

# Patient Safety: Review of the Contemporary American Experience

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In the language of safety science, health care workers provide direct patient care work at what is known as the “sharp end.” The sharp end refers to those points of vulnerability in the care delivery system where errors are likely to show up. The work of management is referred to as the “blunt end.” Blunt end work – policies, procedures, allocation of resources – creates latent or hidden conditions for error, which later emerge at the sharp end. In contrast to the traditional health care response to accidents that punishes the worker at the sharp end (e.g. the person closest to the error), a safe culture requires that management assume major responsibility for safety and implement changes at the blunt end that will make the sharp end safer.

The past several decades have borne witness to unthinkable technological progress in modern medicine, producing miracles in terms of cures for conditions and illnesses considered incurable not long ago. Paradoxically, these advances have introduced new complexities and new opportunities for error into an already complex system. Health care is a high-risk industry. Much like industries such as aerospace, aviation, and nuclear power, health care must grapple with the reality that complex systems and human beings are fallible, and in so doing, admit the possibility and probability of accidents. Health care has increasingly recognised its high-risk status over the past decade, and as a consequence the topic of medical error has gained prominence as a public health issue in the United States. This article provides an overview of the patient safety movement in America.

## WHY IS PATIENT SAFETY IN PUBLIC FOCUS?

In the mid-1990s, patient safety initiatives began in earnest in the United States following several highly publicised accidents. In Texas, an infant died shortly after receiving a ten-fold overdose of digoxin. In Florida, a seven-year-old boy died following administration of the wrong medication prior to minor surgery, and in another Florida case, a wrong leg was amputated. In Massachusetts, a well-respected health care reporter battling breast cancer died from a chemotherapy overdose.

Two facts made these events particularly noteworthy and captured the attention of the media. First, each of the institutions in which the accidents occurred enjoyed a superb reputation. Second, most of them had not only received accreditation from the Joint Commission on Accreditation of Healthcare Organisations (JCAHO), but had received accreditation with commendation. Thus, questions were raised about how such accidents were possible and about the meaning of accreditation. The patient safety movement was launched in this environment, and early initiatives focused on raising awareness of the problem of medical error and gaining understanding of its complexity.

Errors are a common occurrence in health care, and there is a remarkable concordance of major findings about the many thousands of patients who are injured each year as a result of medical error. Empirical evidence documenting harm to patients from medical care is not new<sup>(1)</sup>. Research showing that health care professionals often make mistakes that harm patients was published almost forty years ago, recording that as many as 36% of admissions to a general medical unit and 13% of admissions to intensive care units followed adverse events, most often due to medications<sup>(2)</sup>. For almost two decades, medical error was either explained away as the unfortunate and unavoidable consequence of powerful, modern therapies rather than health care professionals’ mistakes, or its cause was not addressed at all<sup>(3-5)</sup>.

In the mid 1980s, one study “broke rank” and proffered a unique explanation, suggesting that up to half of all admissions related to error were due to “lack of attention on the part of physicians or patients<sup>(6)</sup>.” This was followed by the publication of the Harvard Medical Practice Study (HMPS) which introduced the subject of medical error as a topic worthy of formal academic study<sup>(7)</sup>. Relying on a retrospective medical chart review from 51 hospitals in New York State, HMPS found that almost 4% of patients suffered adverse events as a result of their medical care<sup>(1)</sup>. Negligent care accounted for 28% of adverse events; of these, 6% of patients were

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permanently injured and 25% of the patients died. Despite initial resistance to these findings from the medical community, the HMPS was replicated and validated in a study of discharges from acute care hospitals in Colorado and Utah<sup>(8)</sup>. Yet another replication, conducted in Australia in 1995, attracted considerable interest when it reported that half of the errors were preventable<sup>(9)</sup>.

As research began to identify which types of patients are likely to experience error and which areas of the health care organisation present the most risk, it was learned that while all patients are vulnerable, those who are oldest, most critically ill, and subject to the riskiest interventions are at greater risk of harm<sup>(10)</sup>. Not surprisingly then, surgery results in a considerable share of error. However, negligent injury is no more common among patients undergoing high-risk surgery than among medical patients.

Despite the fact that most health care in the United States is provided in the ambulatory setting, there is little research and information on the incidence and prevalence of errors in any setting outside the hospital. What we do know is that preventable adverse events are more common among medical than among surgical cases, and errors typically consist of failures in diagnostic judgment (in formal terms, failures of action or incorrect acts) and preventive care (failures to act or errors of omission)<sup>(11)</sup>. A single chart review study of medication-related complications in primary care sites identified adverse drug events among 3% of patients. The most frequent complications were allergic reactions, gastrointestinal symptoms, and neurological complications; 13% were preventable<sup>(12)</sup>.

Debates have emerged about the validity of these studies, primarily questioning the true number of excess deaths attributable to error. Analyses of population-based studies raise concerns about the reliability of clinicians' judgments about error and failure to account for the morbidity of hospitalised patients before calculating adverse event rates<sup>(13,14)</sup>. The most important limitation of the research is the reliance on medical record review, because events that were not reported or recorded are unknown; however, experts are in agreement that the number is substantial, a fact corroborated by observational methods that demonstrate higher error rates<sup>(15-19)</sup>. There is a definite need for more robust studies of medical error, and these studies must focus on all health care settings and conditions. Despite the methodological debates, the bottom line is that preventable medical error is a serious public health problem.

Employers, the largest purchasers of health care in the United States, have realised not only that medical errors are frequent but that they are costly. The total

national cost of medical error is estimated to be between \$17 billion and \$29 billion<sup>(20,21)</sup>. Direct health care costs represent over one-half that amount. Moreover, for every 100 admissions to the hospital, there will be two preventable adverse drug events, adding an extra \$4,700 to each admission and 10% to overall utilisation; that is, extended length of stay and repeated tests and procedures<sup>(22,23)</sup>. One study estimates that employers spend more than \$1,800 per year per employee on medical premiums and productivity losses from poor-quality care<sup>(24)</sup>. Precious human, physical, and fiscal resources are wasted when errors occur. In other words, if errors were reduced, the money lost to medical error would be available to supply other desperately needed health care resources.

When employers compare high medical error rates to the low percentage of defects they strive for in their own production and service operations, they see a clear opportunity for improvement<sup>(25)</sup>. They calculate the impact of unnecessary deaths and injury from errors on their covered population and see workplace accident prevention programmes yielding far fewer losses than a hospital or clinic visit. Error rates in low-back-pain treatment, post-heart attack drug therapy, mammography screening, and inpatient medication accuracy have been shown to be more frequent than errors in airline baggage handling<sup>(26)</sup>.

Attempting to reduce the share of their health expenditures that are wasted on harmful "care" and the extra costs of attempting to recover from avoidable mistakes, employers and business coalitions have initiated strategies to "force" safety in health care. Facing ever-increasing inflation in health benefit premiums, employer coalitions and consultants have developed new purchasing policies and consumer information programmes to reduce the cost of poor-quality health care, including error.

Leading employers and business coalitions are asking their health insurance plan administrators to tell them how medical errors are being monitored with health care providers and what steps are being taken to reduce these problems in the future. For example, a group of eight coalitions within the National Business Coalition on Health are standardising questions on patient safety for use in Health Maintenance Organisation Requests for Proposal/Information in major metropolitan markets across the country. They are also pushing accrediting organisations to revise their standards and criteria to include active error prevention programmes assessment in hospitals and other care settings<sup>(27)</sup>.

As consumers receive more and better information, in print and via the Internet, they will be ever more attuned to the substantial chance of error in health care.

The growing body of information available to consumers provides questions and sources of information to use in reducing the chance of harm. Increasingly, health care providers will see patients who expect to assume a primary role in making choices about their care and expect to partner with providers in the maintenance of good health.

The Institute of Medicine (IOM) of the National Academy of Sciences, is an independent research institution that influences public policy. In late 1999, the Institute of Medicine (IOM) published a report entitled *To Err Is Human: Building a Safer Health System* that quickly and dramatically changed the landscape of patient safety<sup>(28)</sup>. The news that as many as 98,000 individuals die annually from preventable medical error captured the attention of both the lay and professional public, and established patient safety as a priority issue on the American national agenda. The nature of patient safety activity also changed.

Americans followed the report closely as was evidenced by expansive news reporting. The citizenry's expectation of safe health care, coupled with the realisation expressed in the IOM report that care was unsafe, created public outrage. That outrage has been manifested in numerous actions taken by government, business, regulatory groups, and others that are described in greater detail later in this paper.

Original efforts had focused on producing evidence about the existence of medical error in order to create awareness. Those efforts were followed by research that described the nature of error in medicine – for example, types of errors, where they occurred, and their frequency and apparent causes. With the publication of the IOM report, a demand was created for practical applications of existing knowledge.

The publication of the IOM report constituted a watershed event in the politics and practice of health care in the United States. One of its major accomplishments was to introduce concepts that carry the potential to transform health care. These “transforming concepts” send powerful messages. For example, one message conveys the notion that most errors occur not because of flawed humans, but because of flaws in poorly designed systems. Another message is that the design of safer systems of care is contingent on substantial change in the culture of health care.

#### **MOVING TO A CULTURE OF SAFETY**

To date, a formal definition of a “culture of safety” has not been proposed, but the characteristics of a culture of safety can be deduced from lessons from high reliability organisations and from the initiatives of cutting-edge health care organisations. For example, blameless voluntary reporting, analysis, and resolving

action to reduce risk are hallmarks of a safety culture, as is an unflagging commitment to patient safety from the leadership of the organisation<sup>(2)</sup>. Other elements include open communication about safety and error that includes the patient, and a focus on individual accountability. A safety culture requires trust, knowledge, and appropriate system design.

The culture of health care as it currently exists presents enormous barriers to patient safety. The greatest barrier is what is euphemistically called the “blame and shame” mentality. When an error occurs, the typical response is to blame, criticise and sanction the individual who happened to be closest to the failure or accident. The vast majority of professionals who are involved in accidents are caring and conscientious and are devastated by the experience of failure. Personal feelings of guilt are compounded by the isolation, shame, and secrecy that surround errors. As a consequence, all learning stops and the opportunity to develop predictable prevention methods is lost. Accordingly, the conditions that produced the accident persist, and another similar failure has a high likelihood of occurring.

Societal judgment mirrors the health care culture. This is reflected in regulatory and legal systems that emphasise individual culpability and punishment for error, rather than addressing vulnerabilities inherent in system and process failures. Licensing boards in medicine, nursing and pharmacy often focus narrowly on individual culpability for error and look to limit or remove practice licences. This approach can jeopardise the livelihood of professionals and perpetuate an environment of fear, which results in most errors being driven underground due to fear of blame and punishment.

The other characteristic of the health care culture that poses a major barrier to safety is the hierarchical nature of medical practice. For example, the hierarchy that exists between patients and physicians intimates that the doctor is the expert and the patient a subordinate recipient of services, rather than a partner in his or her own care. This same hierarchy exists between the several health professions and results in an *authority gradient*. The authority gradient refers to the interpersonal dynamics present in any situation of real or perceived power. The authority gradient is not unique to health care and exists, for example, in the military and the airline industry.

In a situation governed by the authority gradient, the truth, particularly if it is perceived to be bad news, is often withheld. This presents a huge risk for error. To confront the negative impacts of the authority gradient in the airline industry, pilots and co-pilots receive mandatory communications training. In this common practice, dubbed *crew resource management*

*training*, all crewmembers are not only trained to communicate with each other more effectively, but empowered and obligated to report observed system or process vulnerabilities that might lead to an accident.

All changes to the health care culture must facilitate movement away from a culture of blame and shame. As opposed to ascribing error solely to individual failure, a culture of safety brings errors and near-misses out into the open for learning. Errors are valued as learning opportunities to make the delivery system safer. At the tactical level, this means reducing reliance on vigilance and memory and focusing on system improvements so that avoidable errors are revealed and corrected before they harm patients.

The magnitude and complexity of transitioning to a culture of safety can seem overwhelming. Priorities must be established to make the task manageable. Some of these priorities are: 1) implementing a systems approach; 2) training health care professionals appropriately; and 3) involving consumers as partners in their care.

The systems approach makes the fundamental assumption that health care-related or medical errors are, with rare exception, not caused by incompetent or uncaring physicians, nurses, or pharmacists. People make mistakes no matter how hard they try. Analyses of errors clearly reveal that underlying vulnerabilities in the system are the primary problem. This means that the health care system must cease blaming individuals and design checks and balances (“fail-safes”) into care delivery processes to catch and correct errors before a patient is harmed. One way to do this is to institute techniques and strategies that have been tried and proven successful in other industries. Another is to speed up the adoption of information technology and automated systems that other industries have embraced. The other major approach is to institute voluntary reporting processes with peer review protection and to study errors and “near-misses” for the patterns that inevitably emerge. Solutions to remedy local system problems can then be designed.

The training of health care professionals often occurs in “silos”, separate and distinct domains that lack the transparency and connectedness that characterise a system. This model is inconsistent with error reduction, an endeavour that requires high-level team functioning and effective communication.

The emergence of better-informed patients who are determined to make decisions about their care in collaboration with health care providers will help change the culture of health care. Effective communication that engages the patient and family as part of the health care team has been shown to reduce errors. Health care providers have an obligation to

communicate the seriousness and complexity of medical interventions to patients, and to disclose information about errors that affect patients to those patients and their families.

There are a host of other interventions that can be implemented to change the culture of health care, such as working constructively with the media, obtaining institutional leadership commitment, and moving towards arbitration as an alternative to legal remedies. However, the priorities outlined in this paper have been selected for a specific reason: If health care commits to safeguarding individuals, then it must fully understand the processes of delivery systems, and from this be willing to analyse, evaluate, and develop changes to continuously improve system design. The results of these efforts will produce a more efficient model of care, delivered by a more knowledgeable and team-focused workforce who recognise the significance of their roles in protecting individuals and reducing risk in care delivery.

The Institute of Medicine’s latest report on the quality of health care in America did not garner the same media attention as did *To Err is Human*. However, *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century* makes a bold statement that the health care system as it is currently structured cannot consistently deliver effective care in a safe, timely and efficient manner<sup>(29)</sup>. The obvious conclusion is the imperative for fundamental change in the organisation and delivery of health care in America. This report emphasises the “quality gap,” between the care that is presently delivered and the care that could be delivered. The report acknowledges the growing complexity and capacity of science and technology to improve quality. It lays bare the fact that technology’s capabilities have far exceeded the health care system’s ability thus far to effectively manage technologies to improve care delivery. Health care practitioners are inundated with information because the knowledge base has become so vast. The number of drugs, medical devices, diagnostic techniques, and other technological supports continues to grow. This creates a tremendous challenge for the clinician’s ability to provide care based on the best and most current scientific evidence.

*Crossing the Quality Chasm* also recognises the need for services to be organised in ways that reflect the changing patient population (i.e. people living longer and needing effective systems of care to manage chronic conditions common to older age). The current system is not organised to provide the full complement of services for effective and efficient treatment of chronic illnesses, which affect 100 million people in the U.S. and limit the daily activities of one in six persons. It is a contradiction in logic that the majority

of resources are devoted to the treatment of chronic disease with little attention to strategies for preventing them. The decentralisation of the current system is addressed in the report as a significant problem that creates unnecessary complexity and confusion and promotes waste.

#### **MAJOR U.S. INITIATIVES IN PATIENT SAFETY**

The National Patient Safety Foundation (NPSF), launched in 1997, is an independent, nonprofit research and education organisation dedicated to the measurable improvement of patient safety in the delivery of health care. Founded by the American Medical Association, CNA HealthPro, 3M, and Schering-Plough Corporation, NPSF works collaboratively with a broad base of constituents to accomplish its goal of guiding the transition from a culture of blame to a culture of safety. NPSF seeks to achieve its goal through the following objectives: raising awareness, building a knowledge base, creating a forum for sharing knowledge, and facilitating the implementation of practices that improve patient safety.

The Joint Commission on Accreditation of Healthcare Organisations (JCAHO) is the major standards-setting and accrediting body in health care in the United States<sup>(30)</sup>. Founded in 1951, JCAHO's mission is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organisations. The Joint Commission evaluates and accredits nearly 18,000 health care organisations and programmes in the United States and is an independent, not-for-profit organisation.

JCAHO plays a significant role in patient safety in United States through the design of standards to improve patient safety and reduce risk to patients. JCAHO's patient safety standards recognise that error reduction requires an integrated, coordinated approach. Accordingly, the standards emphasise integration of existing and newly-created patient safety activities with an identified focus of accountability within the organisation's leadership, and the creation of an environment in which patients, their families, and organisation staff and leaders can identify and manage actual and potential risks to patient safety. Importantly, in terms of culture change, the JCAHO patient safety standards emphasise focus on processes and systems, and minimisation of individual blame or retribution.

The prominent business leadership group in patient safety is The Leapfrog Group, a consortium of 96 of the country's largest employers<sup>(31)</sup>. Organised in response to the problem of health care error,

this coalition of companies that provide health care benefits to their employees was created to help save lives and reduce preventable medical mistakes. It is a voluntary programme aimed at mobilising large purchasers to alert the health care industry that breakthrough improvements ("big leaps") in patient safety and customer value will be recognised and rewarded with preferential use and other intensified market reinforcements. The Leapfrog Group also provides consumers with information to help them make more informed choices about hospitals.

The Leapfrog Group has developed three initial methods or practices to improve patient safety: the implementation of computerised prescriber order entry (CPOE) systems in hospitals; evidence-based hospital and clinic referrals for patients requiring elective procedures and treatments; and staffing of intensive-care units with physicians certified (or eligible for certification) in critical care medicine. These standards are the primary focus of the Leapfrog Group's health care provider performance comparisons and rewards.

There are four major initiatives to reduce medical error at the federal level: legislative proposals; research funds appropriated by Congress and administered through the Agency for Healthcare Research and Quality (AHRQ); coordination of patient safety initiatives throughout the federal health care system via the Quality Interagency Coordinating Task Force (QuIC); and the agency work of the National Center for Patient Safety at the Veterans Health Administration within the Department of Veterans Affairs<sup>(32)</sup>.

AHRQ's research initiative represents the federal government's largest single investment to address medical error. With over \$50 million appropriated by the United States Congress, 94 new research grants, contracts and projects have been funded which are now being carried out at state agencies, major universities, hospitals, outpatient clinics, nursing homes, physicians' offices, professional societies, and other organisations across the country. The agency funds several special categories of patient safety-related research, including demonstration error-reporting projects; information technology in error prevention; impact of working conditions on patient safety; innovative approaches to patient safety improvement; and dissemination of research results.

The Quality Interagency Coordinating Task Force (QuIC) is also coordinated by AHRQ<sup>(33)</sup>. Established in 1998 in accordance with a Presidential directive, the purpose of the QuIC is to ensure that all federal agencies involved in purchasing, providing, studying or regulating health care services work in a coordinated manner toward the common goal of improving quality of care. Finally, the Secretary of Health and Human

Services has established a Patient Safety Task Force within the Department of Health and Human Services to coordinate a joint effort among several department agencies to improve existing systems to collect data on patient safety. The federal agencies leading this effort include the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS). The goal of this Task Force is to identify the data that health care providers, states, and others need to collect to improve patient safety.

The National Center for Patient Safety (NCPS) of the Department of Veterans Affairs (VA) has demonstrated an uncompromising commitment to reducing and preventing adverse medical events while enhancing the care given to patients<sup>(34)</sup>. The NCPS represents a unified and cohesive patient safety programme, with active participation by all of the 172 VA hospitals supported by dedicated patient safety managers. The programme is unique in health care, focusing on prevention rather than punishment and applying human factors analysis and the safety research of high reliability organisations (e.g. aviation and nuclear power) targeted at identifying and eliminating system vulnerabilities.

At the federal level, legislation introduced by Senators Kennedy, Frist, and Jeffords focuses on the identification, evaluation, and reporting of health care errors through specific mechanisms, namely the development of error reporting systems with legal protections, for both mandatory and voluntary reporting. As of this writing, passage of this legislation has been impeded by the protests of litigation attorneys. Legislative initiatives at the state level are also underway. To date, fifteen states have legislated the implementation of patient safety reporting systems<sup>(35)</sup>.

#### **LEARNING FROM HIGH RELIABILITY INDUSTRIES**

A *high reliability organisation* (HRO) can be defined as an organisation that carries out high-risk activity with low rates of error<sup>(36)</sup>. HROs share certain characteristics such as a leadership commitment to policies, procedures, and resource decisions that influence the safety of work processes, and a prevailing culture of safety that supports learning and willingness to change<sup>(37-40)</sup>.

High-risk industries that have achieved high reliability, such as aviation, aerospace, chemical processing, and nuclear power, provide examples that can be examined for their adaptability to health care. HROs not only acknowledge risk; they also audit it.

They pay great attention to process control, specifically, developing rules, procedures and protocols; investing in training; building in strategic redundancies to avoid error; fostering teamwork development; and migrating decision making to the front lines. The leadership of HROs makes a visible and unflagging commitment to error reduction, and reporting of errors is rewarded. HROs are flexible in decision-making and resilient in the face of unusual circumstances. Aircraft carrier flight deck operations are often used as the prototype because they run inherently hazardous operations for long periods of time but experience low accident rates. Several characteristics explain their success<sup>(41)</sup>. HROs are preoccupied with the risk of failure and therefore remain collectively vigilant at all times. Refusing to over-simplify interpretations of events, leaders in HROs cultivate a wide variety of opinions and train their workers to assume less and notice more. Experience and expertise are valued above hierarchical prerogatives in crisis situations<sup>(42)</sup>. Every member of the team has the authority to stop any given process to prevent an accident, regardless of their rank or status in the organisation.

Unlike its high-risk counterparts, the health care industry cannot claim safety as its top priority, or *mission one*. Other industries use "six sigma" as a measure of acceptable error rates. Six sigma on the normal curve represents 3.4 defects per million activities or opportunities. Contemporary research in health care quality indicates that an "acceptable" error rate in our industry could be safely expressed as *one* sigma, or approximately 294,000 defects for every million opportunities - a stark testimony to safety's stature among corporate health care leadership. To date, few institutions include safety goals in their mission statements, few boards review safety performance indicators at their regular meetings, and few hospital CEOs hold the leaders in their hospitals accountable for fostering safety.

Lessons from the few organisations leading patient safety in the United States (for example, Children's Hospitals and Clinics in Minneapolis and the Veterans Healthcare Administration) indicate that the organisational transformation to a culture of safety requires a steadfast leadership commitment and takes about five years to achieve. Actions employed in hospitals that have significantly enhanced patient safety include the following:

- The governing board and senior management declare patient safety to be an urgent priority and demonstrate this by allocation of resources.
- The safety system is built on current, solid knowledge from multi-disciplinary sources, such as process engineering and human factors sciences.

In addition, lessons learned from other industries, such as aviation, are applied to accelerate an organisation's efforts and safeguard against well-intended but misdirected interventions.

- Policies and practices are clear concerning disclosure of mistakes, failures, and near misses to the appropriate professional sources and to patients and families. The principle of full disclosure and truth telling is the basis for trust and accountability.
- The culture engages the patient and family in the care process.

High reliability organisations draw heavily from the field of human factors engineering. A basic premise of human factors is the recognition that human failures are, for the most part, the result of inevitable, "hard-wired" limitations of human cognition or endurance, including the limits of short-term memory, sustained vigilance over long periods of time, judgment impacted by lack of sleep, and problem solving under stress. Thus, the human factors sciences emphasise methods of improving human performance in complex work systems, doing so by recognising that work systems must be designed to compensate for inevitable human fallibility. Experts identify four different dimensions that apply directly to improving patient safety: the design of equipment or tools, the design of tasks, environmental conditions of work, and selection and training of staff<sup>(43)</sup>. Lessons from human factors become more important as advanced information system technology is used to improve safety. In health care as in other high-risk industries, particular attention must be paid to the human/computer interface and ways in which this alters patterns of work and information flow. Failure to do so is expected to create new paths to failure<sup>(44-47)</sup>.

In contrast to other high-risk industries, health care introduces new technology with little thought on how to use it safely and efficiently and regularly hides mistakes and failure. For a culture of safety to become a reality, major challenges have to be recognised and overcome. One major challenge is the blaming environment that characterises most health care organisations and punishes people for making mistakes. Unlike other high-risk industries, the prevailing misconception is that the individual is entirely to blame for his or her mistakes and that punishment will serve both to improve performance in that individual and to deter error in others. Abundant evidence in the human factors and cognitive psychology literature recognises that most human errors are symptoms of underlying systems failures.

## MAJOR CHALLENGES IN BUILDING A SAFE HEALTH CARE SYSTEM

Securing meaningful commitment by the leadership in health care organisations remains a challenge. However, more and more leaders of health care organisations are exerting their political will and affirming that patient safety is their ethical obligation. They are beginning to lead the patient safety challenge because it is the right thing to do. It is an ethical imperative. These leaders take a leap of faith, believing that safer care for patients results in lower costs due to fewer accidents. A leader who actively and visibly accepts responsibility, demonstrates accountability, and leads by example, fulfils his or her ethical responsibility to the patient. Leadership in this mode means to cultivate and demonstrate the organisation's commitment to patient safety within the community that it serves.

Good news and bad news alike about patient safety are shared on a regular basis with the organisation's board of trustees. For example, management must address such issues as work hours, workloads, rotation schedules, sources of distraction, staff turnover, unit reassignment, and use of temporary staff. Everyone in the organisation is engaged and held accountable for identifying weaknesses in existing care delivery processes and designing strategies to avoid reliance on memory through the use of protocols, checklists, and standardisation of work processes. Team training and simulation are provided for physicians and other health care professionals assigned to work together in teams.

Error reporting is another leadership challenge. The purpose of voluntary reporting is to learn from mistakes and near misses in order to design safer systems. For a voluntary reporting system to be effective, reporting of errors by physicians, nurses and pharmacists must be rewarded and not discouraged. Thus leaders must openly discuss with everyone in the organisation the importance of patient safety, the importance of surveillance, and the expectations for reporting patient safety concerns and errors. Leaders must celebrate success in improving the reporting of errors and must communicate how reporting has been used in improving in systems to prevent future opportunities for error.

The National Patient Safety Foundation has articulated the requirements of a voluntary reporting system<sup>(48)</sup>. To be effective, a voluntary reporting system must be independent of political and regulatory enforcement that would influence its activity. It must be confidential so that no individual or organisation is identified. A voluntary reporting system must be non-punitive, by design and in operation, and must be objective, with an independent technical analysis of

reports. Finally, it must be equipped to receive reports from anyone having direct experience with the event.

Fearing retribution for reporting errors, health care personnel tend not to report errors they can hide and are hesitant to discuss them. As a result, voluntary reporting identifies few of the errors that actually occur. This means that until the culture changes, voluntary reporting is of little value in assessing the magnitude of errors and making subsequent systemic changes that will improve patient safety. For these changes to occur, leaders must work to create an environment where reporting errors is the rule rather than the exception.

The legal or tort system is another barrier to patient safety in the United States. From a public policy perspective, an individual malpractice claim compensates patient and/or family for loss sustained because of the negligence of a caregiver. The financial award is a penalty intended both to punish the individual caregiver and to encourage a change in practice or behaviour to avoid repetition of the adverse event or circumstance. In the discovery process and in the telling of the story about the events in court, the patient and the family may gain a better understanding of the events that contributed to the negative outcome. In some instances, this may be the only way for a patient or family to obtain an adequate understanding of the circumstances to allow them to resolve the loss and move forward with their lives. Often though, the legal process becomes protracted and adversarial, fostering antagonism between patient or family and caregiver and doing little to allay the grief of all involved. Typically the defendant's professional liability carrier will erect a "wall of silence," discouraging contact between practitioner and patient. Tension and courtroom posturing follow, eroding what remains of the trust and confidence once shared between the two.

Physicians fear being reported to the National Practitioner Data Bank (NPDB), a listing of practitioners who have been involved in serious error or malpractice complaints. To protect a physician defendant from being reported to the NPDB, liability is often ascribed to nurses, pharmacists, or other named defendants. Clearly this process creates a significant incentive for health professionals to conceal errors.

## CONCLUSION

The rational drivers for safety in health care lie in both the public and private sectors. Because a culture of safety requires such a massive transformation of the health care system, a greater vision is required; that is, the joining of public and private forces to form a partnership for safety. The public and private consortium now addressing quality measurement under the auspices of the National Quality Forum is

one example of such a partnership. Aside from public and private partnerships, the legal and regulatory efforts exert a stronger influence because safety is non-negotiable. More rapid action for culture change may come from the new JCAHO Standards on Patient Safety and from new state regulatory developments.

The second Institute of Medicine report calls for a "new chassis" upon which the 21<sup>st</sup> century health care system needs to be built. The assumption expressed is that there are presently so many deficiencies in health care delivery that starting over and redesigning the system from the ground up is the only way that patient safety will become a reality. The combined weight of public outrage, changing cultures and attitudes, and changes in leadership and administration, may finally tip the scales to make patient safety a national priority. Despite this optimism, patient safety still needs sustained energy from every stakeholder.

The business case for patient safety seems simple. Errors cost money. Research findings have addressed only a small portion of the economic consequences and do not integrate the costs of litigation, malpractice insurance premiums, out-of-pocket expenses for medical, legal, or other support for families touched by error, or the cost of medical error in ambulatory settings, where most care is rendered. One way to determine whether or not investment in patient safety is good business is to conduct a cost-benefit analysis of the expenses associated with a specific category of error (e.g. those within defined care delivery processes) versus the financial investment required to fix the care processes. Lessons from high-reliability organisations teach us that it is possible to model work processes such that every operational process within the organisation is examined and aligned for effectiveness and efficiency. The costs of care are reduced through the elimination of defects, errors and accidents.

The heart of health care lies in delivering safe services to patients. Attention to individual well-being is inherent in a commitment to relieving suffering and improving quality of life. Health care systems must demonstrate a genuine desire to provide harm-free care in an atmosphere of professionalism and compassion. Only by doing so can we earn the trust of patients as they navigate the increasing complexity of our care delivery systems. Practising patient safety requires a concerted, collective effort from all health care stakeholders – setting and attaining clear goals in terms of quality, efficiency and economics.

Significant strides are under way in the United States to address the critical issues discussed here. Properly harnessed, the tools and information at our disposal can propel the cause of patient safety into a new and better era. Can today's momentum fulfil



tomorrow's potential? This question will be answered, and the answer accounted for, by those who operate, regulate, and pay for America's health care.

## NOTES

1. An adverse event was defined in this study as an extended hospitalisation, disability at the time of discharge, or death that resulted from medical care rather than the natural course of disease.
2. The characteristics of a culture of safety have been articulated by Veterans Healthcare Administration and the Pennsylvania Patient Safety Collaborative. See the VHA's web site: <http://www.vha.gov>

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