ISSUE BRIEF

The Massachusetts Health Policy Forum

Medical Errors and Patient Safety in Massachusetts: What is the Role of the Commonwealth?

A discussion moderated by Trish Riley, Executive Director
National Academy for State Health Policy
Portland, Maine

Thursday, September 28, 2000
8:30 to 9:00 – Registration and Breakfast
9:00 to 11:00 – Discussion

Omni Parker House Hotel
School and Tremont Streets
Boston

Registration: Please call Sue Thomson at 617-338-2726 as soon as possible.

NO. 10

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This Issue Brief was prepared by Paul Barach, MD, MPH, a cardiac anesthesiologist, intensivist, and patient safety researcher at the Massachusetts General Hospital and Harvard Medical School, and Michael J. Kelly, JD, an attorney who represents clinicians in the Boston area, and also is the Executive Director of the Professional Liability Foundation.

Executive Summary

"…. The value of history lies in the fact that we learn by it from the mistakes of others, as opposed to learning from our own which is a slow process"

W. Stanley Sykes[1] *(1894-1961)*

It has long been recognized that medical care itself has the potential to cause harm.[2] However, general acknowledgement that much iatrogenic injury may be due to preventable human error or system failure appears to have been slow in the coming. Healthcare is a risky business. Simply being in an acute hospital in Massachusetts carries, on average, a 200-fold greater risk of dying from the care process than being in traffic, and a 2000-fold greater risk than working in a chemical industry, or flying on a plane.

In November 1999, the Institute of Medicine (IOM) published a landmark report entitled "To Err is Human: Building a Safer Health System." Produced by the IOM's Committee on Quality of Health Care in America, the report estimated that 44,000 to 98,000 Americans die in hospitals each year as a result of medical errors. Nonfatal "adverse events" (injuries caused by medical management rather than by the underlying condition of the patient) are ten- hundredfold more numerous than deaths due to errors. 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. Based on the *IOM Report* and assuming similar care, in Massachusetts we can expect between 1000 and 2000 preventable deaths a year.

Release of the *IOM Report* generated enormous coverage in the media, and intense focus on this issue has continued unabated. There is substantial evidence that the majority of health care errors are preventable, and are the result of systemic problems rather than poor performance by individual providers. Proposals have surfaced in Congress and from the White House to implement the IOM's recommendations, and several bipartisan-supported Congressional hearings have fueled discussion and debate on the subject.

In Massachusetts, where much of the work in patient safety has been pioneered, there is proposed legislation which includes a near miss reporting system, changes in mandated reporting systems and the creation of a new state agency to coordinate and support patient safety efforts and research. It also calls for confidentiality protection to encourage sharing of sensitive data. It is vital that all stakeholders, government, the professions, healthcare administrators, industry and consumers be involved at all stages and that mechanisms for ongoing, effective consultation and communication be provided at local and state levels.

There are ethical, humanitarian, and financial imperatives to find out what is going wrong, to collate, and analyze the information, and to devise and implement strategies to better detect, manage, and prevent these problems. Despite clear policy guidance and compelling ethical rationale, which support disclosure of adverse events, there are legal, regulatory and cultural barriers that perpetuate the current situation. Patients and families sometimes are not being told about adverse events that have led to bad outcomes or injuries.

This report concludes with a set of recommendations that encourages open debate on patient safety initiatives in Massachusetts. The Commonwealth can help create a culture of safety. If the fear of litigation continues to countervail the efforts to improve patient safety, transformation from the present unsatisfactory situation into a culture promoting safety for our patients may never be fully realized.

The following discussion is intended to provide background from a number of perspectives on the impact of the role of the state on patient safety. Several options for state level action in Massachusetts are presented. These include:

- Recommendation 1: Create and endow a Patient Safety Center for the Commonwealth
- Recommendation 2: Structure a leadership vehicle for the future development of patient safety programs
- Recommendation 3: Mandatory adoption of error prevention strategies
- Recommendation 4: Implement Incident Reporting Systems

- Recommendation 5: Provide and ensure appropriate confidentiality protection
- Recommendation 6: Study alternatives to the current medical liability and accountability systems

I. Introduction

The Emerging Issue of Patient Safety

While millions of Americans receive medical care every day in one of the world's safest heath care systems, high profile cases have brought medical errors to the public's attention. Modern medical care is complex, expensive and at times dangerous. Hospitals are a vital part of our healthcare systems, routinely providing valuable services, but they are also places where poor care can lead to avoidable harm. Medical injuries are adverse events attributable to the medical management of patients. In November 1999, the Institute of Medicine (IOM) published a landmark report entitled "To Err is Human: Building a Safer Health System."[3] 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 US, with many fold more suffering injuries.[4] 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.[3] The annual toll of these errors exceeds the combined number of injuries due to motor vehicle and aviation crashes, suicides, falls, poisonings, and drownings.[5] Medical errors are adverse events which are preventable with our current state of medical knowledge. The *IOM Report* concluded that a 50% reduction in medical errors is achievable over the next five years and should be a minimum target for national action.

During the past 25 years, three large-scale studies have examined the incidence of adverse events in hospitals. Adverse events were defined as injuries caused by medical management rather than by the disease or condition of the patient. The first, an analysis of approximately 20,000 records of patients hospitalized in California in 1974, found that adverse events occurred in 4.5% of hospitalizations and negligent adverse events in almost 1% of cases.[6] The second study, in which researchers reviewed approximately 30,000 records of patients hospitalized in New York State in 1984, revealed comparable proportions.[4] The study team concluded that among the 2.8 million admissions to New York Hospitals, there were about 98,000 adverse events, of which approximately 37,000 involved substandard care. More recently, similar results were reported in a two stage medical record review in Utah and Colorado.[7] Finally, a large Australian study using the same methodology of the New York study found similar results.[8] There have also been more narrowly focused studies, using different methodologies which indicate that medical injury continues to be a serious problem. These data can and have been challenged, but nevertheless, experts agree that it is the best information available. The term "patient safety" encompasses prevention of errors of action and judgement, making errors visible, and mitigating the effects of errors. It is critical to recognize that not all bad outcomes for patients are due to medical errors.

In 1997, a study of 1000 hospitalized patients in a large teaching hospital found that 177 of these patients received inappropriate care that resulted in serious adverse events.[9] They also concluded that the likelihood of experiencing another such event increased about 6% for each additional day of hospitalization. In the public eye, such scholarly inquires have been overshadowed by media reports that describe, often in graphic detail, the harm done to patients because of poor hospital care. These accounts include cases of preventable death or disability resulting from improper medication, botched surgery, inadequate oversight and lapses in judgement and management.[10] Moreover, it appears that the public's own experiences provide substantiation for concerns about medical injury. A 1997 Louis Harris & Associates poll of more than 1500 Americans revealed that 42% of respondents indicated that they or a close friend had experienced a medical mistake.[11] With this awareness comes increased public expectations for accountability.

Why is it an issue now in the United States?

Why has such a large problem not received more attention in the past? There are several complex interrelated reasons. Release of the *IOM Report* generated enormous coverage in the media, and interest in this issue has continued. There is substantial evidence that the majority of health care errors are preventable. Proposals have surfaced in Congress and from the White House to implement the IOM's recommendations, and several bipartisan supported Congressional hearings have fueled debate on the subject. Recently many lead-

ing medical journals have devoted articles, editorials, and entire issues to this problem.[12-15] The questions are "Why now?" and "Why here in the US?" We will address the timing and location by recapping patient safety milestones, which can be divided into first and second generation responses nationally, and in Massachusetts.

Beginning with a groundbreaking conference at the Annenberg Center for Health Sciences (ACHS) in October 1996, patient safety has gained momentum as an important policy and public health issue for institutional health care providers, clinicians, government, health care payers, consumers, educators, the press and other key constituencies. One of the main initiators of this meeting were several highly visible tragic adverse events reported in the press the previous year. These included amputation of the wrong leg in Florida, a seven-year-old Florida boy who died after receiving adrenaline instead of lidocaine during anesthesia, and a fatal anti-cancer drug overdose administered to Boston Globe health reporter Betsy Lehman in Massachusetts.[10] Since then, Harvard University's Kennedy School of Government has convened an Executive Session[a] on Medical Error and Patient Safety (June 1997), the American Medical Association developed and launched the National Patient Safety Foundation (July 1997),[16] and the Veterans Health Administration established the National Patient Safety Partnership, comprised of government agencies and private partners (October 1997).

In 1997, the death of a Houston newborn made the cover of the *The New York Times Magazine* after it was discovered that he had received an injection of the heart drug digoxin at 10 times the prescribed dose.[10] President Clinton's Advisory Commission on Consumer Protection and Quality in the Health Care Industry[b] designated the reduction of error as one of eight goals for the assurance of quality in healthcare (April 1998). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has developed and adjusted its "sentinel event" monitoring program to emphasize patient safety concerns (1996 to the present). In November 1998, a second major teaching conference was convened at the ACHS that attracted more than 600 participants. A coalition of health care purchasers – self-styled the "Leapfrog Group" – recognized for developing innovative, value-focused relationships with health care plans and providers has been formed to coordinate initiatives to improve patient safety.[c] The Medical Group Management Association (MGMA) announced a new patient safety initiative focused on reducing risk in office practice settings (October 1999). The National Business Coalition on Health has made patient safety a priority for its members.

In November 1999, the Institute of Medicine issued a major call to action on patient safety that generated enormous press attention.[3] Within a week, the Clinton Administration issued an Executive Order directing federal agencies to develop an action plan to implement the IOM's recommendations. These events constitute a new benchmark. The Presidential Quality Interagency Coordination Task Force (QUIC),[19] and General Accountant's Office (GAO) reports[20] called upon these sectors to break the cycle of inaction and fear, and begin discussing the real and alarming issue of medical failure. By bringing into sharp relief the tension between blame and disclosure as competing strategies to improve patient safety, these reports set the stage for a more sophisticated and effective public discussion of risk, partnership, and accountability in health care, aligned behind a fundamental concern for safety. In February 2000, President Clinton announced support for a state-based, nationwide system of reporting medical adverse events.

Patient safety is now a defined priority on the nation's public health/quality improvement agenda. That bipartisan interest in improving patient safety has grown is demonstrated by United States Senate and House hearings which calls for legislation to develop policies to reduce injuries and deaths caused by medical errors. The U.S. Senate Health and Education Committee and Appropriations Subcommittee on Labor, Health and Human Services, and Education all have held hearings on the issue. Bills have been introduced in both the Senate and the House to mandate reporting of adverse events, compile the data, and develop demonstration projects to test alternate ways to report errors. Within

[a] The Executive Session is organized as a series of round table discussions among a group of 30 health care leaders that will meet at least until October 2000, and may be extended.

[b] A successor organization of the President's Commission is the Quality Forum, which is just being organized as a joint public/private initiative. In September 1999, Kenneth Kizer, MD, was appointed Project Director. Previously, Dr. Kizer served as U.S. Undersecretary for Health, Veterans Affairs.

[c] Leapfrog Group members include the Pacific Business Group on Health, the Buyers Health Care Action Group and General Electric (GE).

the Executive Branch, the Agency for Healthcare Research & Quality (AHRQ) is emerging as the leader in the development of government sponsored research and policy development.

Why is it an issue in Massachusetts now?

Massachusetts has a rich tradition of leading hospitals and prestigious medical centers. These are a large part of the local economy, and have been in the forefront of the pursuit of high quality and safe patient care. However, a string of high visibility adverse events in the press starting with the tragic death of the Boston Globe health reporter Betsy Lehman at the Dana Farber Cancer Institute in Boston, brought patient safety issues to the local media and public's awareness. During this period in Massachusetts, the Department of Public Health released the Advisory to Hospitals on Incident Reporting (1995), the Massachusetts Hospital Association began a statewide medication error prevention initiative (1996), and in 1997, the Massachusetts Coalition for Prevention of Medical Errors was established.

If one accepts the methodology employed in the *IOM Report* to calculate the toll of medical errors nationally, we can extrapolate from the number of patients discharged from acute care hospitals in Massachusetts (excluding VA system) and arrive at a "guesstimate" of a possible annual range of one to two thousand patient deaths from medical errors in Massachusetts each year in hospitals alone.[a]

II. Background in Safety Science

Human Error and Performance Limitations

Although there was virtually no research in the field of safety problems in medicine until the mid-1980's, in other fields (e.g., aviation, road and rail travel, nuclear power, chemical processing) the field of safety science, human error and the intense study of accidents have been well developed for several decades.[23,24] Whilst any doctor or nurse could provide examples of occasions on which patients were injured during treatment, or had narrowly avoided serious injury, very few studies had been published. Several factors have contributed to the growing interest in human errors and medical accidents. The rapidly rising rate of litigation in the 1980's, and increasing interest from the media, brought medical accidents to the attention of both doctors and the general public. Systems of complaint and compensation have been widely criticized and this led to calls for reform from lawyers, doctors, and organizations representing patients.

In parallel with these changes, researchers from several disciplines have developed methods for the analysis of accidents of all kinds.[25,26] Theories of error and accident causation have evolved that are applicable across many human activities although they have not as yet been widely used in medicine. These developments have led to a much broader understanding of accident causation, with less focus on the individual who makes an error, and more on pre-existing organizational factors which provide the context in which errors occur. An important consequence of this has been the realization that the accident analysis may reveal deep-rooted, unsafe features of organizations.

The most obvious impetus of the renewed interest in human error outside of health care has been the growing concern over the terrible cost of human error: the Tenerife runway collision in 1977 (leaving 540 killed), Three Mile Island in 1979, the Bhopal methyl isocyante tragedy in 1984, and the *Challenger* and *Chernobyl* disasters in 1986.[27] There is nothing new about tragic accidents caused by human error; but in the past, the injurious consequences were usually confined to the immediate vicinity of the disaster. Today the nature and scale of potentially hazardous technologies in society and hospitals means that human error can have adverse effects way beyond the confines of health care settings.

Over the past few years, there has been a noticeable spirit of *glasnost* within the medical profession concerning the role played by human error in the causation of medical adverse events.[28] The involvement of human factor specialists in this inquiry has brought two benefits. First, it has allowed techniques such as the critical incident analysis and event reporting programs. Initially developed in the field of aviation, these may be applied to the medical accident process. Second, these investigations have clearly shown that medical mishaps share many important causal similarities with the breakdown of other social-technical systems.[29]

[a] For 1998, a calculation of one end of this estimated range would be based on the findings of the Harvard Medical Practice Study, yielding an estimate of 2,258 preventable deaths (773,940 discharges x 3.7% of patients with AE's x 13.6% AE leading to death x 58% judged to be due to errors). We can use the more recent Colorado and Utah study results to calculate the other end of the estimated range, which would indicate for Massachusetts 1015 preventable deaths in 1998 (773,940 hospitalizations x 1.9% preventable AE's x 6.9% of AE's leading to death).[7]

The Need for Standardized Definitions

In this emerging field of study many different definitions are used and a common terminology has yet to emerge. Iatrogenic injury means injury originating from or caused by a physician (*iatros*, Greek for "physician").[30] However, the term 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 as well as from acts of commission are included. One of the more difficult problems in discussing patient safety is imprecise taxonomy, since the choice of terms has implications for how the problems related to patient safety are addressed. This makes comparison of different studies and reports problematic. The lack of standardized nomenclature and a universal taxonomy for medical errors complicates the development of a response to the issues outlined in the IOM report.

The National Research Council defines a safety "incident" as an event that, under slightly different circumstances, could have been an accident.[31] The word "accident" is intertwined with the notion that human error is responsible for most injuries. This notion can be challenged since judgements about human behavior retrospectively are strongly influenced by hindsight bias.[32] We assembled definitions from the literature of the most common terms used to describe adverse events (see Appendix A). With few exceptions, the existing studies each report data from different populations, and they frequently differ in the way they define, count, and track adverse events. We found major variations in nomenclature with no fixed and universally accepted definitions. Experts commented on the importance of accepted definitions to focus priorities, data collection, research, and impact of systems changes.

Active and Latent Failures

Human decisions and actions play a major part in nearly all accidents. This is not so much a question of incompetence or irresponsibility as of opportunity. All potentially hazardous technologies are designed, built, operated, and maintained by human beings. Catastrophic breakdowns of complex human-machine systems arise from the combined effects of human failures in all of these activities. Humans contribute to accidents in two ways: through active failures and latent failures.[33] These two categories are distinguished both by the time taken for the failure to have a negative impact upon the safety of the system, and by the kind of person responsible.

Active failures are unsafe acts committed by those at the "sharp end" of the system (pilots, train drivers, maintenance crews, surgeons, nurses, anesthesiologists etc.). They are the people at the human-system interface whose actions can, and sometimes do, have immediate adverse consequences. Quite often, these unsafe acts involve the circumvention or disabling of safety devices designed to protect the system against serious breakdown.[34]

Latent failures arise from fallible decisions, usually taken within the higher echelons of the organization or within society at large. Their damaging consequences may lie dormant for a long time, becoming apparent only when they combine with local triggering factors (i.e., active failures, technical faults, atypical system states, and so on) to breach the system's defenses. Most often, the people primarily responsible for the commission of these latent failures are separated in both time and distance from the hazardous workplace.[35]

Until quite recently, it was usual for most accident investigators to focus upon active rather than the latent human failures. Most investigators saw their task as identifying those people or equipment items that were immediately responsible for the system breakdown, and then specifying the list of local measures that would prevent recurrence of that particular accident sequence. In general, they had neither the resources nor the training to track down the long-standing organizational causes. In many of the adverse events that happen in hospitals, the front-line personnel were the inheritors rather than the instigators of disaster. Their role was to create the conditions under which the latent system failures could manifest themselves.

Three Universal Accident Ingredients

There are three reasons why the possibility of an adverse event occurring to any hazardous activity can never be discounted.

1. All human beings, regardless of their skills, abilities, and specialist training, make fallible decisions and commit unsafe acts. This human propensity for committing errors and violating safety procedures can be moderated by selection, training, well-designed equipment, and good management, but it can never be entirely eliminated.

2. No matter how well designed, constructed, operated, and maintained they may be, all man-made systems possess latent failures to some degree. These failures are analogous to resident pathogens in the human body that combine with local triggering factors (i.e., life stress, toxic chemicals, etc.) to overcome the immune system and produce disease. Like cancers and heart attacks, adverse events in well defended systems do not arise from single causes but from multi-factorial reasons. The adverse conjunction of such factors, each necessary but insufficient alone to breach the defenses, are behind the majority of adverse events. This is particularly true in systems, which are tightly linked with little tolerance or room for error.

3. All human endeavors involve some measure of risk. In many cases, the local hazards are well understood and can be guarded against by a variety of technical or procedural counter-measures. No one, however, can foresee all the possible adverse scenarios, so there will always be chinks in this protective armor.

These three ubiquitous accident ingredients reveal something important about the nature of the "patient safety war." They tell us that the fight against adverse patient events is not like a conventional war in which decisive victory can be followed by a long period of relative peace, but more like a battle of attrition with guerilla conflict in which rigidity, complacency, and over-reliance on technical solutions and guidelines, are certain routes for defeat. Maintaining safety within acceptable limits requires constant vigilance and chronic unease, both difficult to sustain when there are always many other demands upon limited resources, both human and financial.

Measuring Safety: The Accident Paradox

Many organizations use adverse event data as an index of the relative safety of their constituent parts or subsystems. Adverse events, like the number of errors, are poor indicators of the general 'safety of the system.' Only if the system had complete control over the factors causing adverse events and near misses could an adverse event history provide a reliable measure of its safety. Hazards can be moderated but they cannot be eliminated. This may lead to the 'accident paradox' where 'safe' organizations can still have bad adverse events, while relatively 'unsafe' systems can escape them for long periods. Furthermore, progress creates new risk that is difficult to anticipate but is a feature of new procedures and technologies.

One way to resolve this paradox is to recognize that safety has two faces. The positive face of safety (i.e., intrinsic resistance to chance combinations of hazards, unsafe acts, technical failures), like good health, is difficult to pin down and even harder to measure. By comparison, the absence of safety, like bad health, is all too clearly signaled by near misses, injuries, and fatalities, which lend themselves to close analysis and quantification.

However, the data provided by accident and incident reporting systems, while essential for understanding the causes of past mishaps, are both too little and too late to support measures directed at enhancing a system's intrinsic safety. Many organizations treat safety management like a negative production process. They assess their negative outcome data and then set themselves reduced targets for the coming accounting period. The trouble with this approach is that errors and adverse events are not directly manageable.

A more effective model for safety management is to monitor the system's 'vital signs' on a regular basis (i.e., indices relating to quality management, equipment design, and construction, conditions of work, safety procedures, communications, maintenance and so on) like a long-term fitness program. The program is designed to bring about continuous, step by step improvement in the system's intrinsic resistance to chance combinations of latent failures, human fallibility and hazards. This entails managing the manageable; that is the organizational factors, which lie within the direct spheres of influence of the system operators and managers.

The Organizational Accident

The accidents and adverse events that still occur within systems, which possess a wide variety of technical and procedural safeguards (such as operating rooms and intensive care units), have been termed organizational accidents.[27] These are mishaps that arise not from single errors or isolated component breakdowns, but from the insidious accumulation of delayed action failures lying mainly within the managerial and organizational spheres. Such latent failures may subsequently combine with active failures and local triggering factors to penetrate or bypass the system defenses.

The etiology of an organizational accident can be divided into five phases:

(1) organizational processes giving rise to latent failures;

(2) error and violation producing conditions within workplaces (operating room, pharmacy, dialysis unit, etc.)

(3) the commission of errors and violations by sharp end individuals

(4) breaching of defenses or safeguards

(5) outcomes that vary from a "free lesson" to a catastrophe

Viewed from this perspective, the unsafe acts of those in direct contact with the patient are the end result of a long chain of events that originate higher up in the organization. One of the basic principles of error management is that the transitory mental states associated with error production—momentary inattention, distraction, preoccupation, forgetting—are the least manageable links in the error chain because they are both unintended and largely unpredictable. Such states can strike anyone at any time. These errors have their cognitive origins in highly adaptive mental processes. Correct performance and errors are two sides of the same coin. Human fallibility is not the result of some divine curse or design defect, rather it is the debit side of a cognitive balance sheet that stands heavily in credit. The resource limitations on the conscious "workspace" that allow us to carry us through selected plans of actions in the face of competing situational demands also lead to information overload and leakage of memory items.

Whereas even the simplest accident, such as tripping on the stairs, has some organizational roots, it is probably the case that certain high risk systems are more prone to organizational accidents than others. Indeed, it could be argued that for certain complex, automated, well-defended systems, such as nuclear power plants, aviation, organizational mishaps are really the only kind left to happen. Such systems have largely been proofed against single failures, either human or technical, but they can be quite opaque to the people that work within them.[36] It is of course true that people at the sharp end commit errors and violations, but—it is neither the whole truth, nor even the most important part of that truth.

The Importance of Near Misses In Learning and Recovery

There exists a continuous cascade of adverse events from apparently trivial incidents to near misses (NM) and full-blown adverse events.[37] Consequently, the same etiological patterns and their relationships precede both adverse events and near misses. Only the presence or absence of recovery mechanisms determines the actual outcome.[38,39] It could be argued that focusing on near miss data can add significantly more value to quality improvement than a sole focus on adverse events. Schemes for reporting near misses, close calls, or sentinel (i.e., "warning") events have been institutionalized in aviation,[40] nuclear power,[41] petrochemicals,[42] steel production,[43] and military operations.[23] In health care, efforts are now being made to create medical near miss incident reporting systems to supplement the limited data available through mandatory reporting systems focused on preventable deaths and serious injuries.

Analysis of NMs versus adverse outcomes offers advantages:[44] (1) NMs occur three to three hundred times more frequently, enabling quantitative analysis; (2) fewer barriers to data collection exist allowing analysis of interrelationships of small failures; (3) recovery strategies can be studied to enhance proactive interventions and de-emphasize the culture of blame; and, 4) hindsight bias is more effectively reduced. Finally, NMs offer powerful reminders of system hazards and retard the process of forgetting to be afraid.

Engineering a Culture of Safety

How do we create an environment in healthcare that fosters safety? What are the ingredients of a safety culture? How can it be engineered? Whereas national cultures arise largely out of shared values, an organizational culture is shaped mainly by shared practices. Acquiring a safety culture is a process of collective learning.

The usual reaction to adverse incidents is "Write another procedure," and "Blame and train." Although this does not make the system more resistant to future organizational accidents, it does deflect the blame from the organization as a whole. Reason identifies the four elements required to create an effective culture of safety. It must be a reporting, just, flexible and learning culture.[27] A "no blame" culture is neither feasible nor desirable. A small set of adverse events are egregious (substance abuse, sabotage etc.) and warrant sanctions. A blanket amnesty on all unsafe acts would lack credibility in the eyes of the public. What is needed is a just culture, where an atmosphere of trust is encouraged and rewarded, where there is a line between acceptable and unacceptable behavior.

There is evidence indicating that High Reliable Organizations (HRO)—domain leaders in health, safety, and environmental issues—possess the ability to reconfigure in the face of high tempo operations or certain kinds of danger.[45] Such adaptability depends on respect—in this case respect for the skills, experience and abilities of the workforce. When all four elements interact to create an informed culture, we are talking about a safety culture.

III. Incident Reporting Systems, Barriers and Ethical Imperative

The Barrier Analysis

How can we transform the current culture of blame and resistance to one of learning and increasing safety? Understanding the balance of barriers and incentives to reporting is the key first step (see Table 1).[46] It will be essential to introduce norms that inculcate a learning, non-punitive safety reporting culture in professional schools and graduate training programs, with support from consumers, patient advocacy groups, regulators and accreditors. A certain amount of trial-and-error learning will be necessary. Legal protection for reporters will need to be reinforced, as it has as been in Australia and New Zealand, where incident reporting systems (IRS) have been successful in gaining acceptance and credibility.[21]

The sum of barriers and incentives can be considered in terms of their impact on individuals, organizations, and society. Powerful disincentives to reporting depend on the organizational culture, and include extra work, skepticism, lack of trust, fear of reprisals, and lack of effectiveness of present reporting systems. Incentives to reporting included in addition to confidentiality, that IRS be prophylactic (provide some degree of immunity), philanthropic (reporters identify with injured patients and other health care providers that could benefit from data), and therapeutic (reporters learn from reporting about their adverse events). Incentives for society included: accountability, transparency, enhanced community relations, and sustaining trust and confidence in the health care system.[47]

Complex interdependencies were found to exist between all barriers and incentives to reporting at the individual, organizational, and society levels. Barriers tended to be more visible and specific than incentives. However, incentives were tied to higher governing values at most levels. Fears and attitudes appeared to be limiting the usefulness of structural incentives already in place.

The Value of Incident Reporting Systems

The understanding that adverse events are a common and expected result of using complex systems has led to new approaches to improving safety. The recognition that adverse events often result from poor system design has led to the development of reporting systems. This allows adverse events to be collected and analysed to determine whether there are root causes leading to patterns of adverse events. The development and function of incident reporting systems (IRS) depends largely on the ability of the reporter to feel "safe" and confident that reporting will lead to a meaningful change in the system. Reporting systems are only a part of a "culture of safety" which understands adverse events as opportunities for learning and improvement rather than mishaps to be hidden. Health care has lagged behind other industries in implementing IRS and other safety-related initiatives. However, in the last five years, there has been a concerted effort in this direction. Studies in Anesthesia,[48] Intensive Care,[49] Transfusion Medicine,[50] Occupational and Industrial Medicine,[51] and Pharmacy,[52] represent successful adverse event reporting systems.

For health care IRS, there must be incentives to promote voluntary reporting—completely, confidentially, and objectively. Reporting should be the right, easy, and safe policy for health care professionals. To maximise the usefulness of IRS, there will be a need to balance accountability, system transparency, and protections for reporters. In order to ease IRS implementation, the community must be involved in system oversight, support and advocacy.

Lessons from Non-Medical Domains

Studies of safety in non-health care sectors where errors or accidents can cause death or injury, such as aviation, nuclear power, the armed forces and chemical manufacturing, have led to an improved understanding of the causes of adverse events. These Highly Reliable Organizations (HRO) operate in environments where failure has severe consequences.[53] Studies in these fields demonstrate that adverse events occur from both human errors – that is the failure of individuals to assess situations properly and to choose the correct courses of actions, and from systems failures – that occur as the

Table 1: Barriers and Incentives to Reporting (from Barach[44])

Concerns		INDIVIDUAL	ORGANIZATIONAL	SOCIETY
Legal	**Barrier**	**Fear of reprisals Lack of trust**	**Fear of litigation, costs Sanctions undermine trust Bad publicity**	**Legal impediments to peer-review, confidentiality, and multi-institutional databases**
	Incentive	**Provide confidentiality and immunity**	**Provide confidentiality and immunity**	**Insure accountability; Enforce reporting statutes**
Cultural (values, attitudes, beliefs)	**Barriers**	**Profession-dependent; Code of silence Fear of colleagues in trouble; Skepticism Extra work**	**Organization-dependent; Pathological. beaurocratic, and generative cultures Don't want to know**	**Wide public trend towards disclosure; Lack of trust due to highly publicized medical errors; Concerns that professions are too privileged; Lack of education about systems effects**
	Incentive	**Professional values-Philanthropic, integrity, educational; cathartic**	**Become a leader in safety and quality; good for business**	**Enhanced community relations; build trust, Improve health care Transparency**
Regulatory	**Barrier**	**Exposure to malpractice, premiums will go up. Investigation and potential censure. License suspension and subsequent loss of income**	**It doesn't apply to us, we do our own QA process. They can't understand our problems anyway.**	**Need more effective regulations Resource intense**
	Incentive	**Prophylactic, Follow the rules.**	**Fear of censure**	**Enhances regulatory trust. More public accountability**
Financial	**Barrier**	**Loss of reputation, job Extra work.**	**Wasted resources; Potential loss of revenue, patient care contracts; Not cost-effective.**	**Cost more tax dollars to enforce; More buearacuracy.**
	Incentive	**Safety saves money**	**PR, improve reputation of quality and safety**	**Improves confidence in Health Care system**

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result of poor design and/or poor maintenance. In complex systems, adverse events occur when poorly designed systems interact with or cause poor human performance and lead to bad outcomes. Lessons learned in those sectors are now beginning to be applied to health care – a most complex, highly dynamic service sector.

Experience with non-medical reporting systems in aviation, nuclear power, petrochemical processing offer lessons applicable to the design of safety reporting systems in health care.[54] The aviation industry has discovered that faulty teamwork among crew members is a frequent causal factor in airline accidents. Many scientists involved in improving airline crew performance are now applying these same concepts to health care teams. By adopting strategies structured to improve teamwork, caregivers are finding that medical accidents are preventable This groundbreaking work, used by teams in emergency departments, will probably result in significant patient care improvement.[55]

Aviation Near Miss Reporting Systems

Public accident investigation, and confidential near miss analyses, have been complementary elements in the remarkably successful effort to improve air safety. After three decades, over 500,000 confidential NM reports (currently over 30,000 reports annually) have been logged by the Aviation Safety Reporting System (ASRS).[56] Eligibility for limited immunity for non-criminal offenses is a powerful incentive to report. Cracks in the framework of trust among aviation stakeholders have been associated with marked decreases in reporting. Billings, a physician who led the effort to create the ASRS in 1976, stresses the value of learning with minimal indemnity.[47]

Risk management in aviation illustrates how organizations learn by applying NM information to augment the sparse history of crashes and injuries. Data from IRS has been used effectively to redesign aircraft, air traffic control systems, airports, pilot training programs, and, reduce human error. An overarching lesson from 25 years of aviation experience is that the data collection methods and structures evolved to simultaneously maximize confidentiality and optimize bi-directional information flow, and local process. The decades-long aviation effort to improve safety through system monitoring and feedback holds many important lessons for health care, all of which cannot be presented in this report.

Nuclear Power Safety Systems

In the highly charged political, financially accountable, and legal environment of the nuclear power industry, no penalties are associated with reporting non-consequential events, or "close calls," to the Human Performance Enhancement System.[57] The Three Mile Island disaster (TMI) led to the emergence of industry-wide norms which supported communitarian regulation. The dread of even a single potential catastrophe and its implications for all industry members outweighed any objection to IRS. Backed by community pressures, local proactive safety methods were institutionalized and put into effect across the industry.[58] The intensified approach to process improvement through a focus on safety led to financial gains through better power production, (Fewer outages, shut-downs, and reductions in capacity). As in aviation, there is a trend to capture the most subtle information using a nested systems approach, with confidentiality and other protections increasing in proportion to the sensitivity, value, and difficulty encountered obtaining essential information.

Successes in Healthcare

The field of Anesthesiology is one of the few examples in health care, in which an organized and continuous effort over a period of 15 years has led to major strides in patient safety. The safety of anesthetic procedures, has improved up to tenfold in the last 30 years (from 2 deaths/10,000 to one death/300,000 patients).[3] Many feel that the overall approach in the field of Anesthesiology has led to a hundredfold safer profile than the rest of health care. The capture of technical, human performance, and organizational data from the perspectives of those intimately involved in Anesthesia incident occurrence is a critical first step in improvement of training, systems, and safety culture. The tools used routinely in this field to improve safety include team training, simulation, incident reporting, and systems training.

Although Anesthesiology has led the evolution of incident reporting (IR) in health care, no comprehensive mechanism exists in health care by which errors can be reported to an external group or agency in a confidential manner without threat of disciplinary action. Other specialties that have made important strides include emergency medicine with an emphasis on team training, and transfusion medicine.[50] The national safety level of transfused blood has improved hundredfold over the last 15 years.

Over the past three decades, incident reporting systems have evolved from mandatory to voluntary, from anonymous to confidential reporting, from accidents to near misses, and from root causes to non-linear multiple causes. Non-punitive, protected voluntary incident reporting systems produce much valuable safety information unobtainable by other means. To improve the usefulness of incident reporting systems at the local level in real time, novel approaches to increasing accountability and protections for reporters have developed. Experience with non-punitive reporting systems in aviation, nuclear power, pharmacy, transfusion medicine, and anesthesia, may offer lessons applicable to the design of error reporting systems in health care.

Ethical Framework for Analysis of Disclosure of Adverse Events to Patients

Analysis of the ethical dimensions of the disclosure of adverse events to patients reveals support for disclosure.[59] Evaluation of the rationale for disclosure is important because, despite clear agreement on the ethical imperative to disclose, there are many barriers to disclosure that inhibit clinicians from conforming to ethical and policy standards. Disclosure of adverse events to patients is part of the duty clinicians owe to patients. Ultimately frank disclosure leads to trust and improved patient care.

When patients seek medical care they entrust their health to their health care giver, who has a responsibility or "fiduciary duty" to act in the best interests of the patient. Injured patients and their families want to know the cause of their bad outcomes, especially if the adverse event was caused by an error. The words of comedian Dana Carvey, whose cardiac bypass was performed improperly, sum up common patient feelings: "I felt this was a matter of right and wrong. There was no letter of explanation, no phone call. I wanted to be satisfied that the surgeon would not be hurting someone else and would acknowledge his error."[60] In the case where an adverse event leads to the need for further treatment, the health care professional is obligated to tell the patient in order to permit the patient to give informed consent to the treatment.[61]

Disclosure benefits patients by allaying potential worries about the etiology of a medical problem and alerts them to the possibility of obtaining deserved compensation. It can benefit clinicians, who often feel intense emotional distress after making errors, and to the extent that disclosure focuses the attention of the clinician on the adverse event, it may be an opportunity for clinicians to improve their care.[62] Disclosure can begin the process of healing for both patients and clinicians.[63]

The ethics and values inherent in professionalism also require that physicians disclose adverse events to patients. Some professional organizations, such as the American Medical Association and the American College of Physicians have statements in their codes of ethics that require physicians to disclose errors to patients.[64] Codes of ethics for members of some dental, medical subspecialty and nursing societies, contain general requirements that their members conduct themselves with honesty and integrity. Most of these codes do not directly address whether there is an affirmative duty to disclose adverse events.[65] It is in the core values of professionalism – honesty, integrity, and the duty to advocate for the patient that a strong argument for disclosure is found. Professionalism also fosters trust between patient and clinician, and deceiving a patient by lying about the cause of a bad outcome threatens to undermine the therapeutic relationship that makes successful healing possible.

IV. The National Dialogue: Implications for State Policy Makers

The reports issued by the IOM and the QuIC over the past year are expected to frame the national policy debate on patient safety, and have wide-ranging implications for the policy debate at the state level as well. The states are front and center in the federal recommendations to create mandatory reporting of errors that result in serious harm or death.

In addition, the National Academy for State Health Policy recently issued a report on state incident reporting systems that has implications for state policy makers in Massachusetts as well as officials in other states.[66] The states bear chief responsibility for licensing and monitoring health care providers. As regulators and as large purchasers they have a key role in improving patient safety and reducing medical errors.

In this section of the Issue Brief the recommendations of all three reports are examined, along with their implications for state policymakers.

THE IOM REPORT[3]

The *IOM Report* released in November 1999, captured the media and public attention in a manner unlike any previous policy document. It has elevated the

debate around patient safety policy to a national priority. The *IOM Report* also contains a remarkable declaration that has received relatively little attention:

"The composite goal of [the IOM Report's] recommendations is for external environmental forces to create sufficient pressure to make errors costly to heath care organizations and providers, so they are compelled to take action to improve safety."

The *Report* in effect declares not only that past attempts at self-regulation and self-improvement by the health care industry have failed, but that change will only come in reaction to forces outside the industry.

The *Report* sets out a series of recommendations in what it describes as a four-tiered approach:

1. Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;

2. Identifying and learning from errors through the immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;

3. Raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and

4. Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level; this is the ultimate target of all the recommendations.

National Patient Safety Center

To realize the first of these goals, the *Report* proposes the creation of a Center for Patient Safety that would set goals, build and disseminate a knowledge base of methods to improve patient safety. The *Report* recommends initial funding for the Center at $30 to $35 million, growing to $100 million.

Incident Reporting and Confidentiality

Described as a "critical component" of a comprehensive strategy to reduce medical errors, the *IOM Report* has called for the development of a uniform, state-based system for mandatory reporting of adverse events. This is the recommendation that has proved most controversial and grabbed most attention from providers, media, and health policy analysts.

The *IOM Report* looks to build on the network of existing mandatory reporting systems in the states, but calls for the development of uniform standards so information may be aggregated across state lines. States would be free to collect additional data beyond that required for the national system. The *IOM Report* recommends that this mandatory incident reporting system should be narrowly focused, but does not attempt to define reportable incidents for the new system.

The *IOM Report* also encourages the development of voluntary incident reporting systems, including "near-miss" reporting systems, and recommends that pilot programs be funded and evaluated as part of the process for identifying "best practices" for such programs.

The *IOM Report* recommends national legislation to protect the confidentiality of data related to patient safety and quality improvement, and that the confidentiality of voluntary reporting systems should be protected. The *Report* recognized the stifling effect that liability concerns have on the willingness of clinicians to identify, analyze and report errors and adverse events. With respect to mandatory reporting systems, however, the *IOM Report* recommends that the most serious injuries found to result from medical errors should not be shielded from some form of public disclosure, in order to promote accountability. The degree of disclosure that should be required, however, is not specified in the *Report*.

Performance Standards and Licensing Requirements

The *IOM Report* calls on regulators and purchasers to establish performance standards and expectations for health care organizations. The *Report* recommends that health care organizations be given a reasonable time to develop programs, and that purchasers provide information concerning these programs to their enrollees. The *IOM Report* also calls upon licensing agencies to incorporate patient safety performance standards in their provider requirements.

The QuIC Report

A week after the IOM released its report, President Clinton directed the Administration's Quality Interagency Coordination Task Force (QuIC) to evaluate the IOM's recommendations and respond with a strategy to

identify prevalent threats to patient safety and to reduce medical error.[19] QuIC consists of representatives of eleven departments and agencies of the executive branch involved with providing, purchasing, studying or regulating health care. These range from the Department of Health and Human Services to the Department of Defense. In February 2000, QuIC released its report and recommendations in response to the President's request.

The *QuIC Report* contains 93 specific action items that will be undertaken by QuIC agencies and departments across a broad range of areas, from establishing and funding a national safety research agenda to implementing a computerized medical record system within the Department of Defense.

The majority of action items in the *QuIC Report* are centered around the following programs:

- Encouraging research to identify effective patient safety program elements and evidence-based measures, such as examination of the transferability of human factors principles and the lessons learned from other industries to health care, and identification of the critical components of successful incident reporting systems
- Piloting and testing programs such as mandatory reporting and elements of a patient safety curriculum for medical education
- Developing of infrastructure such as core sets of measures that will be necessary to move the health care industry forward on patient safety
- Providing technical assistance to clinicians, state regulators, and plans, by convening conferences and establishing clearing houses
- Providing education and training to clinicians, purchasers and consumers

Only a relative handful of the ninety-three action items in the *QuIC Report* involve federal mandates:

a. Eventual deployment of a mandatory incident reporting requirement for hospitals participating in Medicare, but only after piloting and testing of mandatory program involving the reporting of preventable errors and assessing the uses that consumers make of the resulting information

b. 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

c. Leveraging the federal government's purchasing power to require that health plans enrolling federal employees include error reduction programs and provide information on those programs to enrollees

d. Expansion of the FDA's blood banking mandatory reporting program

e. Development of new FDA standards for naming, packaging, and labeling of proprietary drugs

The emphasis of the *QuIC Report* on research and the development of program infrastructure rather than mandated program elements is an indirect acknowledgement of the relative immaturity of the science of patient safety. (See Section II on Safety Science).

It is worth noting, with respect to the mandatory incident reporting system to be developed by HCFA for hospitals, that the proposed pilot program will focus on a set of "egregious errors that are preventable and should never occur."

National Academy for State Health Policy Report

States bear chief responsibility for licensing and monitoring health care providers, and as regulators and large purchasers, have a key role in improving patient safety. Fear of blame and punishment may limit the openness with which individuals participate in a reporting system. A recent survey of state requirements of serious adverse events by the National Academy for State Health Policy (NASHP) confirmed first an ambiguous use of terms, without any standardized definition of adverse events or medical errors, or which types of events to be reported.[66]

State programs vary considerably with regard to the types of reports called for, with some requiring anonymous submission of aggregate data and other requiring identified information. Fifteen states require mandatory reporting from general and acute care hospitals of adverse events, as defined by the state in a way that encompasses part of all of the IOM definition. Six states (including the District of Columbia) have voluntary reporting of medical errors or adverse events. Six states have pending legislation to require reporting of medical errors or adverse events. While 12 of the 15 states that require mandatory reporting from hospitals do so for unexpected patient deaths, much variability exists in the other types of events

that must be reported, including major loss of function, wrong site surgery, and medication errors.

Most states that require mandatory reporting indicate that they protect at least some reports from legal discovery, although states vary in the types of information and reports that are protected. Five states protect data in the case of a request under the Freedom of Information Act. Seven states protect access to names, while others remove certain identifying information, anonymous reporting and destroying once data is extracted. The most frequent use of data from reports is aggregating data to identify trends (ten states), while in others administer sanctions (nine states), and eight states issue public reports. The survey provides a snapshot of what states are doing to track and reduce medical errors and adverse events. States cited under reporting and inadequate resources as their two greatest concerns with their reporting system. Almost all states surveyed, noted a need for technical assistance in improving their reporting systems, and developing subsequent quality improvement projects.

Implications of the IOM, QuIC and NASHP Reports for State Policy Makers

The implications of the three Reports for Massachusetts policymakers looking at the issue of patient safety are myriad, and range from the obvious to the subtle. Space limitations preclude a thorough exploration of the range of implications, and accordingly this Issue Brief highlights just three of the most obvious.

The first implication from the two reports is that spending on patient safety must increase dramatically if meaningful progress is to be made toward the achieving the goal set out in the *IOM Report* of a fifty percent decline in medical errors over the next five years. The recommendations and action items in the two *Reports* will cost money. As previously noted, the *IOM Report* recommended an initial budget for a national patient safety center of $30-35 million, anticipating it to grow to $100 million. The Clinton Administration has proposed funding at the $20 million level for a national patient safety center, and the two major congressional proposals (Senate 2743, filed by Senator Kennedy, and Senate 2738, filed by Senator Jeffords) each propose funding the national patient safety center at $50 million. On the federal level, at least, substantial investments are being made in patient safety; the VA, for example, has budgeted $478 million over three years to support its patient safety program, with $137.5 million already appropriated.[66]

A second implication, acknowledged at least indirectly by the heavy emphasis in the IOM and QuIC reports on the need to fund research on patient safety in health care, and that safety science in health care is relatively undeveloped when compared to High Reliability Organizations (HRO) in non-medical domains (see Section II). Much of this Issue Brief is devoted to a review of the progress made to date in safety science in health care and the translatable lessons from other industries.

A third implication from the three Reports is that change is coming for mandatory incident reporting systems, and is needed even for Massachusetts, which relatively speaking has played a leading role among the states. The Commonwealth is probably unique in having not one, but two well-established mandatory systems in place (these systems are described in the section V of this report entitled “Current Patient Safety Programs and Proposals for Change in Massachusetts”.) It is clear from the three reports that a uniform set of definitions and fields will need to be incorporated into existing incident reporting system(s) 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 HCFA for hospitals participating in Medicare. This program will be piloted in states with existing mandatory reporting systems.

Thus, not only will Massachusetts be called upon to restructure its existing reporting systems over the next few years, but hospitals in Massachusetts face the daunting task of gearing up and complying with a possible *third* mandatory reporting system. Together, these developments would seem to invite hospitals and regulators to come together to work to redesign a new, unified system for mandatory incident reporting in Massachusetts.

V. Current Patient Safety Programs and Proposals for Change in Massachusetts

Massachusetts has anticipated many of the recommendations in the *IOM Report*, and even surpassed them in some respects. Massachusetts already has mandatory reporting systems for hospitals, has set uniform standards for patient safety programs for hospitals and other health care facilities, incorporated patient safety program elements into licensure requirements, and provided confidentiality protection for peer review

processes. Provider organizations, such as the Massachusetts Hospital Association, the Massachusetts Medical Society and the Massachusetts Nurses Association, have all been engaged in promoting patient safety programs and disseminating "best practice" recommendations. In addition to the regulatory and voluntary efforts, hospitals and clinicians in Massachusetts are subject to national patient safety and quality assurance standards, and regulations promulgated by HCFA and the Joint Commission on the Accreditation of Health Care Organizations.

Massachusetts, however, does not have a unified, coordinated patient safety strategy as outlined by the federal agencies in the *QuIC Report*. Neither does it have a state counterpart to the national patient safety center proposed by the IOM and others, charged with providing leadership on patient safety for the Commonwealth. Instead, the elements of the state's patient programs are spread across two agencies, creating substantial overlap and duplication with respect to mandatory incident reporting, but with no statutory or regulatory requirement for coordination of the programs. The Coalition for the Prevention of Medical Errors, described below, has been formed in an attempt by health care industry leaders and regulators to fill this need for coordination and leadership through a public-private partnership. The Coalition is not adequately funded, has no legal authority, and is still in the process of establishing its administrative and financial infrastructure. There is a proposal (Senate Bill 2195, described below) to create a patient safety center in Massachusetts to provide overall leadership and responsibility for the Commonwealth on patient safety. The legislation, however, did not pass before the conclusion of the legislature's formal session on July 31st.

At present Massachusetts has no state budget for an organization to provide leadership in developing and implementing a patient safety strategy. The Massachusetts Hospital Association and the DPH have supported the work of the Coalition out of their budgets, and both have pledged substantial support for the Coalition. The Coalition is in the process of developing its overall budget and identifying potential funding sources. It remains to be seen whether the Coalition can effectively perform the leadership and coordination functions, and fund the research agenda which is needed without the support of state appropriations which would be in the seven figure range. Introducing SB 2195, Senator Moore proposed to budget $500,000 for the patient safety center but this was dropped from the state's FY 2001 budget. It is difficult to believe that the center could provide the leadership needed with that level of funding.

Current Regulatory Structure for Hospital-Based Patient Safety Programs in Massachusetts

While patient safety is a concern across the health care system, most discussion (including this Section) centers on care provided in the hospital setting. This section will begin with an examination of several selected features of the regulatory structure for patient safety in Massachusetts, which correspond to recommendations in the *IOM Report*. These are:

1. Mandatory reporting of adverse events.
2. Required participation in patient safety programs.
3. Confidentiality provisions for patient safety programs.

Focus will then shift to potential vehicles for developing and implementing a patient safety strategy for the Commonwealth: the Coalition for the Prevention of Medical Errors and the Lehman Center for Patient Safety and Medical Error Reduction, as outlined in Senate Bill 2195.

Mandatory Reporting in Massachusetts

Fifteen states have mandatory incident reporting programs.[66] Massachusetts has two such programs, one administered by the DPH, the other by the Medicine Board of Registration in Medicine (BORIM). While the two systems have slightly different reporting requirements, there is considerable overlap in the reporting criteria of the two systems, and a fair interpretation of the regulations of each agency would require that hospitals report any serious injury or death of a patient due to a medical error to both agencies.[67] Each agency has its own timetable for reports, and each agency has its own set of data elements that must be reported.

While the two agencies have very similar requirements for their incident reporting systems, they play different roles. The DPH is the licensing authority for hospitals, and as such is the state's enforcement authority for hospitals. It uses its incident reporting system to monitor compliance with quality standards and regulatory requirements as part of its enforcement apparatus. The Medicine Board, not being responsible for hospital care, is able to segregate its Patient Care Assessment function, including its incident reporting system, from

its enforcement function and play a more educational, monitoring role. The difference, however, is one of emphasis. The DPH looks to identify system issues from its incident reporting database, and the Medicine Board is very much focused on compliance with its program requirements for hospitals.

Table 2 below shows the number of incident reports received by both agencies in recent years. Each agency has received 400 to 600 reports annually.

Several features of the two systems are worth consideration. First, information reported to the Medicine Board is subject to statutory confidentiality protection, both at the Board and at the reporting institution. In contrast, reports sent to the DPH become public records after the DPH completes its investigation.[68]

A second important feature of the two systems is that there is considerable overlap in the type of incidents that each agency requires be reported, and the information that each agency collects. We are unaware of any law or regulation that requires data sharing between the agencies, although the DPH does forward results of investigations to the appropriate board of registration (medicine, nursing, or pharmacy) when the results of the investigation demonstrate involvement of individual licensed practitioners. Third, despite the large areas of overlap in the two systems, there are some differences in reporting criteria that may affect the relative yield of each system in terms of the number of incidents reported. For example, the Medicine Board's data for the years displayed included fetal deaths without regard to causation, while the DPH does not require fetal deaths to be reported unless those deaths occur as a result of a serious incident.[69]

Unfortunately, these reporting systems are used primarily for compliance and accountability. No research has been funded to examine the resulting data systematically for broader patient safety or public policy purposes. For example, given the controversy around the recommendation in the *IOM Report* that state-based mandatory reporting systems make information publicly available, it would be valuable to compare the information reported to both of these agencies to determine what impact, if any, the confidentiality shield for the Medicine Board's system has had on the relative compliance of hospitals.

The number of incidents that should be reported to each agency is unknown, rendering any estimate of compliance conjectural. Surveys by the Massachusetts Medical Society and clinicians privately suggest that there is substantial under-reporting to the two agencies. This may be the case.

There is evidence from studies conducted in Massachusetts which indicates that compliance with mandatory reporting requirements by hospitals is as low as 4%.[70] Table 3 displays an estimated range of patient deaths due to medical errors in Massachusetts for several recent years, using the same methodology adopted by the IOM in its Report to estimate the number of patient deaths attributable to medical errors nationally.[71] As previously stated, a fair reading of the regulations of both the DPH and the Medicine Board indicates that *every* death caused by a medical error is reportable. Even assuming that all events reported to each agency involved patient deaths (which is not the case), these data suggest that at most only one quarter to one half of the patient deaths in which medical errors played a causal role are being reported to *either* agency in Massachusetts.

As with the degree of compliance with reporting requirements, little is known about the impact of these reporting systems on patient care in Massachusetts. No

Table 2: Hospital Incident Reports, Medicine Board and DPH, 1995-1999

YEAR	Number of Major Incidents Reported to Medicine Board	Number of Incidents Reported to DPH
1999	N/A	493
1998	572	513
1997	522	390
1996	509	415
1995	463	N/A

Sources: Medicine Board data: Annual Report 1999, Board of Registration in Medicine. Available at http://www.massmedboard.org/arweb.pdf.; DPH data: DPH Table, Hospital Complaints and Incident Reports Received by Reporter Type, Calendar Years 1996-1999 [reports from Consumer/Advocates not displayed](March 2000).

Table 3: Annual Hospital Discharges and Estimated Range of Patient Deaths Due to Medical Error, Massachusetts, 1996-1998

Year	Number of Hospital Discharges*	Estimated Number of Patient Deaths Due to Medical Error
1998	773,940	1,015 – 2,258
1997	769,827	1,009 – 2,246
1996	762,836	1,000 – 2,226

**Source for hospital discharge data: Mass. Health Data Consortium.*[72]

formal research has been conducted with the data accumulated by either agency.

Both agencies are constrained from "mining" the data collected through their incident reporting systems by a lack of resources. The situation at the Medicine Board is particularly stark. The Medicine Board's Patient Care Assessment (PCA) Program, held up as a national model, does not compete successfully for budget resources against the Board's disciplinary and licensing functions.[73] The entire PCA Program, of which its incident reporting system is only one part, is overseen by three volunteer Board member supported by a staff of just three employees. In contrast, the Medicine Board's other nationally acclaimed program, the Physician Profiling Program, has its own line item and is guaranteed funding in the state budget. Notwithstanding these severe limitations, the Board has been able to analyze its data sufficiently to issue safety bulletins to Massachusetts hospitals. It is clear, that neither incident reporting systems realizes the potential that could be achieved through a properly supported research program using the data accumulated over the past decade by the two agencies.

Required Participation in Patient Safety Programs: The Board of Registration in Medicine's Patient Care Assessment (PCA) Program

The *IOM Report* recommends that licensing bodies require participation in patient safety programs, a mandate that has been in place in Massachusetts for physicians and hospitals since 1986 through the Patient Care Assessment Regulations of the Board of Registration in Medicine.

In brief, the Medicine Board's PCA regulations require that hospitals establish comprehensive quality assurance and risk management programs that have the following features:[74]

- Responsibility and involvement with quality assurance and risk management activities at the governing board level[a]
- Credentialing and periodic re-credentialing for members of hospital medical staff[b]
- Systematic review of indicators of quality of patient[c]
- Periodic reports to the Medicine Board concerning the functioning of the hospital's PCA program[d]
- Reporting of defined "Major Incidents" directly to the Medicine Board (discussed above)[e]

While technically not a part of the Medicine Board's PCA Program, the Board also requires that physicians earn risk management credits as a requirement of maintaining their licenses.[f]

Aside from occasional "tweaking," the Medicine Board's regulations have remained largely untouched in

[a] 243 CMR 3.07 (3) (g)

[b] 243 CMR 3.30

[c] 243 CMR 3.05

[d] 243 CMR 3.07

[e] 243 CMR 3.08

[f] 243 CMR 2.06 (5) (a) 2a.

the fifteen years since they were first written. No studies have been funded to gauge the effectiveness of the program or to examine, systematically, enhancements or modifications that might improve its impact on patient safety. While the Medicine Board has extensive requirements for hospital patient safety programs, it should be noted that hospitals are licensed by the DPH and not the Medicine Board. The DPH retains and exercises authority over patient safety issues at hospital level.

Confidentiality and Public Access to Patient Safety Information

All current confidentiality protection for patient safety activities in Massachusetts derives from the two statutes that make up the state Medical Peer Review Law. M.G.L. c. 111, §§ 204 and 205 (Also known as the Medical Peer Review Privilege).[75] This law provides considerable protection for the confidentiality of a narrow range of information and records at the institutional level and at the Medicine Board, but not at the DPH.

Within hospitals, the Massachusetts Medical Peer Review Law protects the proceedings and records of medical staff peer review committees, but not the entire quality assurance process. The law also protects incident reports and certain other PCA materials at hospitals, but the scope of this confidentiality protection is unclear with respect to PCA information other than incident reports. For medical peer review materials, the protection applies to the records within the hospital. It is unclear whether, under current law, the confidentiality protection is waived if the information is shared outside the institution's usual internal processes of medical peer review. For PCA materials, the protection applies both at the institution and at the Medicine Board. These protected materials are declared by the law not only to be confidential but also legally privileged. They are immune from subpoena or discovery and cannot be admitted into evidence or disclosed in judicial or administrative proceedings except under narrowly-defined circumstances.[76]

There are several shortcomings with this legal structure. First, and most notably, is that the confidentiality protection centers on the work of institutional medical peer review committees, and not the entire quality assurance process. Generally, if a document or information is not prepared for or created by a medical staff peer review committee, it is not protected.

A second shortcoming of the current legal structure is that it is institution specific. That is to say, it is unclear which medical peer review materials can be shared outside institutional walls (even with the JCAHO or DPH) without waiving the privilege.

A third major shortcoming of the current statutes is that the reach of the protection afforded to PCA materials (other than incident reports) is unclear, due to the statutory requirement that the information must be "necessary to the work product of a medical peer review committee" in order to be protected.

Even with respect to materials that are protected under the Peer Review Law, the barrier is not absolute. The Medicine Board clearly has authority to access PCA records that are otherwise protected under § 205. With respect to the records of medical peer review committees, while neither the Medicine Board nor the DPH have statutory authority to access those records, the DPH is able to draw upon federal authority to access medical peer review records that are otherwise protected against disclosure under state law.

There have been reports that sensitive medical peer information which has been inspected by DPH has found its way into DPH reports which are public record, and then became available to the media and personal injury lawyers. The DPH and the health care community have examined this problem and have been considering means to prevent inappropriate or unnecessary disclosures of medical peer review materials in DPH reports.

Setting the Future Agenda: Potential Agents of Change

The Massachusetts Coalition for the Prevention of Medical Errors

The Coalition for the Prevention of Medical Errors is a unique public-private partnership devoted to improving safety in health care organized in 1997. The Coalition has grown to include representatives of 21 organizations, encompassing most of the agencies that regulate health care in Massachusetts, most of the associations that represent the providers of care in Massachusetts, and the AARP.[77] The Coalition has been widely acclaimed as an innovative approach to improving patient safety.[73] The mission of the Coalition is :

1. to establish a mechanism to identify and implement best practices to minimize medical errors;

2. to increase awareness of error prevention strategies through public and professional education;

3. to identify areas of mutual interest and minimize duplication of regulatory and Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) requirements so that efforts are focused on initiatives that can best improve patient care.[78]

While the Coalition has no legal authority to set the patient safety agenda for Massachusetts, it does in its mission, undertake to provide leadership, direction and coordination for patient safety efforts throughout the state.

The Coalition has launched a number of initiatives. It endorsed and adopted a series of evidence-based "best practices" which the Massachusetts Hospital Association developed and distributed to hospitals in 1999. The MHA is in the process of developing a survey to learn about the progress that has been made in implementing medication best practices. The Coalition is currently preparing to identify and disseminate "best practice" recommendations for the use of restraints, the reduction of blood transfusion reactions, and the prevention of wrong site surgery.

The Coalition has begun to examine ways that regulatory duplication can be minimized. Its educational efforts have not been limited to providers and recently it produced a brochure for patients on safe medication use. Some start-up funding and leadership support for the Coalition was provided by DPH and the MHA, but to date the Coalition has relied primarily upon volunteers. The Coalition is in the process of institutionalization prior to formal incorporation, and the engagement of a full time Executive Director. Some have questioned the makeup of the Coalition, noting that not all the stakeholders are represented. The sole consumer voice on the Coalition is the AARP.

THE LEHMAN CENTER: SENATE BILL 2195, AN ACT TO ESTABLISH A PATIENT SAFETY AND MEDICAL ERROR REDUCTION PROGRAM FOR THE COMMONWEALTH (SEN. RICHARD T. MOORE, LEAD SPONSOR)

Senate Bill 2195 is a comprehensive patient safety bill filed by the co-chairs of the Massachusetts Joint Committee on Health Care, Sen. Richard T. Moore and Rep. Harriette L. Chandler, and others.[79] It is fair to say that Senator Moore, the first sponsor named on the bill, has been the legislature's champion on patient safety issue over the past two years. The legislation implements and builds upon most of the key recommendations of the *IOM Report* at the state level, and has features similar to the federal action plan set out in the *QuIC Report*.

Reflecting the recommendations in the *IOM Report* and the *QuIC Report* for a national patient safety center, Bill 2195 would create a Center for Patient Safety and Medical Error Reduction, which it proposes be housed at the Division of Health Care Finance and Policy.[80] The Center would be named after Betsy Lehman, the *Boston Globe* health care columnist who died in 1994, as a result of a medical error at the Dana-Farber Cancer Institute. The Center would have a tripartite governing board, consisting of the Secretary of Health and Human Services, the Director of Consumer Affairs, and the Attorney General.

SB 2195, like the recommendations in the *IOM Report, QuIC Report* and bills filed in Congress by Senators Kennedy and Jeffords, would charge the Safety Center with developing and supporting a research agenda.[81] Patient safety initiatives at the federal level have projected initial funding for their corresponding centers at $ 30-35 million (IOM), $ 20 million (QuIC and Administration budget), and $50 million (Kennedy and Jeffords bills). Senator Moore proposed an initial state funding for the Center of $500,000. While the Senate version of the state FY 2001 budget contained that funding, the budget recently passed by the legislature, signed into law by Governor Cellucci, makes no provision for funding the Lehman Center.[82]

Patient safety programs for physicians and hospitals in Massachusetts are now enshrined in two licensing agencies, but there is no formal mechanism that coordinates their respective programs. SB 2195 would provide a formal link for those programs, charging the Center with creating minimum standards for patient safety programs that would apply to not only the Medicine Board and the DPH, but also all other health licensing bodies and state agencies which provide or purchase health care services, not limited to hospital settings.[83] The baseline standards to be developed by the Center would include:

1. A uniform definition set;

2. Standards for identifying and analyzing adverse events and "near misses";

3. Requirements for audits of error reduction programs;

4. Standards for corrective actions; and

5. Formats and standards for reporting patient safety data and information to the Center by the various state agencies which regulate health care, provide or purchase health care services.

In this respect, Senate 2195 differs substantially from federal proposals (QuIC, Kennedy, Jeffords), which do not propose vesting consolidated regulatory authority over patient safety programs in their proposed patient safety centers.

Senate 2195 also has provisions for both voluntary reporting of "near misses" and for the existing mandatory systems. For near misses, SB 2195 outlines a pilot program with voluntary reporting of incidents directly to the Lehman Center.[84] SB 2195 proposes that the Medicine Board and DPH feed information from incident reports into the Lehman Center, which would develop the format and method of incident reporting.[85]

The expectation is that the Lehman Center would provide the analysis that this data needs if it is to realize its potential as a learning tool for patient safety. Massachusetts has not yet funded research studies of the data collected under its two mandatory reporting systems, and thus has neglected a potentially valuable resource. Substantial resources will be necessary to support systematic research utilizing these databases. Both incident reporting systems in Massachusetts are now severely hampered by underfunding. Properly done, these programs are expensive. The VA, for example, recently signed a four-year, $8.2 million contract with NASA to develop an external near miss reporting system, modeled on NASA's widely-acclaimed Aviation Safety Reporting System. This is *in addition* to the internal, mandatory system already in place in the VA network.

Senate Bill 2195 does address confidentiality of patient safety information, but the provisions fall short of similar proposals at the federal level, which protects data both at the site at which it is generated and at the agencies which collect it. Providers are likely to be adamant that any requirements to generate and disclose additional information about the causes of medical injuries must be protected against use in medical malpractice litigation, arguing analogy to the privilege against self-incrimination. It is unlikely that clinicians will engage in any meaningful self-reflection or candid analysis of mishaps if they anticipate that the likely end use of their analysis will be as an exhibit introduced into evidence against them.

Working from the baseline standards to be developed by the Lehman Center, and following the broad outlines of the *IOM Report*, SB 2195 would require agencies providing health care services to institute patient safety programs, and would require state agencies purchasing health care services to include patient safety program standards in their contracts with vendors.[86] Again, following the outline of the *IOM Report*, SB 2195 would require state agencies licensing health care clinicians and organizations to mandate participation in patient safety programs as a condition of obtaining or maintaining their licenses.[87]

There is no public information component in SB 2195 beyond annual reports by the Center on the state of patient safety in the Commonwealth. The *IOM Report* recommends, for example, not only that purchasers consider safety issues in their contracts with providers, but that the relevant information concerning provider programs be furnished to their subscribers and enrollees. Likewise, the *QuIC Report* commits the GPO to providing information on the patient safety programs to federal employees on the various health plans providing coverage to those employees. The bill does not create a legal obligation for clinicians or health care organizations to disclose errors to patients.

The current regulatory framework for patient safety, physicians and hospitals has been subject to most of the regulatory requirements found in SB 2195 for more than a decade. What is new in SB 2195 is the designation of a single agency, the Lehman Center, to develop and supervise the Commonwealth's patient safety agenda, providing both leadership and coordination to the state's efforts. What is missing is a commitment on the part of the state to provide the necessary funding which a vigorous effort by the Lehman Center requires. Without adequate funding, there is a danger that the Lehman Center would add yet another layer of bureaucracy onto the regulatory system without adding value. This would create cynicism about the state's commitment to patient safety and undermine future support for patient safety initiatives.

VI. 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 usual approach within medicine has been 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 systematic flaws that contribute to the genesis of adverse events, but also perpetuates a myth of infallibility that is a disservice both to clinicians and their patients. There needs to be alignment with the core value of doing no avoidable harm, while aligning the external incentives with the healthcare system.

There is a long tradition in medicine of examining past practices to understand how things might have been done differently. However, morbidity and mortality conferences, grand rounds, and peer review, all share the same shortcomings:

1. A lack of human factors and systems thinking;

2. A narrow focus on individual performance excluding analysis contributory team factors and larger social issues;

3. Retrospective bias; a tendency to search for errors as opposed to the myriad causes of error-induction;

4. A lack of multidisciplinary integration into an organization-wide safety culture thus perpetuating a "code of silence." 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.

Ambulatory Care

Unfortunately, shocking as they are, for two important reasons, the IOM numbers probably underestimate the extent of preventable medical injury. 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 or by inattention, or more likely, because they are not recognized. Secondly, the reason that the IOM report estimates of the totat burden of medical injury are probably low is that they do not include injuries which occur in ambulatory care and other non-hospital settings. Ambulatory care has expanded several fold since 1984 with the majority of surgical procedures today being performed in ambulatory settings.[88] None of the complications associated with outpatient care were included in any of the studies unless they resulted in hosptilization. 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 of 10% error in office prescriptions, and several reports of deaths during liposuction, are not encouraging.[89] Florida has recently suspended most ambulatory surgical procedures for 90 days pending several invesitigations into suspected preventable deaths.[90]

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 exacerbate blame and increase litigation. Public discussion of the IOM report could transform the healthcare sytstem. For this to happen, however, all stakeholders, motivated by a common goal must move forward prudently instead of instituting quick fixes which encourage divisiveness, gaming and non-compliance.

Attributing errors to system failures does not absolve physicians and nurses of their duty to care. In fact, to that duty it adds the responsibility to admit errors, investigate them, and participate in redesign of the system. This is more challenging than simply punishing wrongdoers. The study of "errorology," the search for the absolute number of errors, is misguided, and leads to an unproductive and ultimately divisive debate. The problem is the inconsistent use of the label "error." The inappropriate use of the term "error" poisons the discussion on patient safety.

VII. Recommendations for State Action

We believe that Massachusetts can make a signification positive impact on reducing health system problems by considering the following recommendations:

• Recommendation 1: Create and endow a Patient Safety Center for the Commonwealth

Massachusetts needs a comprehensive, coordinated patient safety strategy. This implies the need for a patient safety center to develop and identify evidence-based "best practices" and support the dissemination and implementation of effective patient safety program components through a sustained, systematic effort, which provides leadership for the health care industry and regulators. Creation of such a center will be expensive. Proposals for a national patient safety center have

had initial budget estimates ranging from $20 million to $50 million, growing over time to $100 million. It should be expected that a vigorous patient safety center in Massachusetts would need a budget of millions dollars as it matures as would a near-miss incident reporting system. To date the only proposal circulated in Massachusetts for funding such efforts is for one-half million dollars; It seems likely that this proposal is too low, perhaps by as much as an order of magnitude.

Fortunately, Massachusetts is enjoying a period of remarkable prosperity and there is substantial surplus in the Commonwealth's budget that makes a substantial investment in patient safety possible. We recommend taking steps to ensure that a sustained patient safety effort can be undertaken, and that program be protected against budgetary vicissitudes by funding an endowment for a Patient Safety Budget. Massachusetts leaders should be challenged to create a Patient Safety Endowment Fund in the range of $25 million for five years.

• Recommendation 2: Structure a leadership vehicle for the future development of patient safety programs

Massachusetts needs a comprehensive, coordinated patient safety strategy. Two models have emerged which aim to provide leadership for patient safety efforts in the Commonwealth, and there is a danger that energy needed for developing a patient safety agenda could be lost in competition between the two models. The two potential vehicles are the Coalition for the Prevention of Medical Errors, a public-private partnership, and the Lehman Center for Patient Safety and Medical Error Reduction, a more traditional regulatory vehicle proposed in Senate Bill 2195.

When the Coalition for the Prevention of Medical Errors was formed by health care industry leaders and regulators long before publication of the *IOM Report* it aimed to provide leadership and coordination on patient safety efforts in Massachusetts. It has taken important steps to do so, most notably with the dissemination of the set of best practices identified in the medication error prevention project of the MHA. The Coalition offers the potential power of consensus-driven change. It has been a largely volunteer effort, and has not had its own research budget or full-time professional staff. Assuming, however, that leading the Commonwealth's patient safety program will require a multi million dollar budget annually, it is unclear whether the Coalition will be able to develop a system strong enough to provide the leadership that is needed in Massachusetts without substantial financial support from the Commonwealth.

Likewise the development of a patient safety agenda for Massachusetts is at the heart of Senator Moore's patient safety bill, Senate Bill 2195. This legislation contains proposals to create and provide funding for the Lehman Center, which would:

(1) Serve as a central publicly accessible clearinghouse for information concerning patient safety

(2) Analyze and evaluate the data generated by mandatory reporting systems.

(3) Conduct and fund research on the causes of and best practices to reduce medical adverse events;

(4) Disseminate evidence based information to guide the development and continuous improvement of best practices.

(5) Provide technical assistance to state agencies and health care organizations on standards and best practices.

Strong arguments can be made in favor of either approach. What Massachusetts must avoid is being side tracked in a competition between the models. The leaders for the patient safety movement in Massachusetts should meet to develop a joint, progressive strategy. If necessary, a prestigious commission should be created to determine the best organizational and administrative structure, eliminate regulatory duplication and provide funding for patient safety programs.

• Recommendation 3: Mandatory adoption of error prevention strategies

There are several error prevention strategies that are economical, have a proven track record in Massachusetts or elsewhere, and which could be easily implemented in healthcare institutions in the Commonwealth. Once such strategies are identified and have proven effective and economically viable, compliance should be mandated. We also recommend that there should be penalties for failures to report or comply with requirements for internal error prevention programs. While consensus-driven programs should be encouraged and are likely to be an effective route to change, it needs to be clear at some point that improving patient safety is a mandate, and that eventually all health care organizations and clinicians must meet patient safety requirements.

• Recommendation 4: Implement Incident Reporting Systems

Mandatory Systems—at the national level there is considerable activity to implement the *IOM* recommendations regarding the development of standardized definitions and data fields for state reporting systems. The proposals being made at the federal level, when considered with the prospect that the Health Care Financing Administration (HCFA) is preparing to add a third mandatory incident reporting system in Massachusetts, should prompt the Commonwealth to rationalize the existing incident reporting systems. This may imply a single, unified mandatory incident reporting system, or a reduction in the substantial duplication that now exists. Massachusetts has two mandatory incident reporting systems for hospitals that appear to be duplicative. Neither system has been studied in a peer reviewed, systematic way.

Rationalization of mandatory incident reporting systems in Massachusetts will require policymakers to grapple, not only with the differing reporting criteria of each of the current systems, but also the different balance that has been struck on the issues of confidentiality and public access. One system, (BORIM) is completely confidential, while the other (DPH) has no confidentiality provisions and is open to public inspection. Data from each system should be compared, to determine not only which reporting criteria have generated useful data, but also whether confidentiality has in fact promoted compliance.

Data from studies of internal hospital reporting systems indicate that concerns over confidentiality inhibit the willingness of clinicians to participate in reporting adverse events. It is unclear, however, whether this is a factor with the external, mandatory systems in place in Massachusetts. There is, a substantial countervailing interest in public accountability that favors disclosure of at least some information from mandatory reporting systems. With respect to confidentiality, the choices ought not to be limited to all or nothing. A careful study of the data accumulated over the past five years by the two systems should reveal information that will permit judgments about the degree to which reported data should be confidential or accessible to the public.

HCFA Pilot—The Health Care Financing Administration (HCFA) is planning to sponsor a "confidential, penalty free mandatory reporting learning system" through its PROs in selected states, such as Massachusetts, that have mandatory reporting systems. We expect that HCFA will provide substantial incentives to participation in the these programs, and encourage the state hospitals and medical society to consider the desirability of undertaking a demonstration project in Massachusetts. The database, which will be de-identified, will have no referral to enforcement or regulatory agencies.

Pilot Near-Miss Incident Reporting System—Experience in other industries where errors are lethal or cause serious injuries suggest that confidential, voluntary "near miss" reporting systems can be invaluable in identifying systemic problems and providing information useful to improving safety. These systems complement the mandatory reporting systems used by regulatory agencies to monitor compliance and assure accountability. Near miss reporting systems share the characteristics of being confidential, nonpunitive, and voluntary, and are administered by agencies that do not have regulatory or oversight responsibilities. Development of such near miss incident reporting systems in health care has been limited to date. Given the potential contributions of a voluntary near miss reporting system to improving patient care, Massachusetts should consider developing a pilot program. Such a program, however, will have substantial costs. The VA, for example, recently signed a four-year $8.2 million contract with NASA to develop a voluntary incident reporting system based on the Aviation Safety Reporting System.

• Recommendation 5: Provide and ensure appropriate confidentiality protection

The laws protecting the confidentiality of quality improvement activities need to be reviewed and updated by the legislature as part of the patient safety agenda. It no longer suffices to shield the processes of medical peer review committees, as our current law does. Quality improvement requires more than the involvement of medical staff committees. The law should recognize and accommodate interdisciplinary efforts and protect sensitive information that is needed by state agencies, accreditors, and other institutions.

SB 2195 should be amended to provide appropriate confidentiality protection and restrictions on use of patient safety data. We must engage in the difficult process of creating better systems that encourage clinicians to report and discuss errors yet maintain and improve accountability.

• Recommendation 6: Study alternatives to the current medical liability and accountability systems

In an ideal environment, all incentives would be aligned with patient safety oriented goals. Our current liability system, however, cuts exactly in the opposite direction, requiring that individual clinicians be blamed for adverse events that injure patients before patients can be compensated for their injuries. Massachusetts should investigate the feasibility of developing a pilot no-fault system for compensating victims of medical injuries. A no-fault compensation system would also promote compliance with the ethical imperative of full disclosure. We might consider the successful New Zealand no-fault compensation system for medical adverse events.

Despite the lessons of safety science about the nature of error and the necessity of a systematic approach to promote safety, many believe that our current tort system provides accountability and important incentives for the adoption of safe practices. We need to pursue more effective ways of promoting safety and accountability on the part of the health care system (both the organizations and the people who work in them) for doing everything possible to prevent doing avoidable harm.

VIII. Conclusion

The information gathered for this report suggests that patient safety in Massachusetts is a critical topic, which must be addressed at the state level. Despite being the home of many of the national pioneering safety programs in the country, there is still a perception and several indications that many patients suffer unnecessary adverse events in Massachusetts acute care hospitals and ambulatory settings.

Any approach to improving patient safety should, at least include a non-punitive mechanism for reporting adverse events following the incident, analysis to identify system changes required to prevent recurrences and state guaranteed legislative protection from disclosure of all information gathered to improve patient safety. Massachusetts should consider the experience of the past several decades in preventing hospital acquired infections. These studies have been executed in a blame-free environment in which learning was the major goal. More data collection however for the sake of having more data, in the absence of specific goals and scientifically designed studies, is unlikely to yield real improvement in patient safety. Statewide dissemination of the solutions identified would do a great deal more to improve safety in the Commonwealth.

Massachusetts should strongly support the IOM recommendations that Congress provide the funds and technical support necessary to analyze the information obtained from current error reporting systems (such as the BORIM) and conduct follow-up action as needed. True reform must involve all stakeholders: Hospitals, physicians, nurses, pharmacists, regulators, attorneys, nursing homes, ambulatory care clinics, home health agencies, and patients. The common goal must be to detect error-producing environments and systematic barriers to correction before patients are harmed.

The matter of public accountability for negligent or incompetent actions by physicians and other health care providers is already well established in our health care and judicial systems. State and Federal courts, state licensing boards, and accrediting bodies such as JCAHO all participate in the maintenance of and standards and accountability. However fear of legal liability or the misapplication of existing legal constraints, are the greatest hurdles to advances in patient safety. The health care system needs to transform the existing culture of blame and punishment which suppresses information about errors and adverse events, into a culture of safety which focuses on openness and information sharing to improve health care and prevent adverse outcomes.

Massachusetts can create a culture of safety by encouraging medical professionals to discuss patient safety problems and potential solutions openly without having their discussions, findings, or recommendations becoming the basis for class action or other lawsuits. If fear of litigation continues to impede efforts to improve patient safety and quality, our transformation into a culture of patient safety may never be realized. These problems can only be addressed through public action.

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a. Maternal deaths that are related to delivery
b. Death in the course of, or resulting from, elective ambulatory procedures
c. Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part
d. All deaths or major or permanent impairments of bodily functions (other than those reported above) that are not ordinarily expected as a result of the patient's condition on presentation. 243 CMR 3.08 (2).

There are three classes of incidents that must be reported by hospitals to DPH:
a. Certain specific incidents (suicide, serious criminal acts, serious physical injuries to patients resulting from accident or unknown cause) are reportable immediately by telephone. 105 CMR 130.331. (A).
b. Maternal deaths are reportable within forty-eight hours to DPH. 105 CMR 130.628 (C).
c. Serious patient injuries (incidents that "seriously affect the health and safety" of patients) must be reported in writing within one week. 105 CMR 130.331 (B).

The DPH has issued guidance defining for hospitals the type of serious injuries that it requires be reported. As a general rule under this third category of "serious injury", the DPH requires hospitals to report any error that is life threatening, results in death, or requires a patient to undergo significant additional diagnostic or treatment measures. Circular Letter DHCQ 12-98-385. Division of Health Care Quality, Massachusetts Department of Public Health, Boston, MA (1998).

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[74] While the Board's definition of "health care facility" captures virtually all organizations licensed to provide health care services, the Board has set out less comprehensive regulations for health maintenance organizations (243 CMR 3.13), nursing homes (243 CMR 3.14) and clinics (243 CMR 3.15) than those applicable to acute care hospitals. Unless indicated to the contrary, this summary is restricted to the regulations applicable to hospitals.

[75] M.G.L. c. 111, § 205. This rather unclear language is the result of a legislative compromise that has not been fully interpreted by the courts, and the scope of confidentiality protection afforded to PCA materials consequently is uncertain. The Carr case, previously cited, concerned only hospital incident reports. Despite the Medicine Board's current

protectiveness of the confidentiality of its PCA data, the Board opposed the legislation conferring this confidentiality protection when it was being debated in the legislature in 1987.

[76] This is the import of the language and thus far the Supreme Judicial Court has interpreted the privilege as broadly as it is written. See the Court's decisions in Beth Israel Hospital Association v. Board of Registration in Medicine, 401 Mass. 172 (1987) and Carr, supra note 68.

[77] The following organizations are members of the Coalition:
American Association of Retired Persons
American College of Physicians
Boston University School of Medicine Center for Primary Care
Harvard Risk Management Foundation
Health Care Financing Administration Regional Office
Harvard School of Public Health
Institute for Healthcare Improvement
Joint Commission on Accreditation of Healthcare Organizations
Massachusetts Association of Behavioral Health Systems
Massachusetts Board of Nursing
Massachusetts Board of Pharmacy
Massachusetts Board of Registration in Medicine
Massachusetts Department of Public Health
Massachusetts Extended Care Federation
Massachusetts Hospital Association
Massachusetts Medical Society
Massachusetts Nurses Association
Massachusetts Organization of Nurse Executives
Massachusetts Peer Review Organization
Professional Liability Foundation
PRO Mutual Group

[78] Mission Statement, Mass. Coalition for the Prevention of Medical Errors, http://www.mhalink.org/mcpme/mcpme_welcome.htm#Mission Statement (Accessed September 3, 2000).

[79] Senate Bill 2195, adding § 24 (a) to M.G.L. c. 118G.

[80] Id., adding § 24 (b) to M.G.L. c. 118G.

[81] Senate Bill 2210, § 2, line item 4100-0063.

[82] Id., adding § 24 (c) to M.G.L. c. 118G.

[83] Id., adding § 24 (d) to M.G.L. c. 118G.

[84] Id., adding § 24 (e) to M.G.L. c. 118G.

[85] Id., adding § 24 (c) to M.G.L. c. 118G.

[86] Id., adding § 24 (f) and (g) to M.G.L. c. 118G.

[87] Id., adding § 24 (h) to M.G.L. c. 118G.

[88] June Gibbs Brown, Inspector General. The External review of Hospital Quality: A Call for Greater Accountibility. July 1999, OEI-01-97-00050.

[89] Lidocaine dose questioned in liposuction deaths. " AMNews, February 15, 1999 pp. 30-32.

[90] http://www.ama-assn.org/sci-pubs/amnews/pick_00/prl20904.htm

Appendix A

Definitions Used in Incident Reporting Systems

Error

Failure to perform intended action that was correct given circumstances[7]

Failure to complete action as intended, or use of wrong plan to achieve aim[1]

Near miss

Case where accident was narrowly averted[2]

Any situation in which ongoing sequence of events was prevented from developing further and hence preventing occurrence of potentially serious consequences[6]

Error that almost happened but was prevented[5]

Non-events that can be called near histories—events that almost happened[4]

Regarded as incidents which under different circumstances could have far more serious consequences[1]

Dangerous occurrences: no personnel injury, but material damage—warnings of coming events[10]

Mishap that causes, or close call that has potential to cause major impact to space flight operations or prevents accomplishment of primary mission objective[8]

Non-consequential events

Occurrence that could have led to dangerous breakdown[9]

Incidents

Event that under slightly different circumstances could have been an accident[7]

Near misses and accidents[6]

Any unusual event or occurrence in which potential liability may occur[12]

Critical incident

Occurrence that is significant or pivotal in either desirable or undesirable way[10]

Occurrence which if not discovered or corrected in time did or could lead to patient morbidity or mortality[11]

Accident

Random event that is unforeseen, unfortunate, and unexpected[13]

Caused by side effects of decisions made by different actors distributed in different organizations, at different levels, and during activities at different points in time[5]

Unplanned, unexpected, and undesired event, usually with an adverse consequences[3]

References for Appendix A

Non-medical near miss reporting systems

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