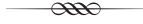


# *Preventing Medical Errors*



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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.

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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*


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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.

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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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