policy Panel of the National Academy of Social Insurance acknowledged, “Despite its gaps in covered services, Medicare is an essential source of health care coverage for Social Security disability beneficiaries” as well as chronically debilitated older adults (Mashaw and Reno 1996, 144). Indeed, Medicare meets many high-cost service needs of enrollees with disabilities, such as inpatient intensive care, cardiac revascularization, or joint replacement surgery.

Tensions between patients’ needs and coverage limits primarily involve routine non-acute care and services and technologies for maintaining, restoring, or maximizing function. Changes in four areas—medical necessity determinations, homebound requirements, coverage waiting periods, and office visit reimbursement—could considerably improve the lives of Medicare beneficiaries with disabilities. Related issues emerged repeatedly during 119 interviews I conducted with persons with mobility problems and their family members, physicians, physical and occupational therapists, and medical directors of health plans, as the following stories reveal (all proper names are pseudonyms, Iezzoni 2003).

Revising the Definitions of Medical Necessity

“I can’t keep up with this walker,” said Erna Dodd, moving slowly and laboriously, breathing oxygen from a canister dangling from her walker’s handlebars. She had many medical problems: emphysema, diabetes requiring insulin, congestive heart failure, seizures, obesity, and debilitating arthritis. Nonetheless, she refused our proffered wheelchair. Ms. Dodd said, “[I don’t] want people pushing me in a wheelchair. So Max [her nurse] put in to get me a [motorized] scooter. He had my doctor fill out some paper for it. This was a letter they send, telling me they wouldn’t give it to me.” Reaching into her handbag, she retrieved a legal-size envelope containing a single sheet of paper.

“Medicare sent this to you?” I asked, looking at the letterhead, then read aloud, “‘We have received a prior authorization request for the above named beneficiary for a power operated vehicle. This request has been denied because the information did not support the medical necessity of the equipment. If you do not agree with this decision, you may request a review in writing within six months of the date indicated in this letter. Submit any additional documentation to the review department.’ Did Max appeal this for you?”

“I don’t know. I was going to call my doctor and talk to him about it. It would help me a lot.” Dr. Baker, her primary care physician, did contest Medicare’s denial, but Erna Dodd died during the appeals process (Iezzoni 1999, 2003).

Decisions on health insurance reimbursement typically involve two stages: organization-wide decisions about what services will be covered and case-by-case decisions about the medical necessity of covered services for individual persons

(Singer and Bergthold 2001). (As noted below, a third-order decision, critical for some individuals with disabilities, concerns whether persons can receive services at home.) Congress makes Medicare's broad benefit decisions, which are then codified in federal regulations. Local Medicare carriers determine whether individual beneficiaries receive the items or services they request, such as assistive technologies and physical and occupational therapy.

In its pamphlet *Your Medicare Benefits*, CMS informs beneficiaries that original Medicare covers services or supplies that are medically necessary or that:

- Are proper and needed for the diagnosis or treatment of your medical condition;
- Are provided for the diagnosis, direct care, and treatment of your medical condition;
- Meet the standards of good medical practice in the local area; and
- Are not mainly for the convenience of you or your doctor. (CMS 2003d)

Two major questions generally drive decisions regarding requests from individual Medicare beneficiaries: (1) How long will the person need the service? Chronic needs raise more questions than short-term demands; and (2) Will the service result in measurable improvement of physical deficits caused by medical illness or injury? Neither question is especially propitious for persons with disabilities. By definition, these individuals generally need services long-term, and their impairments are unlikely to improve. Medicare also explicitly denies items judged only for personal comfort or not primarily medical in nature, such as hearing aids, grab bars, and routine foot or dental care (42 C.F.R. Sec. 411.15). This prohibition against convenience items likely doomed Erna Dodd's request for a motorized scooter. Long-term physical, occupational, or speech-language therapy to maintain function or prevent further declines would likely also fail these tests as the term treatment assumes recovery or improvement. In addition, decisions regarding individual medical necessity often appear idiosyncratic and subjective and deficient communication compounds the problem (Rosenbaum et al. 1999). "Denial letters rarely explain who made the decision, the reason for the decision, what sources of evidence were considered, what coverage policies were applied" (Singer and Bergthold 2001, 204).

These problems are well recognized. The IOM's Committee on a National Agenda for the Prevention of Disabilities lauded the potential for rehabilitation services, assistive technologies, and even modest items like grab bars to improve safety and quality of life for persons with disabilities. The committee noted that coverage and payment policies impede people from getting these devices, which could potentially save health care dollars downstream: "Denial of reimbursement for technology that assists in the performance of daily activities and reduces risk of secondary conditions is likely to result in long-term costs that exceed initial savings. For example, Medicare regards grab bars for bathrooms as convenience items, even though falls in the bathroom are a leading cause of hip fractures and other injuries among the elderly. The health care costs associated with hip fractures alone are large and growing. This shortsightedness is also reflected in the

inadequate coverage that most insurers provide for long-term maintenance and replacement of the few assistive technologies they do fund” (Pope and Tarlov 1991, 227).

Like this committee, a panel of the National Academy of Social Insurance put this topic among its short- to mid-range recommendations for making Medicare more responsive to chronic care.

Strive to include services related to function and health-related quality of life:

- Cover durable medical equipment with the specific intent of maintaining or restoring function.
- Provide for assistive devices that compensate for sensory or neurological deficits.
- Support rehabilitation as a tool to improve, maintain, or slow the decline of function. (Eichner and Blumenthal 2003, v)

Medical necessity judgments, while ostensibly ensuring that Medicare covers only “health-related needs,” also serve as a form of rationing available resources. Yet Medicare’s current provisions deny the realities of a large fraction if not the majority of its beneficiaries—people with chronic debilitating conditions that will not improve. With appropriate technological or rehabilitative support, many of these individuals could continue living independently in the community, postponing the overwhelming expense of long-term institutionalization. Revisiting Medicare’s medical necessity limits on items and services that help people with disabilities function is long overdue.

Enabling People with Disabilities to Go Outside Their Homes

A colleague who lives in a small mountain town described his neighbor. “Mary Jo is her name. She lives three blocks from us. She’s thirty-nine or forty, and she has diabetes. She’s had one leg amputated, and the other leg is constantly in danger. She lives in a low-income apartment, one of those little places like a motel room. Some friends raised the money and gave her an electric wheelchair—a real cheap one, but it allowed her to get out the door and up to a small park. On a nice spring day, she can go out and sit under a tree and come back in. That’s all she ever did with it.”

A home health nurse treats Mary Jo’s ulcerated leg, among other medical problems. “One day, the home health nurse saw the electric wheelchair sitting in the apartment, and she said, ‘You know what? I can’t come anymore.’ Mary Jo is disabled under Medicare, and Medicare won’t pay for home health unless the person is homebound. So the wheelchair has now been folded up and is gathering dust in the corner. It’s been retired from use, and every time a home health aide comes, she tries not to see it.”

Mary Jo’s friends rightly assumed that Medicare would refuse to purchase her power wheelchair since she does not need it within her tiny apartment—as for Erna Dodd, it would not have been deemed medically necessary. So they bought it themselves. The independence conveyed by the power wheelchair, however, could

risk Mary Jo's eligibility for home-based nursing care for her remaining leg ulcerated by diabetes: If Mary Jo sits under a tree in her power wheelchair, she risks losing home health care, so she stashed away her power wheelchair. Staying indoors when she could venture out not only diminishes Mary Jo's quality of life but also could compromise her overall health.

Two paradoxical Medicare policies entrap Mary Jo. The first policy relates to eligibility for Medicare home care. To qualify for home-based services, Medicare regulations stipulate that individuals be homebound, defined as "a normal inability to leave home, that leaving the home requires a considerable and taxing effort by the individual." While absences for medical care, adult day-care, and attending religious services are allowed, other absences must be "infrequent or of relatively short duration" (42 C.F.R. Sec. 1814[a] and Sec. 1835[a]).

Clearly, this policy makes little sense for Mary Jo. To qualify for nursing care in her home, Mary Jo first needed to demonstrate that skilled services were medically necessary. With diabetic ulcerations on her remaining leg needing constant clinical attention, Mary Jo easily met the medical necessity criterion. Traveling daily to a clinic or hospital for this care would pose an enormous, perhaps impossible, burden. Since Mary Jo obviously had compelling medical needs, as well as substantial physical impairments, why couldn't she take short jaunts out in her power wheelchair without risking home care coverage?

For years, concerns about increasing home care costs have stalled efforts to broaden the homebound definition. From 1989 to 1996, Medicare Part A home health spending soared from \$2.8 to \$11.3 billion (U.S. General Accounting Office 1997). To reverse this trend, the Balanced Budget Act of 1997 significantly changed Medicare home health care payment policies. Total home care expenditures plummeted by 50 percent between 1996 and 2001, and the average number of days on home care fell 28 percent, from sixty to forty-three days (Medicare Payment Advisory Commission [MedPAC] 2003b). Some worry that these cuts have gone too far, especially for home care recipients who are frail, disabled, or medically vulnerable. MedPAC (2003b) found evidence "that for beneficiaries with certain clinical conditions, SNF [skilled nursing facility] use may be partly replacing home health use." Furthermore, "A number of home health agencies reported changing the way they operated, being more careful about accepting long-term, chronic, or higher-cost beneficiaries" (MedPAC 2003b, 77). Someone like Mary Jo might now find it difficult to get Medicare home care.

One highly public case underscores the consequences of Medicare's homebound definition. Georgia resident David Jayne had developed amyotrophic lateral sclerosis (ALS) in 1988 at age twenty-seven, and over the years he had become totally physically incapacitated. In 1997 Medicare started paying for skilled nursing care in his home. In 2000, Mr. Jayne traveled out of town with a college friend to watch a Georgia Bulldog football game. The trip and Mr. Jayne's story appeared in an Atlanta newspaper, and shortly thereafter his home health agency discharged him for violating the homebound definition. His congressman arranged for Medicare to reinstate the services, and Mr. Jayne began campaigning to reform the homebound definition. He founded the National Coalition to Amend the

Medicare Homebound Restriction and proved an exceptional lobbyist, although now he speaks only with aid of a computer.

Prompted by Mr. Jayne's story and to commemorate the twelfth anniversary of his father's signing of the Americans with Disabilities Act, on July 26, 2002, President George W. Bush addressed concerns about Medicare's homebound requirement. Urging people with disabilities to meet friends, join family reunions, and even attend baseball games, President Bush announced, "We're clarifying Medicare policy, so people who are considered homebound can occasionally take part in their communities, without fear of losing their benefits" (White House 2002). However, Bush did not alter the language requiring considerable and taxing effort to leave home. Anecdotal reports suggest that little has changed since Bush's pronouncement and that Medicare carriers still interpret the homebound definition strictly.

The second paradoxical home-related Medicare policy entangling Mary Jo involves the purchase of her wheelchair. Since most mobility aids will not improve baseline physical function, medical necessity judgments cannot in this case rely on the usual standard of restoring function. Instead Medicare seeks to determine whether the equipment allows someone to perform minimal activity—moving around within one's home. Medicare "pays for the rental or purchase of durable medical equipment . . . [only] if the equipment is used in the patient's home or in an institution that is used as a home" (42 C.F.R. Sec. 410.38[a]). Getting around outside the home is a convenience and not medically necessary, as Erna Dodd found.

According to this stringent standard, many people with progressive chronic conditions who still get around inside their homes, such as by furniture surfing, cannot qualify for mobility aids through Medicare. Requirements are even stricter for power wheelchairs. To obtain a power-operated vehicle (POV) for their patients, physicians must complete the "certificate of medical necessity" (form DMERC 07.02B and OMB No. 0938-0679). Section B of the form asks:

- Does the patient require a POV to move around in their residence?
- Have all types of manual wheelchairs (including lightweights) been considered and ruled out?
- Does the patient require a POV *only* for movement outside their residence?

Medicare's intent is clear: It will pay for the more expensive POV only if cheaper options are ruled out. But standards for ruling out manual chairs remain unspecified, leaving considerable leeway for subjective judgments and denials. A social worker told me about a man paralyzed by a stroke whose POV request was refused. Medicare asserted that his elderly wife could push him in a manual wheelchair within their home although she is also frail and weak. In the past, compared with other types of durable medical equipment, POVs were relatively rarely requested, and no evidence suggested that they were over-prescribed (Wickizer 1995). However, since 1999, power wheelchair purchases through Medicare have soared, and fraudulent practices by unscrupulous vendors cost Medicare \$84 million in 2002 (Janofsky 2004). Medicare has recently cracked down on abusive practices,

causing consternation among advocates for persons with disabilities. POVs are now even harder to obtain than before. As one woman whose husband is severely debilitated by multiple sclerosis said, “I don’t believe there’s massive abuse, that people are buying things that they don’t need. There’s a 20 percent copay. My husband’s wheelchair is \$20,000. That’s a \$4,000 copay. Do you think I’m going to spend \$4,000 just for the fun of it?”

Policymakers must recognize that requiring persons to remain in their homes and denying them mobility aids ignores a critical reality. Today’s assistive technologies allow people with substantial physical impairments, such as Mary Jo and David Jayne, to leave their homes and participate within their communities. People with disabilities no longer accept being shut away in their homes.

Medicare Coverage from Day One of Disability

Jimmy Howard is in his late forties with arthritis and diabetes. He has a high school education and lifted heavy boxes in ManuCo’s warehouse for years before being fired because he had difficulty walking. Mr. Howard moves firmly with an aluminum cane, although sometimes he falls unexpectedly. After ManuCo fired him, he applied to SSA for disability benefits. He has incapacitating stiffness each morning and other “objective medical evidence” of “arthritis of a major weight-bearing joint,” as specified in *Disability Evaluation under Social Security* (SSA 1998).

Five months following his disability determination, Jimmy Howard started receiving cash SSDI benefits. According to federal regulations, he must wait another two years to obtain Medicare coverage—a total of twenty-nine months beyond the date of SSA’s disability determination. Mr. Howard, however, can’t wait for health insurance to keep his diabetes under control, as well as treat his arthritis. So he pays \$400 per month for private health insurance under COBRA provisions. Sometimes he and his wife, who also doesn’t work, can barely make this payment.

P.L. 92-603, signed by President Richard Nixon on July 1, 1972, granted Medicare coverage to individuals who have received SSDI cash benefits for twenty-four months (42 U.S.C. Sec. 226[b][2][A]). The law also reduced to five months the waiting period between qualifying for SSDI and actually receiving cash payments. On July 1, 2001, Congress passed a special waiver rescinding the twenty-four-month wait for Medicare coverage, but only for persons who qualify for SSDI because of ALS. This exemption, won through active lobbying by ALS advocates, reflects the reality of rapid debilitation that generally accompanies that disease. But what about other SSDI beneficiaries who also need care, including Jimmy Howard with his diabetes and arthritis?

Separating Medicare coverage from disability determination makes little sense. The 1972 law aimed both to limit Medicare costs and avoid dislodging private employer-sponsored health insurance that SSDI applicants presumably had. To receive SSDI, applicants must prove disability by meeting explicit medical criteria determined by the SSA: “The inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment(s)

which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months” (SSA 1998, 2). Surely applicants who might face imminent death and can’t work ought to receive health insurance coverage immediately! Persons who qualify for Supplemental Security Income, another financial support program that uses identical application procedures as SSDI, obtain immediate Medicaid coverage.

The reasons for this baffling incongruity remain murky. Vladeck and colleagues explain the roots and tenacity of the Medicare gap as reflecting “ambivalence about the meaning of disability itself: The truly disabled—those who have a clear right to protection—cannot be easily identified in the modern social context in which disability is a matter of degree. . . . Disability consists of a hard physical core with an expanding penumbra of mental and psychological nuance not generally as visible (or acceptable) to society. As a result, gaps in services betray a deeply rooted ambivalence toward certain classes of the disabled. Most especially, a fundamental skepticism of those who are disabled because of a mental illness, alcoholism, or drug addiction seems ingrained in the culture” (1997, 87).

In earlier years, most new SSDI recipients qualified because of conditions that obviously warranted close medical attention. In 1981, circulatory conditions accounted for 25 percent of disability determinations, followed by other systemic diseases at 19 percent; musculoskeletal conditions contributed 17 percent, and mental disorders 11 percent (IOM 2002b). Two decades later, the situation has changed considerably. In 2001, mental disorders contributed the largest percentage (26.8 percent) of new SSDI beneficiaries (1.5 million persons), with musculoskeletal conditions in second place (21.7 percent, 1.2 million persons) (SSA 2002). Circulatory disorders fell to 9.6 percent.

No publicly available data describe SSDI beneficiaries during the waiting period. Dale and Verdier pieced together information from various sources to sketch this population, which they estimated at 1.26 million individuals in 2002. Approximately one-third, or 400,000 persons, lack health insurance during their waiting period, while roughly 40 percent, or 504,000 adults, enroll in Medicaid programs, costing the federal and state governments \$7.6 billion in 2002. Eliminating the waiting period would add about \$8.7 billion (3.4 percent) to Medicare costs at 2002 spending levels. However, lower state and federal Medicaid expenses would offset roughly 30 percent of the Medicare rise (Dale and Verdier 2003).

Questions remain about what health care services SSDI recipients obtain during the wait. Being uninsured, even for one to four years, may worsen general health status (IOM 2002a). Having financial access to health care services is essential to “fostering early interventions to prevent diseases or impairments from becoming permanent work disabilities” (Mashaw and Reno 1996, 135). While awaiting Medicare coverage, uninsured SSDI beneficiaries might skimp on care that could prevent or slow progression of their diseases, thus decreasing longevity, hastening functional declines, and increasing health care costs. One study of persons who had been continuously uninsured from ages sixty through sixty-four years found that, upon joining Medicare, they considerably increased their use of basic covered services. For instance, upon getting Medicare, “continuously

uninsured adults with arthritis reported greater increases in arthritis-related medical visits and limitations of activity than continuously insured adults with arthritis” (McWilliams et al. 2003, 762).

Adding new SSDI beneficiaries to the Medicare rolls would undoubtedly fractionally increase costs, at least in the short term. However, longer-term savings could outweigh these costs. Jimmy Howard’s primary care doctor told me a year or two later that his diabetes had been poorly controlled and he risked losing toes to gangrene. Might Medicare coverage have prevented or slowed that progression?

Paying the Right Amount for Office Visits

Joe Alto, a former backhoe operator in his late thirties, has had multiple sclerosis for twelve years and has used a wheelchair for three. Mr. Alto’s primary care physician does not have an adjustable examining table—a table that automatically lowers to wheelchair height with the touch of a pedal. Instead, the physician uses a fixed-height table, conveniently positioned for standing physicians. “There’s no way for me to get onto their examining tables—they’re too high,” Mr. Alto reported. He worries that his primary care physician gives him short shrift. “Most of the time, he wants to do my physical exam in my wheelchair. I’m not even undressed. All he does is listen to my heart and ask what’s wrong. He can’t diagnose me in my wheelchair. I want to get on the table. Get me undressed like the rest of the people—treat me like the others!”

Joe Alto believes that the problem is money and time. Examining tables with pedal-operated lifts cost at least twice as much as standard, fixed-height tables. He also worries that some physicians want to avoid patients who use wheelchairs. “When they see you coming in the wheelchair, they say, ‘That’s going to be a lot of work,’” said Mr. Alto. “Insurers don’t pay extra for someone like me, so the doctor isn’t going to want me there.” Minute by minute, “The doctor’s not getting as much money for a disabled person as he’s getting for someone else.”

Roughly 85 percent of Medicare beneficiaries belong to the traditional fee-for-service program, up several percentage points from 1998, the peak of managed care enrollments (MedPAC 2003a). In 2004, Medicare expects to pay about \$48.7 billion to nine hundred thousand fee-for-service physicians and other providers, rising from an estimated \$47.9 billion in 2003 (CMS 2003c). To be paid for the office visit, Joe Alto’s primary care physician must submit a claim to Medicare listing an evaluation and management (E&M) code indicating the level (from one to five) of the visit. His physician will choose the E&M code that matches the extent of the clinical history, the physical examination, review of body systems, clinical issues discussed with Mr. Alto, and the time spent. Medicare’s resource-based relative value scale, the basis for physician payment for the last decade, sets payments for each code physicians list on their claims. This scale attempts to narrow the reimbursement gap between primary care and specialist physicians. However, “reimbursement for routine primary care visits is insufficient for the care of many with chronic conditions, as care for this population usually takes a considerable amount of time, particularly when self-management and mul-

multiple conditions are addressed. . . . [Furthermore, the E&M classification] is a barrier to chronic care. E&M codes account for almost half of Medicare-paid physician services. These codes fail to adequately reflect the additional complexity and time requirements associated with care for many beneficiaries with chronic conditions” (Eichner and Blumenthal 2003, 30).

Other aspects of Medicare’s physician reimbursement policies are also problematic. The Medicare statute requires adjusting up or down the physician fee schedule based on how actual expenditures compare to a target rate, the sustainable growth rate or SGR. CMS (2003c) calculates the SGR “based on medical inflation, the projected growth in the domestic economy, projected growth in the number of beneficiaries in fee-for-service Medicare, and changes in law or regulation.” Substantial growth in Medicare physician outlays, combined with the slow economy, led to cuts in Medicare physician payments in the early 2000s. In fiscal year 2003, Medicare cut physician payments by 5.4 percent, and CMS proposed a 4.2 percent cut for 2004 (CMS 2003c).

Continued cuts in physician payments could make it harder for people like Joe Alto to find routine care. In 2002, 70.1 percent of physicians accepted new Medicare fee-for-service beneficiaries, down from 76.4 percent in 1999 (MedPAC 2003a). Even some generalist physicians avoid new Medicare beneficiaries. A spokesperson for the American Academy of Family Physicians reported that more than one-fifth of family physicians no longer accept new Medicare patients (Pear 2003b). In March 2003, MedPAC warned, “If the Congress does not change current laws, . . . then payments may not be adequate in 2003 and a compensating adjustment in payments would be necessary in 2004” (2003a, 72).

Physicians clearly need more time to fully examine persons using wheelchairs and persons with other disabling and complex conditions and to discuss their medical concerns. Paying more per visit for persons with disabling conditions than for healthier, able-bodied persons (i.e., “risk adjusting” office visit fees for patients’ health-related risks) therefore makes sense. Risk-adjusting E&M codes could substantially improve quality of care (Eichner and Blumenthal 2003).

Ensuring Health Care Quality

Current Medicare coverage policies do not match basic needs of persons with disabilities for interventions to maintain, restore, or maximize their functioning. These policies pose barriers to “patient-centered” care—care that is “respectful of and responsive to individual patient preferences, needs, and values” (IOM 2001, 42). Many strategies now exist to allow persons even with significant disabilities to live independently in the community, minimizing their risks of developing debilitating and costly secondary conditions. But coverage gaps prevent people from obtaining this care.

Addressing the four targets described in the previous section could substantially ameliorate this situation. However, skyrocketing costs pose formidable obstacles. Total Medicare expenditures are expected to reach \$450.1 billion by 2011, compared with \$245.6 billion one decade earlier (Heffler et al. 2002). Expanding

coverage to include more function-related services has always proved politically unpalatable: “The cost implications of disability-related services . . . frighten policymakers away from contemplating all but the narrowest of expansions. What looks like a half-empty glass when benefits are being designed may be a bottomless pit once the payments begin to flow” (Vladeck et al. 1997, 88).

Although I concentrate here on Medicare, deep cuts in state budgets are fraying Medicaid’s safety net. In designing Medicaid, Congress recognized that low-income persons have little to spend on care, so it adopted broader benefits than for Medicare. All states must cover core services (e.g., inpatient hospitalizations, skilled nursing facility stays, home health care), but they can also offer various optional services including prescription drugs, physical and occupational therapy, prosthetic devices, eyeglasses, and durable medical equipment. In 2002, Medicaid insured about 42.8 million persons, including 7.7 million low-income individuals, eligible because of disability or blindness, who consumed 37.8 percent of Medicaid’s resources (CMS 2002).

When facing substantial budgetary shortfalls, states frequently cut benefits, eliminating or reducing payments for optional items and services. In 2003, forty-five states implemented cost controls on prescription drugs, and twenty-five reduced Medicaid coverage for vision care; dental services; physical, occupational, and speech therapy; and home oxygen (Smith et al. 2003). With continuing budget deficits, state legislatures will likely continue chipping away at Medicaid benefits.

With these cuts, failures to expand Medicare coverage, and other related policy decisions, our nation consciously chooses to limit the quality of life, independence, and even health of many persons with disabilities. Politicians could credibly argue that coverage costs are too high, competing with other pressing societal needs. To counter such arguments, we need better evidence about potential cost trade-offs. For example, does providing a power wheelchair to improve independent mobility save money in the long run by reducing secondary disabilities, such as falls and depression, and lowering costs of home-based and institutional care?

As countless others have said, how we care for our most vulnerable citizens speaks volumes about our values as a nation. With mounting federal and state budget deficits, little will likely change in the next few years. But rethinking fundamental Medicare coverage policies may gain political momentum as millions of baby boomers care for aging parents and then retire themselves. Sally Ann Jones, a wheelchair user and SSDI recipient, feels that politicians have missed the obvious. “It amazes me that nobody’s gotten this notion yet: the baby boomers are coming. Despite MS and other diseases, they’re going to live longer. We’re not going to warehouse them in nursing homes. These boomers simply won’t do that. They’re not going to go quietly into the night.”

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Specialization, Specialty Organizations, and the Quality of Health Care



ROSEMARY A. STEVENS

Specialization is a defining word for American medicine in our time. If it were still possible for a generalist to understand medicine as a body of knowledge and skills, we would not now have mighty health care corporations, millions of workers in hundreds of health care occupations, sprawling academic medical centers with their associated networks, or even managed care. However, while technological innovation and improvements in the quality of health care available to earlier generations testify to the manifold benefits of medical specialization, its downside has also long been evident.

For more than a century specialization has been portrayed as a force for disorganization in medical care, challenges in medical education, opportunities for profit seeking, and power plays among rival claimants (Rosen 1944; Somers and Somers 1961; Stevens 1971; Starr 1982; Ludmerer 1985, 1999). Today competition for market share in lucrative fields such as cardiology characterizes our health services, jurisdictional disputes mark professional organizations, and massive government programs, including Medicare, Medicaid, and the National Institutes of Health, subsidize and underpin the whole.

For the past two decades medical specialists have moved efficiently into market niches. Health policy has been largely silent about regulating and organizing such services, but signs of change are promising. Here I focus on four essentials: the need for a workable information infrastructure, strategic planning at the community level, encouragement of primary care, and public support of lifelong learning for physicians through “maintenance-of-certification” programs. Achieving these would enhance quality of care by better aligning the advantages of medical specialization with the needs of consumers searching for physicians with top-notch skills and expertise, the latest technology has to offer, and the most effective treatments.

Specialization in U.S. Medicine

Why do we have such a complex and confusing array of specialists? Partly because patients have long been complicit in the rush toward specialized medical

practice. “Between us we have 10 or 12” specialists, reported an eighty-three-year-old Medicare beneficiary in Florida in 2003. His list included a pain specialist, neurologist, cardiologist, pulmonologist, rheumatologist, and urologist. His wife’s experts were likewise defined by body parts, conditions, and diseases (Kolata 2003).

Historically, three social forces have combined to encourage specialization in the United States: the definition of medicine as a science that advances through the subdivision of effort; belief in the superior skills of experts; and competitive (rather than collaborative or bureaucratic) medical practice, supported by private and public health insurance. The managed care movement of the 1980s and 1990s promised to limit direct patient access to specialists by imposing a generalist or “gatekeeper” but roundly failed, attacked by both providers and consumers.

Specialization is an intrinsic, formalized aspect of American medicine. The medical profession is much more formally stratified than the legal profession; for example, and unlike law, which is largely state regulated, medicine is intensely subject to private regulation. Specialties do not just happen. The system that produces and credentials medical specialists is owned and operated by professional organizations, in the time-honored process of public deferment of responsibility. As I will show, specialties are based on demarcations negotiated among major associations. Those groups, working together, are now attempting a major expansion of specialty certification into a system of lifelong learning for all physicians.

For the individual U.S. physician, successful specialist practice requires favorable market conditions, including an available and willing patient base and supportive insurance programs. However, in our legalistic society, successful practice also requires some formal validation of experience that stands up to marketplace challenges such as denial of hospital privileges and malpractice insurance, that is accepted by third-party payers, and that is convincing in the case of costly lawsuits. For the U.S. medical profession and the public, the persona of a “specialist” may suggest success, expertise, and enhanced fees, but for practical purposes this persona must be accompanied by years of education, usually capped with examinations and the resulting certificates on the doctor’s office wall. The credentials embedded in those certificates—ranging, alphabetically, from adolescent medicine to vascular surgery—are almost always those the medical profession has validated through its formidable specialty network: medical school departments and divisions in designated fields, professionally accredited residency programs, and specialty certification.

Specialty Credentials as Essential Standards in a Privately Organized System

In contrast to the constantly shifting organization and financing of U.S. health care, the production system for doctors runs like a finely tuned machine. Specialty identification and credentials provide a necessary standard for consumers (at least in theory, though often ignored) in America’s competitive health care enterprise.

On a practical level, specialty credentials are important for at least four reasons. First, the MD degree is an intermediate, not a final, credential in a market

where physicians are specialists, and thus the specialty (and increasingly subspecialty) diploma has taken over the role once marked by the MD alone. Second, common standards are essential in a context of decentralized, fragmented services without strong, local institutional controls, and where a physician may have relationships with multiple insurers, hospitals, and other providers. Third, credentials serve as markers for patients shopping for specialty services in a market-oriented system and help define a market niche. And fourth, credentials serve health care providers, auditors, accrediting agencies, bond raters, and insurers, all anxious to maintain standards, acquire prestige, protect patients from harm, and avoid legal difficulties.

In the absence of national, state-based, regional, or even large-scale corporate health services, there is no countervailing authority overseeing the quality and use of health personnel. Government has intervened from time to time to stimulate the overall supply of doctors and subsidize training programs, chiefly research fellowships in subspecialty fields and areas deemed undersupplied, such as (in the past) mental health. Federal “health manpower” legislation of the 1970s made a large impact on the number of doctors, but relatively little on their roles or the distribution of their services demographically and geographically (Weissert and Weissert 1996). Meanwhile specialists have made their career choices based on the training available and their perceptions of the changing health care market (Robinson 1999; Scott et al. 2000). Credentials that attest to residency, specialty, and often subspecialty training provide a gold standard in an otherwise uncertain health care environment.

Organized Medicine: One Voice or a Multitude of Agendas?

Through decades of debate over how to provide efficient specialty services, national organizations have represented U.S. physicians, but the pattern of representation has shifted significantly. From the early years of the twentieth century through Medicare legislation (1965) and beyond, the American Medical Association (AMA) offered a united front in political debates, successfully claiming to represent the entire profession. The growth of organized specialties, evident well before 1965 but increasingly powerful and activist, shifted physician allegiances away from the AMA. The specialty rather than the general medical society has become the primary allegiance for American doctors. Today the average internist, pediatrician, cardiac surgeon, and interventional radiologist identifies with his or her specialty organization, meetings, newsletters, and journals for both scientific information and policy representation.

Between 1950 and 1990, as organized specialties consolidated their institutional authority, AMA membership fell away. In 1950 almost 73 percent of all MDs were AMA members; in 1970, 64 percent were, and by 1989 little more than 40 percent of MDs were AMA members (AMA 2002). By the late 1990s the AMA was recognizably weak, representing less than half of all doctors, including those in training. Powerful specialty groups have focused on agendas such as child health policy (American Academy of Pediatrics) and a forty-eight-hour minimum hospital stay after childbirth (American College of Obstetricians and Gynecologists).

Specialty groups have also sought congressional support for a national trauma system, claiming that only eight states have well-organized trauma systems (American College of Surgeons) (Hawryluk 2003).

In the political arena, such focusing may make organized medicine more powerful and effective, at least on targeted policy issues. In the professional arena, though, too much fragmentation may ultimately be self-defeating, as medical leaders are well aware. As specialty credentialing has become ever more important, questions regarding common standards have acquired new significance.

For example, what does the array of specialty and subspecialty training programs say about the production of U.S. doctors? Does certification imply quality of services for patients? Are the certifying boards doing a good job? Should government support them more fully in the Herculean tasks they have set for themselves, which include greater coordination? Or can other groups do credentialing better or more economically? These are important questions with major implications for the quality of care, medical standards, professional responsibility and accountability, and the role of regulation. Though they cannot yet be answered fully, debates about health care quality and outcomes, cost controls, and state licensing require a better appreciation of where credentialing arrangements have come from and how they work.

The Production of Specialists in the United States

Twenty-four independent, “approved” boards divide the U.S. medical profession into specialties and subspecialties. An approved board is one formally affiliated with the American Board of Medical Specialties (ABMS), based in Evanston, Illinois. (Since 1999 I have served as one of three public members representing public policy perspectives on the ABMS). Subspecialty status requires that the individual physician first become certified in a primary specialty field. For example, internal medicine, pediatrics, and radiology are designated specialties, each with its own board: the American boards of Internal Medicine (headquartered in Philadelphia), Pediatrics (Chapel Hill), and Radiology (Tucson). Cardiology, pediatric allergy, and interventional radiology are among the formal subspecialties, respectively, of these boards, each responsible for granting subspecialty certificates.

Each board specifies training pathways, via approved residency or fellowship programs, and administers examinations. Approved training requires completion of residency programs accredited by a group parallel and related to the ABMS, the Accreditation Council for Graduate Medical Education (ACGME). An individual doctor leaves medical school with the MD degree, enters an approved residency program in a specialty for three to six years, and eventually becomes certified in that field. Those who are certified are called “diplomates.”

Together the boards granted thirty-seven basic specialty certificates and ninety-two types of subspecialty certificates in 2003, with more subspecialty categories on the way (ABMS 2003a). In 2000 alone, almost twenty-four thousand physicians became diplomates. The “biggies” were internal medicine, which

granted 29 percent of all primary certificates; family practice (15 percent); and pediatrics (11 percent). These three specialties—together with psychiatry and neurology (which for historical reasons joined together in one board), obstetrics/gynecology, radiology, emergency medicine, and surgery—granted 80 percent of all specialty diplomas in 2000, with the remaining 20 percent scattered across the other sixteen boards. Half of all subspecialties reside in three boards: internal medicine (with sixteen subspecialties), pediatrics (seventeen), and pathology (eleven).

ABMS-affiliated boards now certify 90 percent of U.S. practicing physicians, on a rising trend (ABMS 2003a). Thus these ABMS-approved twenty-four boards and their subspecialty committees define the formal structure of American medicine.

As might be expected, other credentialing groups also exist, perhaps as many as two hundred—there is no formal list. Osteopathic physicians have their own boards that maintain substantial affiliation with ACGME-approved residency programs. Other groups advance the cause of newer specialties not yet covered, in their view, by ABMS-approved boards. (The ABMS, in liaison with the AMA, has a formal process for approving applications from new boards.) Vascular surgeons, for example, though recognized as a subspecialty of the American Board of Surgery, have been pressing—so far unsuccessfully—for acceptance of the American Board of Vascular Surgery as an independent, ABMS-affiliated board (Burton 2003). Leaders of the American Board of Hospice and Palliative Medicine are similarly seeking recognition of end-of-life care as distinct from pain medicine, which is an ABMS-approved subspecialty. This group, too, may eventually seek ABMS approval (Beresford 2004).

Courts have generally upheld the authority of ABMS-approved boards. The American Academy of Pain Management brought an unsuccessful suit against the Medical Board of California for prohibiting physicians from advertising that they are “board certified” unless they meet certain requirements. These include certification by an ABMS-approved board or the “equivalent,” as determined by the Medical Board or by completion of approved postgraduate training. Physicians certified in other ways, such as by attaining the academy’s credentials for multidisciplinary pain practitioners, may not advertise in California that they are board certified. In upholding the Medical Board, the U.S. Ninth Circuit Court of Appeals noted that “‘Board Certification’ is a term of art that the ABMS popularized among physicians and has come to designate a certain level of qualification.” The court also noted that the state has given the term “board certified” a “special and particular meaning,” and that the plaintiffs’ use of “board certified” was “inherently misleading” and thus not protected speech, as the plaintiffs had claimed (U.S. Court of Appeals 2004).

Such challenges push approved boards to recognize their public role, to ask what this means regarding quality of care, and to make major attempts to coordinate their efforts. The legal system thus provides a useful goad to responsible self-regulation.

The Origins of Specialties

The specialty board structure arose out of a long, negotiated history. Multiple professional associations typically organize a specialty board once they have become motivated to seek credentialing. Not surprisingly, these groups found boards at different times for different reasons. The first medical specialty board—for ophthalmology—incorporated in 1917 amid turf battles with well-organized optometrists, who were also seeking professional credentials (Stevens 1971). The newest specialty board is Medical Genetics, approved in 1991, affirming medical jurisdiction when many investigators in the field held the PhD as their primary credential.

The basic pattern was set in the 1920s when otolaryngologists followed the ophthalmologists with their own board (1924), thus making an effective claim for that field, too, as requiring expertise beyond that of the general practitioner. However, specialty boards blossomed into a movement with the economic pressures of the 1930s. By 1944, when sociologist George Rosen published a classic study of medical specialization, self-styled specialists outnumbered general practitioners, making specialization an “essential feature of modern medical practice” (Rosen 1944, 1). Specialism seemed tailor-made for the American public, with its faith in experts and the cachet accruing to those who charged high fees and offered esoteric treatments. As Rosen also observed, specialization intensified the U.S. view of medicine as an economic transaction, becoming a natural partner to and developing alongside market-oriented health care (Rosen 1944, 77).

The specialization movement proved a double-edged sword for the medical profession. As long as general practice remained its actual—or even symbolic—core, the training and recognition of specialists could remain at the margin of organized medicine. Specialization reinforced the profession’s commitment to innovation based on an elite cadre working in science, technology, and clinical advancement in medical schools, while specialists could work as consultants to average practitioners without considering their demographic distribution. However, as the balance shifted toward an entirely specialized profession, the opportunistic and public policy aspects of specialties came more firmly into view.

The formation of the American Board of Family Practice in 1969—amid vocal concern about the decline of general practice and rousing calls for new roles for “personal physicians” and “primary care”—made generalism a “specialty” (Lee et al. 1976; Stevens 2001a). Somewhat similarly, emergency medicine achieved its own certifying board in 1979 following intense public interest in reforming emergency medical services. But by encompassing family and emergency medicine, the certifying boards acquired *de facto* responsibility, however unwillingly, for the design, specialty training, and evaluation of the entire medical profession. Equally, all physicians were now specialists.

At least in theory, the collective influence of the certifying boards, their associated specialty groups, medical school departments and sections, and the residency system on the structure and standards of medicine is now as great as that of universities. However, collective influence implies some cross-specialty collaboration so the profession has a unified voice, and this process is still in its infancy.

For the certifying boards and their associated specialty societies, the key question is whether, now that they have acquired the opportunity for power and influence, they can overcome their history of professional separatism.

Problems with Specialties

Rivalries across fields, encouraged by competitive practice, make it difficult to determine how well the specialty structure helps patients find the right expert for a specific condition. Surprisingly little research has been done on this question. Preliminary studies for the ABMS suggest lack of public awareness of the specialty boards, their standards, and their formal specialty and subspecialty delineations (ABMS 2003b). Left to her own decision, a patient with annoying back pain might decide to take it easy and self-medicate with over-the-counter preparations, consult her primary physician, or seek out a general orthopedic surgeon or one with additional spinal expertise. Or she might ask friends for advice and receive an enthusiastic recommendation for a specific neurologist—or rheumatologist, sports medicine specialist, or pain subspecialist with a background in anesthesiology, neurology, or physical medicine, each offering a different professional perspective. The patient might also try herbal remedies, acupuncture, and massage.

These consultations might produce recommendations ranging from exercise through behavior modification, prescribed medications, laminectomy, and spinal fusion. Becoming a wise consumer is difficult in such circumstances. Nevertheless, the U.S. system, based on free-standing groups of specialists, assumes that the consumer is competent to do so. Indeed, direct access to specialists requires that patients act not only as sophisticated and sensible first-line diagnosticians but also as general contractors for their care. In seeking (or avoiding the need for) specialists, many patients clearly need an intermediary, a role that may be performed by doctors, nurse practitioners, physician assistants, the Internet, or someone or something else.

The Internet may play a powerful role for some patients in initially diagnosing symptoms and matching them with appropriate specialists. But that process may be risky. “Primary care” has long recognized the beneficial role of a knowledgeable generalist who has the patient’s interest at heart. Nevertheless, despite efforts from the 1960s through the managed care movement to designate a specific service role for primary care, no one “specialty” plays that role. Primary physicians may be family physicians, general internists, or general pediatricians, each with their own specialty board and associated subspecialties. Many subspecialists also act as primary care practitioners for their patients.

The field of sports medicine, for example, a formal subspecialty of family practice, internal medicine, pediatrics, and emergency medicine, will naturally appeal to patients primarily for sports injuries. Similarly, practitioners of endocrinology, oncology, and nephrology—among the subspecialties of internal medicine and pediatrics—are likely to draw patients with specialized rather than general needs. Yet these and other specialists may take on primary care roles for at least some of their patients. For example, an obstetrician/gynecologist may serve that

role for a woman, while a child psychiatrist may do so for a child with behavioral problems. The U.S. health system makes no direct connection between the training and credentialing of physicians and the clinical roles they play.

Turf Wars

Market and policy conditions ranging from managed care and Medicare reimbursement through varying competition among specialties and the relative burden of malpractice rates (heaviest for surgeons and obstetricians) affect clinical roles. The AMA designated seventeen states as in “tort crisis” over medical liability insurance rates in 2003 (Albert 2003). Meanwhile, physicians have looked for income opportunities outside their own specialties. To “limit economic shortfalls and to expand boundaries,” primary care physicians have reportedly been offering fee-for-service cosmetic procedures and dermatology, adding their own laboratories and imaging and bone density equipment, and setting up physical therapy programs (Reece 2003). Investment in imaging centers serving privately insured patients by physicians who are not radiologists has evoked public concern, “pitting radiologists against other doctors, and hospitals against free-standing centers, in a fight for health care dollars” (AP/*Dallas Morning News* 2003). Cosmetic surgery may endanger patients when performed by inadequately trained practitioners in unregulated facilities, yet it has been a steadily growing field for men as well as women (Haiken 1997).

Two movements are occurring simultaneously: the encouragement of health care as a market commodity allows patients relatively unfettered access to specialists while muddying specialty roles. Since the 1990s, market forces have stimulated competition between physicians practicing in the same specialty (such as rival groups of orthopedic surgeons), fanned turf wars between specialties, and fostered a decline in multi-specialty practice in favor of single-specialty groups and centers. “As HMOs and hospitals have seen their profit margins narrowed,” wrote one analyst in 1999, “entrepreneurs have turned to niche industries” such as ambulatory surgery centers, eye care companies, oncology, and cosmetic services (Kuttner 1999).

Medicare has also encouraged single-specialty practice by abolishing separate payment codes for the same procedure performed by radiology and internal medicine, for example. Medicare fees for family and general practitioners also rose much faster than for specialties such as ophthalmology, cardiology, gastroenterology, and urology in the 1990s, while fees for some specialized procedures such as cataract removal and insertion of a lens dropped significantly (Iglehart 1999). The Medicare Payment Advisory Commission and its predecessor effectively encouraged interests to lobby for (or against) specialty fields and procedures. A large multispecialty group had thus become “too unwieldy,” claimed members of such a group in Charlotte, North Carolina, as it disbanded. In contrast, a single-specialty group cited an “alignment of incentives” regarding reimbursement and few inter-specialty tensions (Page 2000).

In a competitive, single-specialty system, the patient cannot rely on doctors in different fields to provide comprehensive, coordinated care. Many Americans

do have primary physicians in one specialty field or another whom they trust to manage their care. Many patients, though, make their own choices from a list of specialists who are part of their insurance network or who participate in Medicare. No one is directing the patient to the physician who can best meet the patient's needs.

Better information on clinical results among specialty practices in different communities would greatly help consumers. In a consumer-oriented system, patients should have access to standard information. The simplest way of providing such information is to work toward standardized, computerized patient records with firewalls to ensure confidentiality. If the relatively impoverished National Health Service in England is able and willing to establish a universal health care database over the next two years, entertaining bids for contracts from global corporations such as IBM, why can't the United States (Naik 2003)?

Cooperation across Specialties

Paralleling these market trends are two promising signs of cooperation. The first is joint planning among subspecialties, and the second is a move toward life-long learning and evaluation of physicians, known as maintenance of certification.

Cooperation is important in designing innovative cross-specialty training and evaluation to advance the quality of care, standardizing credentialing, providing consumer-friendly information to help patients choose specialists, and assuring life-long commitment to learning and quality improvement. Cross-specialty alliances are also essential in enabling the medical profession to play a significant role in health care policy (Stevens 2001b).

The human urge to protect and extend one's property applies to organizations as well as individuals. As with primary boards, the creation of subspecialties tends to have a domino effect. One board's creation of a new subspecialty sparks similar moves by other specialties interested in the same field. Oncology is an early case in point. The ABMS approved oncology as a subspecialty of internal medicine in 1972, of pediatrics in 1973, and of gynecology in 1974, following applications from each of these boards. The growing importance of critical care has similarly led to subspecialties in six different boards (anesthesiology, pediatrics, internal medicine, obstetrics/gynecology, neurosurgery, and surgery). Newly visible fields such as geriatrics, sports medicine, toxicology, pain management, adolescent medicine, head and neck surgery, and neurodevelopmental disabilities have sparked the interest of more than one board. Five boards offer immunology as a subspecialty, while four boards offer sports medicine. Part of this movement reflects the fact that clinical medicine and market opportunities continue to shift.

The subspecialty movement has made the specialties less rigid than in, say, the 1960s. Sometimes painful negotiations precede a move toward integrated standards. Recent fights between otolaryngologists and plastic surgeons over the subspecialty of head and neck surgery resolved only after years of negotiation involving the ABMS and two ABMS boards, the American Board of Plastic Surgery and the American Board of Otolaryngology. The latter two were undoubtedly energized by the American Board of Facial and Reconstructive Surgery (ABFRS) and the

American Board of Cosmetic Surgery, neither of which the ABMS recognizes. The potential of state licensing boards to preempt professional standard setting was also clearly an ingredient. Licensing boards in Florida, Colorado, and California recognized the ABFRS as “substantially equivalent” to the ABMS boards in the 1990s. State boards usually work with ABMS-approved boards to set standards for licensing and advertising, but that could change, particularly in areas with “non-approved” specialties, such as physicians without board certification who perform cosmetic surgery in Florida.

Negotiations between otolaryngologists and plastic surgeons within the ABMS were difficult. An editorialist for a major plastic surgery journal wrote in 1996 that “it appears that the old embers of suspicion and distrust still glow too hot to permit closure of this issue” (Neale 1996, 223). Nevertheless, the groups did reach consensus: the ABMS approved a subspecialty program for each board, administered jointly. The otolaryngologists received their approval first, in 1999.

All twenty-four ABMS-approved specialty boards also recently agreed to develop requirements for all physicians to maintain their certificates throughout their careers, thereby spurring “continuous quality improvement” (ABMS 2003a). This move, if successful, will represent a giant step toward integrated education and evaluation of physicians from medical school through their entire careers. The boards are also working with the ABMS and related specialty societies to develop tools for teaching and evaluating physicians in patient communication, professionalism, and systems improvement as well as knowledge and skills. How this commitment plays out will determine the influence of specialty organizations in U.S. health care and health policy. It will also determine whether those groups can meet challenges from state licensing boards, thus maintaining a national credentialing process rather than fifty or more separate ones, and whether public or private entities such as a national quality board, health insurers, or hospitals supercede self-regulation.

Avenues for Change

One could argue that the physician production system is exquisitely attuned to the diffused American health care marketplace, meeting the demands of both doctors and patients. While some evidence shows that physician incomes are declining as managed care, Medicare, and Medicaid fees tighten, few physicians are unemployed. Physicians have become adept at responding to perceived signals in the market. This is not surprising in a climate that encourages consumer choice and specialty proliferation, and where the average doctor is an owner or participant in a clinical corporation.

Proponents of market approaches in the 1980s and 1990s suggested that shaking up the health care system would spur innovation, and, indeed, entrepreneurial medical specialists and many patients enthusiastically embraced innovations (Robinson 1999). These included the rise of single-specialty medical groups and the buying and selling of lucrative specialty corporations, such as orthopedic groups and organ transplantation teams by hospitals and health care systems. Other

innovations included the development of specialty hospitals (such as heart hospitals) and the rise of decentralized specialty office procedures (sometimes unlicensed, such as cosmetic surgery). With or without ABMS approval, newly defined subspecialty fields such as back surgery, sleep medicine, and Alzheimer's disease were part and parcel of the larger redefining movement.

However, assuming a totally free market in health care would be naïve—and blatantly ahistorical. We have long lived with the benefits and distortions of major public insurance programs (notably Medicare), tax subsidies (to employers providing workers with health insurance), federal grants (to states for Medicaid and other programs), federal assistance (for research and university-based postdoctoral training in new fields), and national policies that encourage organizations deemed socially important, such as cancer centers. States have also been a vital resource, funding training programs for family physicians. The policy question is not whether subsidy and regulation of the complex, specialized U.S. system will continue, but how, for what purposes, and by whom.

How best can we improve the overall quality, effectiveness, and efficiency of patient care? Does it make most sense—politically and operationally—to try to regulate the behavior of consumers so they seek services more prudently? Are there practical ways to improve information for consumers in a direct-access system, or to provide incentives for collaborative practice in corporate systems? Or to reform Medicare via compelling incentives for private corporations to establish new systems and for Medicare beneficiaries to participate? Or to change the behavior of specialists as providers? And at what point does it make sense for government to preserve valued social institutions such as hospitals serving the poor, medical teaching institutions, and professional organizations?

These questions have no simple answers. However, some avenues for change appear promising. First, the quality movement is off and running. The U.S. population, steeped in direct access to specialists, is unlikely to flock to HMOs that restrict access, however good their care may be. Quality data may eventually show real advantages to patients in organized health systems or through primary care. Databanks of comparable evidence from competing systems can make a compelling case for consumers attuned to making their own, often intuitive decisions in the marketplace for specialty care. Here is a strong argument for establishing a compatible, national clinical information infrastructure based on automated patient records, and for providing trustworthy analyses that can advance medicine for the public, professions, and health care organizations. The automated medical record—as a basis for public accountability—may even be a necessary precondition for effective Medicare reform.

A second positive sign of change is the apparent willingness of Congress to consider planning and regulating health care, as expressed in the eighteen-month moratorium on new starts of physician-owned specialty hospitals in the 2003 Medicare law (Section 507). This legislation specifically mentions hospitals devoted primarily to cardiac or orthopedic surgery, but the secretary of health and human services may also designate other specialties under the moratorium. The law also restricts such hospitals from adding physician investors, expanding beyond the main

hospital campus, extending services into a new specialty, and increasing the number of beds. Meanwhile, the Medicare Payment Advisory Commission (MedPAC) will study the financial impact of physician-owned hospitals on local full-service hospitals. MedPAC is already studying free-standing centers for plastic and other forms of outpatient surgery to establish Medicare payment rates. The relative value of different forms of medical service is likely to become more prominent in public debates.

The reasons are obvious. “Specialty niche” has become a common health care term, but it is a potential bombshell in its policy implications. Heart and orthopedic hospitals have shown that these specialty centers can be lucrative, but they threaten to strip services and reduce quality in neighboring general hospitals, with potentially serious implications for their bottom line. Not surprisingly, hospital associations lobbied vigorously for Section 507. However, communities also face splintering services and rising costs of care without added value (and perhaps with negative value). Common sense alone suggests that quality will decline when a community sees its general hospital lose its leading cardiologists or orthopedic surgeons.

Hospitals facing competition from new specialty hospitals, particularly those started by their own medical staff, face difficult choices. These range from launching an aggressive campaign of their own—perhaps involving expensive recruitment of another specialist team—to pressing the state legislature and regulatory agencies to limit specialist services to high-volume facilities. The first scenario involves added expenses and duplicated services; the second, expanded state and federal regulation (Devers, Brewster, and Ginsburg 2003). Community benefit and protection of well-established general hospitals may become more powerful considerations in health policy debates as efforts to curb “cream skimming” of patients yield public payoffs.

The need to coordinate and improve access to medical care can also spur strategic planning across traditional specialties. A cancer center offering multiple services, for example, may include subspecialists in radiology, surgery, gynecology, colon and rectal surgery, internal medicine, psychiatry, and pediatrics. The cancer center coordinates the efforts of professionals who come to oncology with diverse training. The concept of bringing multispecialty skills within a larger hospital or health system to patients with identifiable conditions may extend to areas such as Alzheimer’s disease, healthy aging, and stroke.

A third promising movement stems from calls by family physicians and others for renewed attention to the advantages for patients of a “medical home.” To be successful, such a movement may require substantial investment in consumer education regarding the value of primary care and (again) coordinated patient records, so both the primary doctor and the patient can discuss their options and make good decisions. A renewed market for primary care would prompt more medical students to become residents in family medicine, internal medicine, and pediatrics. The move away from such general fields is a rational economic response to present conditions, but these are not immutable. Here again public policy may seek to intervene.

Finally, the move toward maintenance-of-certification programs should attract broader policy attention. The most intense policy focus on physicians now stems from the Medicare payment system. However, except for the studies of specialty hospitals and ambulatory surgery, this focus is narrow, and it encourages specialties to compete to maximize their fees rather than set standards for the entire profession. In this instance public policy is divisive. At the very least, policy analysts need to know how U.S. physicians are being educated and in what fields, how they are evaluated by their professional organizations, what changes are under way, and how that process can advance the broader quality movement. A possible physician shortage, shortages in specific fields, quality of care, patient safety, and computerized patient records and ordering systems are best addressed in conjunction with—rather than in opposition to—specialty organizations, whose members may otherwise be reluctant to move ahead.

Overall, for the past twenty-five or thirty years, coinciding with the shift toward market-oriented health care, hospitals and physicians alike have been seen as self-interested competitors rather than guardians of the public interest or worthy of the public's trust. This dominant perspective views specialty organizations as fighting for turf, new revenue sources, and status. Fight they do. Yet they also pursue more altruistic activities. As noted, ABMS-approved specialty boards are trying to improve standards for communication with patients and peers, professionalism, and effectiveness under the maintenance-of-certification program, which all boards have endorsed. Representatives of the ABMS and the Council of Medical Specialty Societies have been meeting to expedite the program. I speak from experience as a public member representing ABMS in that group.

The broader policy question is whether health professions as well as medical schools and hospitals will be regarded as merely self-serving or as invaluable, irreplaceable social institutions. The former assumes a hostile, confrontational political and regulatory context; the latter, self-regulation to serve the public good. I hope the policy tide will turn from the former to the latter. Government and the medical profession should work together. Absent organized health care on a major scale, it is difficult to see an effective alternative.

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