Patient safety and health policy: a history and review

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High-technologic industrialized medicine transformed the nature of disease and its treatment in the twentieth century, including heretofore “untreatable” diseases such as chronic diseases and cancer. The evolution from an emphasis on vitamin deficiencies and infectious diseases to technologically driven chronic disease management has been accompanied by the rise of a cost-pressured and time-pressured highly distributed complex system. Risk and harm to patients from medical management itself has arguably become one of the biggest unintended consequences of this transformation. Preventable injuries to patients are beginning to be understood in terms similar to adverse events in other complex, risky industries that have learned to rely on the language of systems and causal analysis to create a foundation for continuous quality improvement and high reliability. The terms safety culture, near-miss reporting systems and event recovery, and human factors analyses are finding their way into the health care lexicon.

Emergence of the patient-safety movement

The safety movement in health care, however, can be described as being dormant for many decades, with explosive interest and growth beginning in the mid-1990s. Although “first do no harm” has always been a primary guiding principle for physicians, there are many legal, cultural, logistic, and other barriers to obtaining an honest appraisal of the extent of preventable patient injuries and doing something about the understanding gained. A number of forces converged in the past 15 years to break down these barriers and question long-standing taboos. These forces include a relentless drive for cost containment by payors, changes in social mores that are moving decision-making authority to patients and groups of stakeholders (ie, away from the traditional
paternalistic, physician-driven model), easily available information to all on the Internet, and an emboldened media that has kept celebrated cases of gross mishaps on the front pages. In addition, several relatively recent large epidemiologic studies of harm due to medical management have been picked up by the popular press and replicated in other industrialized countries with similar findings. Despite imperfect methodologies, the studies portray an unacceptable picture of a huge cottage industry that is morally and fiscally irresponsible.

This article describes major policy initiatives that have emerged as a result of these important events. “Policy” is defined as “a plan or course of action…intended to influence or determine decisions, actions, and other matters…a guiding principle, or procedure considered expedient, prudent, or advantageous” [1]. As in the evolution of the bioethics arena since the 1960s described by David Rothman in Strangers at the Bedside [2], the world of safety and quality has brought many new professionals to the dyad of the patient-doctor relationship. Health care delivery organizations, professional societies, large payors and insurers, state and federal governments, and accreditors for medical education and hospital care all create and pursue formal policies and informal practices, and all have placed improving patient safety on the top of their policy agendas.

Although physicians and teams of researchers have played a major role in laying the groundwork for these policy decisions by producing important, early epidemiologic data, in a real sense, the modern story of patient safety and systems change is also about the combined, sustained pressure of the synergy of many players in the external environment brought to bear on the medical establishment [3][4].

In health care, an analogy can be made to the creation and formalization of the field of injury control that has its roots in the lessons of wartime and transportation safety in the 1960s. The likely end result of the safety movement over the next few decades will be the creation of a new science and field of practice in patient safety that will reflect, even more richly, similar developments in industries other than injury control. A range of thoughtful policies will be needed to institutionalize new approaches to learning, an improved balance of incentives for continuous safety improvement, and a refreshed ethical foundation for improved health care economics.

The need for standardized definitions

Iatrogenic is defined as “induced in a patient by a physician's activity, manner, or therapy,” and reflects an emphasis on the physician as the lead causative agent in outcomes (iatros, Greek for physician) [5]. The term, however, has come to have a broader meaning and is now generally considered to include unintended or unnecessary harm or suffering arising from any aspect of health care management. Problems arising from acts of omission and acts of commission are included. One of the more difficult problems in discussing patient safety is clarifying terms because the choice of terms has implications for how the problems related to patient safety are addressed. In this emerging field of study, many different definitions are used, and a common terminology has yet to emerge. This makes comparison of different studies and reports problematic.
Driving policy—the evolution of epidemiologic data and a receptive environment

Preventable harm due to medical management has been a constant, if infrequent, topic in major medical journals throughout the twentieth century. Case reports and admonitions to improve quality and safety were the norm with exception, such as the Hyderabad report on the dangers of chloroform in the late nineteenth century, and scholarly analyses pointing to the problems to come. A seminal article collecting continuous data on 500,000 operative cases for the purposes of studying mortality and morbidity marked the beginning of a new era emphasizing a scientific approach to improving the quality of care. Despite strong conflicting opinions about the methods and conclusions of this study, the impact was to raise the bar in conversations about studying the outcomes of medical management.

A national report on the potential dangers of halothane, a potent halogenated anesthetic volatile agent, appeared in the late 1960s and had the effect of greatly limiting the use of the drug due to suspected liver toxicity leading to death in isolated cases. One of the important corollary findings of the study—significant, unexplained variation in outcomes in leading medical institutions unrelated to the primary objective of studying halothane toxicity—was overlooked in the ensuing policy discussions, however.

Unexplained variation in the degree to which surgical procedures were recommended and performed across the country was elegantly documented by Jack Wennberg, MD beginning in the 1970s. “Geography was destiny” as opposed to an overarching evidence base for the best quality and safest practices. Jeffrey Cooper, PhD built on prior work by Sanazaro in health care and Flanagan in aviation by applying the “critical incident technique” to a qualitative, systematic analysis of confidentially reported incidents in anesthetic care in 1978 and 1984. This was the first time that in-depth systems analyses were applied using human factors and design-engineering principles to address the concept of preventable human error and lapses in safety from a broader perspective than one individual’s vigilance or skill in health care.

Cooper's work sparked an era of critical incident studies in anesthesiology internationally and fed into the larger movement for improved safety in anesthesia as a result of the crisis of malpractice affordability in the 1980s. The establishment of the Anesthesia Patient Safety Foundation by Ellison Pierce, MD brought the full force of a new, interdisciplinary approach to improving patient safety backed by a national professional membership organization (the American Society of Anesthesiology). In addition, the American Society of Anesthesiology supported the creation of an ongoing national data bank of closed malpractice claims for systems analysis and backed the establishment of national standards for monitoring of patients under anesthesia based on a Harvard internal policy directive.

Policy in the field of anesthesiology, therefore, advanced on several levels including expectations for insurability, legal implications for standards of care in malpractice trials, and the creation of a small Anesthesia Patient Safety Foundation research program to
improve safety. Simulators based on aviation training also began to be developed in anesthesiology during 1985 to 1992 [16] and were commercialized in 1994 [17]. These efforts by themselves, however, were not enough to galvanize the house of medicine to take a sector-wide approach to focusing on improving safety. On a policy level, the complete systems approach remained to be implemented. Major barriers existed to obtaining systematic, detailed data about harm events and threats to safety; safety was not a focus of educational curricula but rather a diffuse, ever-present concern in a patchwork quilt of other competing learning objectives, and even the attractive field of simulation remained more of an orphan development in the absence of major funding, research, and new developments in accreditation and licensure.

Lucian Leape, MD, a pediatric surgeon at Tufts University, made a midcareer change and began to investigate the appropriateness of cardiac surgical procedures while working at RAND in the 1980s. He and a team of investigators performed a large epidemiologic retrospective 1984 chart-review study in the State of New York facilitated by the vision of the Commissioner for Health, Alan Axelrod, to begin to create a reliable database to understand the incidence and prevalence of injury, preventability, negligence, and malpractice. The Harvard Medical Practice Study validated the work of a physician-attorney in the 1970s in California [18] but had larger impact because the more in-depth results were published in three consecutive articles in the New England Journal of Medicine in 1991 [19]. Adverse events occurred in 3.7% of all hospitalizations identified in a retrospective review of 30,121 charts from 51 hospitals, and 28% of these adverse events were judged by physician reviewers to be sufficiently below the standard of care to be labeled “negligent.” Nearly 20% of all adverse events occurring in hospitals were due to problems with medications.

A follow-up study by the Harvard team funded by the Agency for Healthcare Research and Quality (AHRQ; at that time, the Agency for Health Care Policy and Research) focused on establishing a better understanding of adverse events due to drugs. In-depth approaches to intensive daily chart reviews stimulated confidential reports by medical personnel, and biweekly confidential systems analyses of ongoing reports of incidents led to capture of rich data about the nature and incidence of these types of events. Publication of these results in the Journal of the American Medical Association occurred at roughly the same time as the celebrated death of Betsy Lehman, a reporter for the Boston Globe [20][21]. Lehman suffered multiple preventable drug overdoses during a complex chemotherapy program at the Dana Farber Cancer Institute and died as a result. Despite her repeated protestations to her care team that something was terribly wrong, they did not find the problem. It took 4 months for routine audit to discover a huge overdose of medication. Another article based on findings from the AHRQ-funded researchers on adverse drug events indicated that the great majority of events, including preventable ones, were not being reported to decision makers and managers who had the knowledge and power to make the needed systems changes to improve safety [21].

The sustained media fallout about Betsy Lehman's death added to tragic reports surfacing from other hospitals in the Boston community and nationally. Combined with the Boston hospitals' Adverse Drug Event study results, a gripping picture began to emerge of an
industry at odds with itself: unaccountable to the public and payors and under extreme pressure to cut costs and streamline operations at the same time that vast improvements in systems were perceived as sorely needed. The next 4 years saw the creation of the National Patient Safety Foundation at the American Medical Association, the convening of the first national meeting on patient safety at the Annenberg Center for the Health Sciences, and an ongoing federal health care quality improvement movement that began to refocus on safety.

Emergence of federal policy

In November 1999, the Institute of Medicine (IOM) published a landmark report entitled “To Err is Human: Building a Safer Health System” [23]. Produced by the IOM’s Committee on Quality of Health Care in America, the report estimated that between 44,000 and 98,000 patients die preventable deaths annually in hospitals in the United States, with many-fold more suffering injuries. The IOM report estimated that total national costs for adverse events (lost income, lost household production, disability, health care costs) are between $38 billion and $50 billion annually. The annual toll of these errors exceeds the combined number of injuries due to motor vehicle and aviation crashes, suicides, falls, poisonings, and drownings [24]. The IOM report made a series of recommendations designed to

- Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety
- Identify and learn from errors through immediate and strong mandatory reporting efforts, as well as encouragement of voluntary efforts, with the aim of making sure the system continues to be made safer for patients
- Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups
- Create safety systems inside health care organizations through the implementation of safe practices at the delivery level

The IOM report concluded that a reduction in medical errors of 50% over the next 5 years is achievable and should be a minimum target for national action. A hallmark of the report was its emphasis on subjects not normally considered under the quality umbrella, including human factors, interdisciplinary teamwork, cultures of safety, and complex issues associated with mandatory and voluntary reporting of events of patient harms and near misses.

The report quickly led to a presidential mandate to all federal agencies dealing with health care to prepare an action plan for improving patient safety. The Quality Interagency Coordination Task Force complied, and offered strong support for the IOM recommendations [25]. Only a handful of the 93 action items in the Quality Interagency Coordination Task Force report involve federal mandates:

1. Eventual deployment of a mandatory incident-reporting requirement for hospitals participating in Medicare, but only after piloting and testing of mandatory
programs involving the reporting of preventable errors and assessing the uses that consumers make of the resulting information (p. 59–60)

2. Mandatory participation in error-prevention programs by hospitals participating in Medicare, including deployment of internal incident-reporting systems, evidence-based error reduction programs, and programs designed to reduce medication errors

3. Leveraging the federal government's purchasing power by requiring health plans enrolling federal employees to include error reduction programs and provide information to those programs to enrollees

4. Expansion of the Food and Drug Administration's mandatory reporting program for blood banks (p. 60)

5. Development of new Food and Drug Administration standards for naming of proprietary drugs and for packaging and labeling (p. 64–65)

The emphasis in the Quality Interagency Coordination Task Force report on research and the development of program infrastructure rather than mandated program elements is an indirect acknowledgment of the relative immaturity of patient-safety science. It is worth noting, with respect to the mandatory incident-reporting system to be developed by the Health Care Financing Administration for hospitals, that the proposed pilot program will focus on a set of “egregious errors that are preventable and should never occur.”

A national summit on patient safety was held in September 2000, and testimony was heard from a wide range of stakeholders including consumers, payors, clinicians, regulators, accreditors, and safety-science experts. The major deliverable of the summit was a detailed research agenda for patient safety, using a framework that delineated short-term, medium-term, and long-term goals in the context of a variety of classes of potential interventions and questions that needed to be answered. This summit agenda served as the basis for a 250 million-dollar, 5-year patient-safety research plan rolled out by the AHRQ under a Congressional mandate in 2001 and 2002. Keystones of the research program include

- The creation of three Centers of Excellence: two focused on reducing medication harms and the third focused on translating safety lessons from aviation to health care
- The creation of over a dozen Developing Centers that will become the infrastructure for sustained research and development in patient safety
- A large reporting and patient-safety demonstration group of grants consuming one half of the available funds in the next 3 years, involving several statewide initiatives in both mandatory and voluntary reporting projects.

The National Quality Forum (NQF) represents another important development, although it is not confined to federal action. Originally conceived by the President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry, the NQF was established as a public-private venture in 1999. The NQF mission is to support care that is effective, safer, more efficient, and of high-quality service. To accomplish these goals, the NQF has placed a high priority on developing standardized, readily available
safety and quality performance and reporting measures. This action will create a level playing field of comparable information about safety and quality and drive appropriate purchasing decisions by payors and consumers. The high priority, strategic areas for NQF action include (1) making patient safety a leadership and management priority, (2) having organizations make an unequivocal commitment to patient safety, (3) creating a health care culture of safety, (4) initiating routine audits for patient-safety hazards, (5) implementing recognized safe practices, (6) increasing education about patient safety, (7) being accountable for patient safety, (8) recognizing and dealing with professional misconduct, (9) making patient-safety research a priority, and (10) supporting efforts to create a nonpunitive environment for health care–error reporting.

In August 2001, the NQF released a preliminary draft of what has been termed never events: serious, preventable adverse events that when reported, would form the basis for a national, state-based event-reporting system.

Bipartisan interest in improving patient safety has grown, as evidenced by Senate and House of Representative hearings and calls for legislation to reduce injuries and deaths caused by medical errors (see later discussion). The Senate Health and Education Committee and Appropriations Subcommittee on Labor, Health and Human Services, and Education have all held hearings on the issue. Bills have been introduced in both the Senate and the House to mandate reporting of adverse events, compile statistics, and develop demonstration projects to test alternate ways to report errors. Within the executive branch, the AHRQ is emerging as the leader in the development of government-sponsored research and policy development.

Finally, patient safety has become an issue internationally, with the Australian and British governments both releasing their own national patient-safety reports, calling for major changes in the way we “incentivize” safe care, train and credential health care professionals, and regulate health care. These reports have come to similar conclusions about the magnitude of the problems surrounding the delivery of safe and high-quality care and the need to redesign the system of health care. Several other countries including Germany, Denmark, and Israel are about to embark on their own national patient-safety fact-finding efforts.

Emergence of state policy

The states bear chief responsibility for licensing and monitoring health care providers, and as regulators and large purchasers, they have a key role in improving patient safety and reducing medical errors. They are central in the federal recommendations to create mandatory reporting of the most serious errors that result in serious harm or death. The focus on hospitals has raised anew the issues of state regulatory roles with regard to hospitals.

Despite the oft-quoted adage that the great majority of safety issues must be resolved at systems-redesign levels, state boards' failure to adequately discipline the very small fraction of the nation's approximately 600,000 physicians who require sanctions keeps
the theme of the bad apple center stage during dialogues on reducing medical mishaps. This failure is itself a complex systems problem. Not only is there an unexplained 14-fold variation in the degree to which states apply sanctions but the National Closed Claims Practitioner Data Bank, which is supposed to close cracks between the states and create a net of national accountability, is also thought to have spawned the unintended consequence of inducing hospitals to downcode physician violations to avoid data-bank reporting. In fact, 75% of all hospitals over a recent 3-year period had not reported a single privileges action to the National Closed Claims Practitioner Data Bank [29].

The first implication of note to be gathered from the federal reports is that change is coming for mandatory incident-reporting systems. One change that is coming is the development of a uniform set of definitions and fields that will need incorporation into existing incident-reporting systems so that data can be aggregated across state lines in a national data base. Another change is the development and implementation of a national incident-reporting system by the Health Care Financing Administration for hospitals participating in Medicare. This program will be piloted in states with existing mandatory reporting systems. There are currently few states with mandatory safety-reporting systems, however, and those are subject to poor compliance, underfunding, and lack of feedback to reporting institutions [29]. It is not clear what balance of incentives will improve this situation as the polemic surrounding serious-harm events continues or whether increased oversight using up already-scarce resources may create additional unintended negative consequences in this arena.

A second implication, acknowledged at least indirectly by the heavy emphasis in both reports on the need to fund research on patient safety in health care, is that there is much to be learned about safety in health care and that the state of safety science in health care is relatively undeveloped compared with mature, high-reliability organizations in other risky, complex industries.

A third implication from the two reports is that spending on patient safety must increase dramatically if meaningful progress is to be made toward achieving the goal set out in the IOM report of a 50% decline in medical errors over the next 5 years. The recommendations and action items in the two reports will cost money, and lots of it. On the federal level, at least, these investments are beginning to be made; the Department of Veterans Affairs, for example, has budgeted 478 million dollars over 3 years to support its patient safety program, with 137.5 million dollars already appropriated.

Role of accreditation

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) has played a major recent policy role in attempting to improve patient safety. Beginning in 1996, JCAHO was stung by media reports of the ineffectiveness of triennial JCAHO surveys in assuring safe health services. Despite winning top JCAHO accreditation status, several hospitals were found by the media and state department of health investigators to have shortly thereafter experienced tragic sentinel events involving preventable death or injury to patients. Gaps in accountability were also found in terms of lack of compliance

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with state adverse-event reporting requirements. The epidemiologic evidence of the Harvard Medical Practice Study published in 1991 that was validated by a similar national study in Australia [31] and in additional United States sites [32] was clear—hospitals were likely experiencing dozens of preventable sentinel events per year despite ongoing quality and positive-accreditation reviews.

JCAHO, therefore, instituted a “sentinel-event policy” that underwent significant revision over the next few years in response to intense feedback from health industry stakeholders. The relationship of JCAHO to the industry it regulates is complex and is discussed in a recent Office of the Inspector General report, which suggests a longer arm's length stance as more appropriate [33]. The complete sentinel policy is readily obtainable; in summary, a range of options is available to health care organizations to manage actual and potentially new legal liabilities that might be encountered during root-cause investigation of serious adverse events and sharing of event data or investigation-process data with JCAHO for accreditation purposes. The core purpose of the policy is to ensure that health care organizations are knowledgeable and able to employ in-depth systems analyses tools to better understand why serious adverse events are occurring, how to prevent them, and how to demonstrate to JCAHO that they have a functional process for doing so. Despite the small fraction of events that are reported to JCAHO versus the number that are actually occurring, over a thousand such deidentified analyses have been compiled on a Web site for easy public access and use in safety improvement.

In addition, JCAHO developed new patient-safety standards. An awareness of the importance of leadership to lead change that challenges old customs, marshals resources, and creates safety culture led to a large thrust of these new standards being directed specifically at the leadership function of hospitals and networks. One of the most controversial of this new group of standards concerns mandatory disclosure of adverse events to patients and their families.

It is widely known that most patients involved in adverse events desire three things: an apology or expression of sincere sympathy and understanding, truthful disclosure, and a pledge to investigate the causes and take proper measures to insure that the event does not happen to someone else. The fear of legal liability, unpredictably large jury awards, and experience with the vagaries of the tort and contingency-fee system, however, have led individuals and institutions to participate in a culture of secrecy around risk management of adverse events. The complete disclosure experience since 1987 of a Veterans Administration medical center in Kentucky has received recent national attention as claims of improved consumer satisfaction and possibly lower, if not unchanged, legal liability costs have been made [34]. Generalizability of these findings, however, has been limited due to the special nature of legal implications of events at federal health care facilities.

**Role of large payors**

Health care premiums rising faster than the rate of inflation have received increasing attention from large employers paying increasingly costly benefit packages. The
Leapfrog Group is an effort sponsored by Business Roundtable to leverage purchasing power to improve patient safety by redirecting patients to health care facilities that at a minimum, can show compliance with three evidence-based practices: (1) computerized physician order-entry systems in hospitals, (2) evidence-based hospital referrals for complex treatments based on annual hospital volumes or risk-adjusted outcomes when available, and (3) the presence during the day of board-certified intensive care physicians in intensive care units. The principles that support the inclusion of these first three directives include strong peer-reviewed published scientific evidence that adoption will significantly improve safety, feasible implementation in the near term, consumer understanding of the directives and implications, and the ability to easily discover whether the directives are in place at a particular institution. Although the Leapfrog Group began as a purchaser-driven program, the intent is to have it become more consumer-driven by educating consumers to be more discerning of health care services and choose safer care. Volume, price, and public recognition will all be used to progressively motivate health care providers to adopt Leapfrog Group recommendations.

A number of interesting research questions are also informing the Leapfrog Group effort; for example, How do medical errors and preventable harms reduce employee productivity and impact health expenditures? Should policy direct consumers or employers to employ leverage over providers? Which purchasing strategies work best in what market contexts to improve safety? Are positive incentives (financial reward, public recognition) more effective than negative ones (financial penalty, public criticism)? What information do consumers and purchasers find useful to make decisions about choosing safer care? In addition, a focus on ambulatory care is emerging due to the movement of the majority of care to that setting, including surgical procedures.

Possible unintended consequences of adopting the Leapfrog Group directives have been identified, such as diminishing the safety of care in watershed areas not served by institutions meeting Leapfrog Group indicators (reduced volume and access for some) and the possible lack of validity of making volume statistics a proxy for quality (ie, reinforcing errors of commission and overuse). Few health care institutions can afford the high costs of instituting computerized order-entry systems, and many have noted that they do not want to be “on the bleeding edge of technology,” given the lack of standardization of systems. In addition, network vendors have been known to leave the field or enter bankruptcy, subjecting already cost-pressed institutions to the need to re-establish another network computer system.

In some parts of the country, hospital and professional association coalitions are resisting Leapfrog Group pressures on a regional basis. That said, JCAHO is working with the Leapfrog Group to better understand the conditions under which evidence-based safety practices can be applied in different institutional contexts.

Organizational level

Health care organizations—hospitals, networks, clinics, home health care providers, nursing homes, and others—have responded to accreditation, payor, media, and public
pressures in a variety of ways. Compliance with JCAHO standards has been an important consideration, but it is not clear yet what impact these efforts will have. Clearly, most institutions are not reporting sentinel events voluntarily, given widespread fears of opening up new legal liabilities. Some organizations have chosen to establish a position of Chief Safety Officer, a structure akin to infectious disease control or quality improvement. Others have viewed safety as a key concern in all operations and services and have found ways to prioritize safety concerns and projects across the board without structural change. Many institutions have begun to focus on the topic of adverse drug events, given their prevalence, tools for improvement, and mounting evidence for cost savings (ie, return on investment).

Improved reporting systems represent a starting point for all safety work because the first issue is understanding the scope of the problem and setting priorities. Many organizations are beginning to cope with classic problems by creating a reporting culture in which reporters feel safe and invested in the process and in which reports generate timely feedback and are used to implement relevant change. Some organizations have been using home-grown paper-based reporting systems; others have invested in commercial products. New reporting systems have become available through institutional consortiums whose main function is leveraging purchasing power or benchmarking quality data, and the AHRQ safety research portfolio is now supporting over a dozen major large reporting demonstrations at the level of states and major health care networks.

Changing data-input forms, systems moving to Web-based entry, multiplying coding and causal analysis schemes, emerging confidentiality compliance issues, and varying liability concerns by state are all creating a turbulent arena. Although a task force is studying the opportunity to create a unified reporting system with agreed upon terms, definitions, and protocols for certain federal agencies, best practices for reporting and standardization of systems is not expected for a number of years.

It has become recognized that strong, sustained organizational leadership must be committed to measurably improving patient safety if change efforts are to succeed. Failures must be embraced and trust established to create a nonpunitive environment, and culture must be changed to reward messengers and move from local to systemic fixes. The Institute for Healthcare Improvement has developed and promulgated a template for assessing where organizations are on the spectrum of the ability to implement change in this area. Key themes are motivation, leadership involvement and commitment, experience with improvement, and an infrastructure to move ideas forward. Where organizations lie on this spectrum is likely to be proportional to their ability to make significant safety improvements and, thus, an honest appraisal is important to help insure success and establish a benchmark to measure change. A framework for thinking about how to begin to work on safety problems includes the themes of event severity, high-frequency events, feasibility, applicability across settings of care (leverage), and cost effectiveness of approaches. A phased-in plan would include actions to improve knowledge of health care processes; improve ability to measure existing processes, creating an infrastructure to identify, implement, and sustain change opportunities to
improve safety; and institute leadership actions to nourish safety culture. In addition, James Conway, COO of the Dana Farber Cancer Center in Boston, developed the tool “Strategies for Leadership: Hospital Executives and Their Role in Patient Safety” to aid in executives’ self-evaluation and offer a framework for how they might nourish safety culture in their institutions [36].

Educational initiatives

Medical education and training play key roles in ensuring that patients receive the best quality care. The content and methods of teaching and acquiring professional knowledge and skills continually advance in response to developments in science and society. The current major emphasis on improving patient safety and the overall quality of health services has significant implications for medical education. Strong federal policy recommendations have addressed improving provider education and training for information and systems management, teamwork, and building cultures of safety and excellence. Although other means of better managing risk and complexity must be implemented at the systems-design level, a number of these solutions (such as introducing new technologies or procedures) explicitly and implicitly depend on linked improvements in medical education, training, assessment, and feedback for their ultimate effectiveness.

In consideration of these trends and current needs, the Accreditation Council for Graduate Medical Education Outcomes Project in conjunction with the American Board of Medical Specialties described six core competencies in 1999. These competencies represent goals and processes intended to provide a framework for governing the next generation of medical education from initialization of trainees to licensure, lifelong learning, and recertification. The six competencies that comprise this framework are patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice [37]. Residents must be able to demonstrate interpersonal and communication skills that result in effective information exchange and teaming with patients, their patients' families, and professional associates … demonstrate an investigational approach to clinical practice … [and] effectively call on systems resources to provide care that is of optimal value.

Investigators performing root-cause analyses of near-miss events in patient care discovered, however, that inadequate educational preparation and organizational causes together played into creating situations with potential for significant patient harm [38]. Work in the context of improving patient safety (discussed later) adds to this impression that new training approaches must be developed along with the infrastructure and enabling systems to support individuals and teams applying the defined competencies of teamwork, information, and systems management. Physicians will be expected to apply principles of quality improvement, practice-based learning, and systems-based care, and to develop interpersonal/team coordination skills. Residency programs will be required to
provide educational experiences that allow trainees to acquire these competencies and to use validated and reliable measures to assess them.

In addition, in September 2000, the Council on Graduate Medical Education and the National Advisory Council on Nurse Education and Practice convened a joint meeting under the aegis of the Health Resources and Services Administration to discuss Collaborative Education to Ensure Patient Safety. Key recommendations included the need for systems reforms to address the dysfunctional historical divide between the medicine and nursing professions and need for improved interdisciplinary training and practice. The use of advanced reporting systems for learning, clinical computing, and practice-based research to improve complex systems of care and suggestions on how to redesign the structure of clinical education were among the position papers offered.

In risky industries such as aviation, nuclear energy, maritime, automotive, and space travel, simulation has become institutionalized for training, certification, and research purposes to insure safety. In the most advanced of these industries, there is an underlying recognition of the role that teamwork plays in error management and carrying out complex work efficiently. Medical simulation techniques have existed for millennia in simple forms and, in the modern age, a convergence of forces is maturing medical simulation as a field in its own right. These include rapidly advancing computer and robotics technologies, cognitive science, and social norms demanding improved quality and safety from complex, risky, and cost-limited health services.

Simulation with immediate video performance feedback has become a recognized method to train and assess for teamwork. Although the field of medical simulation has been rapidly growing in the past 10 to 15 years, there is a need to externally validate the relatively small number of studies and protocols for education and assessment in health care. The increasing formalization of use of Standardized Patients and Objective Structured Clinical Exams (OSCE) has occurred in this context over the past 30 years, resulting in Canadian adoption of OSCE licensing examinations and the United States National Board of Medical Examiners requiring simulations for licensure (expected in 2004) for the first time. The evolution of advanced technology simulation tools and approaches plays into these developments.

The first international meeting to galvanize policy and leadership to advance patient safety in terms of medical education was held in the fall of 2001 at the University of Chicago. The intent of the meeting was to convene leading medical educators, safety-science experts, decision makers from medical education accreditation bodies, and thought leaders to begin to create a long-term road map that developed and operationalized the vision of the Accreditation Council for Graduate Medical Education Outcomes Project and federal reports on patient safety. The forthcoming proceedings of the meeting include (and move beyond) the needs analysis and discuss such themes as ethical issues, the business case for safety education, designing and implementing team training, specifying systems thinking skills, evidence-based safety education, reflective learning, teaching the teachers, and advancing performance assessment.
Professional medical societies have begun to address patient safety in a variety of ways. The Massachusetts Medical Society created a patient-safety task force several years prior to the IOM report on patient safety and soon thereafter performed the only state survey of physicians concerning patient-safety issues, in general, and reporting issues, in particular, as well as a systematic study of interviews with state leaders. The American College of Orthopedics has begun a national initiative to eliminate wrong-site surgeries, and AHRQ in 2001 funded both the American College of Surgeons and the American College of Physicians to create and disseminate patient-safety educational curricula nationally, incorporating the best evidence about what is known to improve patient safety. Given the low impact of traditional means of education on provider behavior change and structural and cultural barriers to providing safer care, it remains to be seen what measurable impact these first-of-a-kind programs will have. An experiential novel project also funded by AHRQ will enable the American Hospital Association and a consortium of cardiologists, simulation experts, and educators to begin to explore how a new cardiac catheterization simulation device can be introduced into formal educational curricula and performance evaluations.

Ultimately, there is a fundamental ethical drive in health care to (1) allow medical trainees to learn without putting patients at risk; (2) introduce new procedures more safely whereby experienced providers are the learners; (3) adopt new methods to help shape and modify provider behaviors and attitudes; (4) systematically train and test to more relevant, inclusive core competency standards including team skills, professionalism, and systems thinking across the continuum of a provider's career; (5) improve knowledge retention; and (6) continuously improve medical education and training.

**Legal policy**

In an ideal patient-safety environment, all incentives would be aligned with systems-focused safety-oriented goals. Our current liability system, however, cuts in exactly the opposite direction, requiring that individual clinicians be blamed for adverse events that injure patients before patients can be compensated for their injuries. Moreover, our current system is enormously inefficient as it plays this “blame game,” devoting upwards of 50% or more of all dollars spent on attorney and expert-witness fees. Safety science tells us that we must move the focus from individual blame to systems improvement if we are to make real progress in reducing medical errors.

Discussion of the myriad federal and state-proposed statutory and regulatory issues concerning patient safety is beyond the scope of this article. The central issue is the creation of mandatory event-reporting systems at the level of the states, which will eventually be standardized to facilitate public accountability at the level of the NQF and Centers for Medicare and Medicaid Services (previously known as the Health Care Financing Administration). States that are unwilling or unable to comply with mandatory reporting programs that capture the requisite “never events” and targeted accountability issues will likely be required to adopt a standardized federal system.
Tort reform is unlikely to provide relief in the near future, given the stimulus of a widely appreciated epidemic of preventable patient harms in an industry that has been perceived to be slow to adopt evidence-based practices. Indeed, the third major malpractice crisis of the past 30 years is well underway, with insurers leaving the market due to fierce competition in the 1990s and artificially low premium rates, historically low reinvestment rates due to limited inflation, and increasing numbers of very high jury awards that leave reinsurers unable to accurately predict future losses. It is hoped that in this environment, insurers will be more likely to incentivize the adoption of and experimentation with safety practices through a trial of premium discounts.

Confidentiality issues, especially those relating to the Health Insurance Portability and Accountability Act, have been dealt with in a recent review. That said, such matters are a moving target. In March 2002, the George W. Bush administration pushed back a key element of the new patient protection legislation, essentially repealing a rule that required patients to give written consent before their records are transferred to other medical facilities, pharmacies, or insurance companies. A notification of their privacy rights would be substituted for the consent procedures. Health and Human Services officials have attempted to placate patient advocacy groups by pointing out that protections have been strengthened by enlarging the scope of the definition of what can be considered “marketing” and, thus, requiring specific record release by patients and their families.

What are the new challenges in health care?

Alignment of external and internal incentives

The health care system has only recently begun to approach patient safety in a more systematic way. The traditional approach within medicine was to stress the responsibility of the individual and to encourage the belief that the way to eliminate adverse events is to get individual clinicians to perfect their practices. This simplistic approach not only fails to address the important and complex systems factors that contribute to the occurrence of adverse events but also perpetuates a myth of infallibility that is a disservice to clinicians and their patients.

There is a long tradition in medicine of examining past practice to understand how things might have been done differently; however, morbidity and mortality conferences, grand rounds, and peer reviews all currently share the same shortcomings: a lack of human factors and systems thinking, a narrow focus on individual performance to the exclusion of contributory team and larger social issues, hindsight bias, a tendency to search for errors as opposed to the myriad causes of error-induction, and a lack of multidisciplinary integration into an organization-wide safety culture instead of perpetuating a code of silence about potentially embarrassing or litigious events. The focus on the actions of individuals as the sole cause of adverse events inevitably results in continued systems failures and the resultant injuries and deaths of patients.
Unfortunately, shocking as they are, the IOM numbers probably underestimate the extent of preventable medical injury for two important reasons. First, they are based on data extracted from medical records. Many injuries and most errors are not recorded in the medical record, either by intent, by inattention or, more likely, because they are not recognized. The second reason is that the IOM-report estimates of the total burden of medical injury do not include injuries that occur in ambulatory care. Ambulatory care has expanded several-fold since 1984, with the majority of surgical procedures now occurring in ambulatory settings. None of the complications associated with outpatient care were included in any of the studies unless they resulted in hospitalization. In 1997, 31 million procedures nationally were performed outside of hospitals. We know very little about the extent of adverse events in ambulatory care, but a recent study revealed a 10% error in office prescriptions. The State of Florida recently put a moratorium on major office-based surgery due to a rash of deaths highlighted in the media.

We must now honestly address the increased public anxiety caused by the IOM report and the danger that our patients' visceral fear of a system now publicly branded “unsafe” could lead to exacerbated blame and litigation [42]. The public discussion of the IOM report has the potential to transform the health care system. For this to happen, however, all stakeholders must thoughtfully and carefully move forward, motivated by a common goal, instead of instituting quick fixes that encourage divisiveness, gaming, and noncompliance.

Attributing errors to system failures does not absolve physicians and nurses of their responsibility to be careful. In fact, it adds to that duty the responsibility to admit mishaps and errors, investigate them, and participate in redesign of a system for safety—a challenge much more difficult than punishing wrongdoers. Virtually all of the progress in safety thus far has been derived from using multiple converging techniques to discover underlying vulnerabilities and potential paths to failure and innovating ways to cope with the potential form of failure in the context of the changing pressures and demands that is health care. The study of “errorology,” the search for the number of errors, is misguided and leads to an unproductive and ultimately divisive debate about an inexact, socially charged, and poorly defined quantity. The unwitting use of different referents for the label “error” confuses the discussion and limits progress.

The error or mishap should be the starting point of study, not the ending point. Using error as a cause of break in human performance is wrong because it misses the confounding factors and systems factors that influence the actual human cognition and performance. In addition, hind-sight bias plagues the literature on error and any attempt to estimate the nationwide rates of preventable deaths and hinders postevent learning and improvement.

Summary

Policy initiatives on many fronts have converged to improve patient safety. A major tension that characterizes this process is the attempt to achieve a balance between learning and control in complex systems with technical, social, and organizational
components. Efforts to improve learning are marked by better information flow, discovery, flexibility in thinking, embracing of failures as learning opportunities, and core incentives to promote voluntary participation of all stakeholders in the process. Efforts to improve accountability are traditionally marked by public disclosure, meeting of certain widely disseminated standards, availability of performance measures, exposure to legal liability, and compliance with mandated directives (statutes, regulations, accreditation requirements). In some sense, these directions are mutually exclusive. Although a more collaborative regulatory-improvement model would be helpful in creating an industry-wide safety culture, it is likely that learning and accountability functions will follow separate tracks. An exception would be policy that stimulates organizations to comply with regulation by showing how well and by what methods they are learning and how others can profit from these experiences.

Any approach to improving patient safety should, at a minimum, include a nonpunitive in-depth mechanism for reporting incidents, postincident evaluations for identification of system changes to prevent subsequent occurrences, and state-guaranteed legislative protection from discovery for all aspects of information gathered to improve patient safety. Nonpunitive approaches have yielded useful results in other industries.

State and federal courts, state licensing boards, and accrediting bodies such as JCAHO all function to maintain accountability and standards; however, the very fear of existing legal liability or its misapplication are the greatest hurdles to pioneering patient-safety efforts. The health care system needs to transform the existing culture of blame and punishment that suppresses information about errors and adverse events into a culture of safety that focuses on openness and information sharing to improve health care and prevent adverse outcomes.

Education and leadership will be most important to creating and sustaining a strong safety culture and arguably the most important defense against preventable harms. Safety culture cannot be legislated, just as the old adage states that it is easier to pull rather than push a piece of spaghetti. Given the imbalances and inefficiencies of market forces in health care, perverse incentives that have strengthened resistance to change, and secrecy when it comes to adverse event information, however, it is likely that policy initiatives will continue to play an important role in the transformation of the industry to more highly reliable, safer levels of care.

References


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