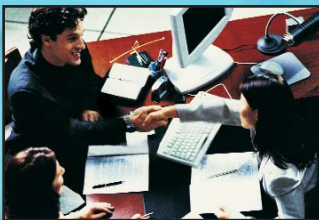


HEALTH CARE AT THE CROSSROADS:

Strategies for Improving the Medical Liability System and Preventing Patient Injury



Joint Commission

on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

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JOINT COMMISSION PUBLIC POLICY INITIATIVE

This white paper is a product of the Joint Commission's Public Policy Initiative. Launched in 2001, this initiative seeks to address broad issues that have the potential to seriously undermine the provision of safe, high-quality health care and, indeed, the health of the American people. These are issues that demand the attention and engagement of multiple publics if successful resolution is to be achieved.

For each of the identified public policy issues, the Joint Commission already has relevant state-of-the-art standards in place. However, simple application of these standards, and other unidimensional efforts, will leave this country far short of its health care goals and objectives. Thus, this paper does not describe new Joint Commission requirements for health care organizations, nor even suggest that new requirements will be forthcoming in the future.

Rather, the Joint Commission has devised a public policy action plan that involves the gathering of information and multiple perspectives on the issue; formulation of comprehensive solutions; and assignment of accountabilities for these solutions. The execution of this plan includes the convening of roundtable discussions and national symposia, the issuance of this white paper, and active pursuit of the suggested recommendations.

This paper is a call to action for those who influence, develop or carry out policies that will lead the way to resolution of the issue. This is specifically in furtherance of the Joint Commission's stated mission to improve the safety and quality of health care provided to the public.

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INTRODUCTION

Increasingly the subject of newspaper headlines and even physician picket lines, the current “medical liability crisis” is beginning to rally policymakers to become serious about reforms to the current tort system. Efforts to stem the rise in liability insurance premiums have most commonly taken the form of seeking caps on non-economic damages awarded in medical liability cases. Indeed, in several states that have implemented such caps, liability insurance premiums have increased less than in states without caps.¹ But capping damages on the back end of litigation does not address all of the factors that lead to litigation on the front end. At a time of growing awareness and acknowledgement of medical error – and active efforts to address this problem -- the effectiveness of the tort system itself in deterring negligence, compensating patients, and exacting corrective justice is being called into question.

There is in fact a fundamental dissonance between the medical liability system and the patient safety movement. The latter depends on the transparency of information on which to base improvement; the former drives such information underground. As a result, neither patients nor health care providers are well served by the current medical liability system. This is seemingly not a real “system,” but rather a

patchwork of disjointed and inconsistent decisions that has limited ability to inform the development of improved health care practices.²

Several studies have, with remarkable consistency, revealed the inconsistency of the medical liability system in determining negligence and compensating patients. The Harvard Medical Practice study found that two percent of negligent injuries resulted in claims, and only 17 percent of claims appeared to involve negligent injury.³ Subsequent studies conducted in Colorado and Utah found similar results.⁴ Few injured patients receive compensation through the medical liability system, and those who do receive highly variable recompense, even for injuries that appear to be quite similar.

It is estimated that at least \$28 billion is spent each year on the inter-related combination of medical liability litigation and defensive medicine.⁵ The latter involves the excessive ordering of non-essential tests and treatments solely for risk management purposes. In a country in which escalating health care costs and diminishing health care access are top-of-mind public concerns,⁶ these costs are increasingly indefensible, especially in the absence of evidence that such expenditures improve patient safety and health outcomes.



AMONG THE SPECIFIC ISSUES ADDRESSED BY THE ROUNDTABLE WAS THE EXTENT TO WHICH THE CURRENT MEDICAL LIABILITY SYSTEM UNDERMINES OR SUPPORTS PATIENT SAFETY, AND IF, INDEED, IT UNDERMINES PATIENT SAFETY, ARE EFFECTIVE REMEDIAL ACTIONS POSSIBLE?



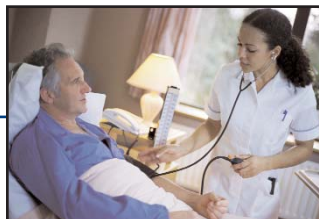
INTRODUCTION

On average, a medical liability case takes three to five years to come to closure.⁷ Closed claims provide valuable data for researchers to mine, but because of the lengthy elapse of time, opportunities for swift intervention to address unsafe practices are often lost. Cases that reach settlement in the intervening years are typically cloaked by “gag clauses” that require complainants’ silence, and squelch efforts to elucidate and ameliorate the factors that lead to injury.

The core of the Joint Commission’s mission is to continuously improve the safety and quality of care provided to the public. In pursuit of its mission, the Joint Commission has, over the past decade, redrawn its accreditation standards to more sharply focus on patient safety. In addition, it has, since 1996, operated a national voluntary adverse event reporting database, and in recent years, has used this database to develop and incorporate into its accreditation process a series of concrete, setting-specific National Patient Safety Goals and Requirements. Among Joint Commission standards is a requirement that health care organizations, through the responsible physician, disclose unexpected outcomes and adverse events to their patients. The ability of health care organizations to comply with this standard and others, as well as to report adverse events to the Joint Commission’s

database, is severely undermined by the medical liability system. The liability system supports a “wall of silence”⁸ -- discouraging disclosure and inhibiting efforts to create cultures of safety inside health care organizations and among practitioners.

Creating cultures of safety within health care and improving quality and access -- indeed, making health care truly better -- requires that legal and medical institutions work together.⁹ In order to frame the complex factors and issues that need to be addressed in order to accomplish such alignment, the Joint Commission convened an expert Roundtable. Among the principal specific issues addressed by the Roundtable were the extent to which the current medical liability system undermines or supports patient safety, and if, indeed, it undermines patient safety, are effective remedial actions possible? Further, if the aforementioned dissonance is serious and real, what short-term steps should be taken to moderate the negative impacts of the system? And finally, what potential long-term alternatives to the current tort system should be considered and how might they best be pursued? This white paper represents a culmination of these discussions. The many recommendations contained herein are all actionable and should be pursued, in no small measure, to better serve the common good.



THERE IS IN FACT A FUNDAMENTAL DISSONANCE BETWEEN THE MEDICAL LIABILITY SYSTEM AND THE PATIENT SAFETY MOVEMENT. THE LATTER DEPENDS ON THE TRANSPARENCY OF INFORMATION ON WHICH TO BASE IMPROVEMENT; THE FORMER DRIVES SUCH INFORMATION UNDERGROUND.



EXECUTIVE SUMMARY

RECOMMENDATION I. PURSUE PATIENT SAFETY INITIATIVES THAT PREVENT MEDICAL INJURY

When the Institute of Medicine released its landmark report, *To Err Is Human*,¹⁰ the frequent occurrence of medical error went public. Now, five years after the IOM report, error remains ubiquitous in health care delivery. To be sure, activities and initiatives aimed at improving patient safety have been and continue to be pursued. However, there are obstacles within health care organizations that stymie improvement – most notably, lack of will, resources and knowledge.

The axiom, “you learn from your mistakes” is too little honored in health care. Near-miss and error reporting is an essential component of safety programs across safety-conscious industries. Within health care, though, many physicians are often reluctant to engage in patient safety activities and be open about errors because they believe they are being asked to do so without adequate assurances of legal protection.¹¹ The stifling specter of litigation results in the under-reporting of adverse events by physicians and avoidance of open communications with patients about error.¹²

The IOM report suggests that 90 percent of medical errors are the result of failed systems and procedures that are poorly designed to accommodate the complexity of health care delivery. If properly designed, these systems and procedures could better prevent inevitable human errors from reaching patients. But understanding the root causes of errors requires their divulgence in the first place. In sharp contrast to the systems-based orientation of the patient safety movement, tort law targets individual physicians.¹³

I.A STRENGTHEN OVERSIGHT AND ACCOUNTABILITY MECHANISMS TO BETTER ENSURE THE COMPETENCIES OF PHYSICIANS AND NURSES

As the IOM reports make clear, multiple broken systems can be identified in the majority of cases in which a serious adverse event has occurred. However, there remains today too little effort to unveil the specific contributory factors to such occurrences. That said, a systems-based approach to quality improvement does not preclude individual accountability. Accountability mechanisms – licensure, certification, and peer review – also need to be strengthened to ensure an optimally qualified health care workforce. The tort system should not be the net to snare incompetent physicians, and it cannot be effective, when it is cast so wide.



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The American Board of Medical Specialties (ABMS) is now in the process of implementing encompassing new requirements for the maintenance of board certification for the 24 medical specialties it represents. These requirements would eventually apply to over 90 percent of practicing physicians. Following suit, the Federation of State Medical Boards is also pursuing an agenda for the maintenance of physician licensure.

While the legal system is often maligned by physicians, some physicians do not hesitate to use it to stave off loss of hospital privileges and licensure. Going forward, to avoid the quagmire in which hospitals often find themselves when they attempt to curtail or remove privileges, these institutions need to be thorough and deliberate in their initial granting of privileges, to consider granting new privileges for shorter periods of time, and to apply objective measures of performance before renewing privileges. This approach would be synchronous with the movement of certification boards to grant time-limited board certification, and to undertake rigorous competency assessment on a continuing basis.

Administrative and clinical leadership must also take greater initiative to ensure the competency of their nurses. Nurse staffing shortages have made the hiring of new nurses a priority, but newly graduated nurses typically receive far too little training before assuming clinical responsibilities, and the monitoring of clinical performance is uneven at best. The growing use of external staffing agencies to fill staffing gaps only makes this problem worse.

I.B ALLOW HEALTH CARE RESEARCHER ACCESS TO OPEN LIABILITY CLAIMS TO PERMIT EARLY IDENTIFICATION OF PROBLEMATIC TRENDS IN CLINICAL CARE

One of health care's principal patient safety success stories is anesthesiology. The American Society of Anesthesiologists uses case analysis to identify liability risk areas, monitor trends in patient injury, and design strategies for prevention. Today, the ASA Closed Claims Project – created in 1985 -- contains 6,448 closed insurance claims. Analyses of these claims have, for example, revealed patterns in patient injury in the use of regional anesthesia, in the placement of central venous catheters, and in chronic pain management. Results of these analyses are published in the professional literature to aid practitioner learning and promote changes in practices that improve safety and reduce liability exposure.

Closed claims data analysis is the one way in which the current medical liability system helps to inform improvements in care delivery. However, reliance on closed claims for information related to error and injury is cumbersome at best. It may take years for an insurance or malpractice claim to close. These are years in which potentially vital information on substandard practices remains unknown. Providing patient safety researchers with access to open claims, now protected from external examination, could vastly improve efforts aimed at identifying worrisome patterns in care and designing appropriate safety interventions.



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I.C ENCOURAGE APPROPRIATE ADHERENCE TO CLINICAL GUIDELINES TO IMPROVE QUALITY AND REDUCE LIABILITY RISK

Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance.¹⁴ In court, clinical guidelines are increasingly invoked to prove or disprove deviations from the standard of care. But there is a more significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to clinical guidelines can have a significant role in reducing legal risk.¹⁵ The study, which focused on obstetrical patients, found a six-fold increase in risk of litigation for cases in which there was a deviation from relevant clinical guidelines.¹⁶ Further, one-third of all obstetric claims analyzed in the study were linked to non-compliant care.¹⁷

I.D SUPPORT TEAMWORK DEVELOPMENT THROUGH TEAM TRAINING, "CREW RESOURCE MANAGEMENT," AND HIGH-PERFORMING MICROSYSTEM MODELING

Teamwork -- indeed, team training -- has been identified by patient safety experts as an essential factor in reducing the risk of medical error. In aviation, "Crew Resource Management" (CRM) is the methodology used to guide team development among pilots, flight attendants and other crew. In this context, predefined roles and responsibilities for various scenarios help to assure the safety of every flight. Consistently applying such an approach to health care delivery could increase the

timeliness and accuracy of communications -- breakdowns of which are commonly implicated sources of serious adverse events. This could also help to enlist clinicians and support staff in committing to a common goal -- safe and effective care -- in the often high-pressure and chaotic environments of health care. Unfortunately, health care professionals are not educated and trained to work as teams or even team members. Recreating the culture of health care delivery to value team-based care must begin at the earliest point of intervention -- health care professional education -- and be continuously reinforced in practice.

Clinical units that successfully foster strong team-based approaches to health care delivery do exist. In their research, Nelson, Batalden *et al* identified high-performing, front-line clinical units called microsystems.¹⁸ A microsystem is further defined as a small group of people who regularly work together to provide care to discrete sub-populations of patients, and share business and clinical aims, linked processes, and a common information environment.¹⁹ Microsystems are often embedded in larger organizations -- the "macrosystem."

High-performing microsystems produce superior outcomes and cost-effective care, and at the same time, provide positive and attractive working environments.²⁰ These units are also characterized by the high value placed on patient safety, as well as compliance with policies and other requirements.



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I.E CONTINUE TO LEVERAGE PATIENT SAFETY INITIATIVES THROUGH REGULATORY AND OTHER QUALITY OVERSIGHT BODIES

A study recently published in *Health Affairs* by Devers *et al* concludes that the major driver for hospital patient safety initiatives is Joint Commission requirements.²¹ The majority of hospitals surveyed as part of the study explicitly noted that they were working to meet Joint Commission requirements – developing better processes for reporting, analyzing, and preventing sentinel events; meeting patient safety standards, including acknowledgement of leadership’s accountability for patient safety and the creation of a non-punitive culture; and meeting the specific National Patient Safety Goals.²²

In the Devers *et al* study, the description of hospital patient safety initiatives also highlights the influence of other third parties in driving patient safety improvements. The Leapfrog Group was frequently mentioned by study participants, particularly with regard to its influence in driving the adoption of Computerized Physician Order Entry (CPOE) systems.

I.F ENCOURAGE THE ADOPTION OF INFORMATION AND SIMULATION TECHNOLOGY BY BUILDING THE EVIDENCE-BASE OF THEIR IMPACTS ON PATIENT SAFETY, AND PURSUE PROPOSALS TO OFFSET IMPLEMENTATION COSTS

In its *Crossing the Quality Chasm* report, The Institute of Medicine underscores the importance of information technology as a key factor

in meeting several of its quality aims. Since then, the momentum toward widespread adoption of information technology has accelerated. Leading proponents include the National Alliance on Healthcare Information Technology, the Markle Foundation’s Connecting for Health initiative, and now the Department of Health and Human Services itself, with the appointment of a national coordinator for IT initiatives last year.

I.G LEVERAGE THE CREATION OF CULTURES OF PATIENT SAFETY IN HEALTH CARE ORGANIZATIONS

The pressures on health care leaders today are great. Increasing costs, increasing demand for services, and unfavorable reimbursement policies mean that patient “throughput” – the time in which patients move into, through, and out of the health care setting – must be accelerated to maintain revenues. This acceleration of the care process heightens the risk of medical error, and compromises effective patient-practitioner communications.²³ Yet, in this environment, a culture of patient safety must be created and emulated from the top down. This responsibility lies both with individual health care organizations and practitioners, and with those who set health care policy in this country.



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I.H ESTABLISH A FEDERAL LEADERSHIP LOCUS FOR ADVOCACY OF PATIENT SAFETY AND HEALTH CARE QUALITY

Until this country both elevates the importance of quality and safety problems and engages in a coordinated approach to solutions, it will be difficult to make significant strides in addressing the foundational patient safety problems that persist today. Creation of an Office of Health Care Quality in the Department of Health and Human Services could provide a powerful platform for setting priorities and direction for improving patient safety and health care quality. Such an office could also coordinate and enhance the efforts of established private and public sector bodies already engaged in patient safety and quality improvement activities.

I.I PURSUE "PAY-FOR-PERFORMANCE" STRATEGIES THAT PROVIDE INCENTIVES TO FOCUS ON IMPROVEMENTS IN PATIENT SAFETY AND HEALTH CARE QUALITY

New public and private sector payer initiatives designed to "pay for performance" may provide a new opportunity to align incentives for increasing safety and improving quality and patient outcomes. In 2003, CMS launched a demonstration project in partnership with Premier Inc. to test the effectiveness of paying hospitals more for better performance according to selected measures. In 2005, a new demonstration project was initiated for large medical group practices.

Small but symbolically significant bonuses are to be based on results in the management of specific clinical conditions and procedures. The pay-for-performance concept essentially envisions rewards for desired behaviors and outcomes.

RECOMMENDATION II. PROMOTE OPEN COMMUNICATION BETWEEN PATIENTS AND PRACTITIONERS

Lack of disclosure and communication is the most prominent complaint of patients, and their families, who together have become victims of medical error or negligence. Years of expensive and wounding litigation often ensue when families are sometimes only seeking answers.

II.A INVOLVE HEALTH CARE CONSUMERS AS ACTIVE MEMBERS OF THE HEALTH CARE TEAM

Health care consumers are playing an important role in the patient safety movement – as educated advocates for change based on their own experiences. When individuals' stories reach the right audience, listeners pay heed. Health care consumers can specifically help to prevent adverse events by being active, informed, and involved members of the health care team.



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For patients and family members, the physical and emotional devastation of medical error cannot be easily overcome. What they want most out of their ordeal is honest and open dialogue about what went wrong, and a “legacy” – having their experience serve as a lesson for prevention in the future.²⁴ Seldom are such communications and assurances forthcoming.

II.B ENCOURAGE OPEN COMMUNICATION BETWEEN PRACTITIONERS AND PATIENTS WHEN AN ADVERSE EVENT OCCURS

An unintended consequence of the tort system is that it inspires suppression of the very information necessary to build safer systems of health care delivery. When it comes to acknowledging and reporting medical error, there is too often silence between practitioners and patients; practitioners and their peers; practitioners and the organizations in which they practice; and health care organizations and oversight agencies.

One of the basic principles of patient safety is to talk to and listen to patients.²⁵ Several elements are fundamental to any disclosure effort. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology.²⁶

The Joint Commission’s accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients, and to their family members when appropriate. A recent study confirms that many hospitals – half of those surveyed – are reluctant to comply with this standard for fear of medical liability suits.²⁷ If disclosure is taken a step further to the offer of an apology, hospitals and physicians are even more likely to gravitate to traditional “defend and deny” behaviors. But there is increasing awareness that openness has the potential to heal, rather than harm, the physician-patient relationship. A growing number of hospitals, doctors and insurers are coming around to the idea that apologies may save money by reducing error-related payouts and the frequency of litigation.²⁸

II.C PURSUE LEGISLATION THAT PROTECTS DISCLOSURE AND APOLOGY FROM BEING USED AS EVIDENCE AGAINST PRACTITIONERS IN LITIGATION

Today, some prominent medical centers have adopted policies that urge doctors to disclose their mistakes and to apologize.²⁹ Insurers, too, are increasingly urging apologies.³⁰ And, a growing number of states are passing laws that protect an apology from being used against a doctor in court.³¹ More such protections will be needed in order for most caregivers and organizations to feel comfortable with apologies, despite the ethical imperatives underlying such disclosure.



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II.D ENCOURAGE NON-PUNITIVE REPORTING OF ERRORS TO THIRD PARTIES THAT PROMOTES SHARING OF INFORMATION AND DATA ANALYSIS AS THE BASIS FOR DEVELOPING SAFETY IMPROVEMENT STRATEGIES

Few caregivers and health care organizations voluntarily break through the wall of silence to report life-threatening medical errors beyond the walls of their institutions. The Joint Commission has had a voluntary reporting system since 1996, but its Sentinel Event Database receives only about 400 new reports of events each year – well below the 44,000 to 98,000 medical error-related deaths estimated by the IOM to occur each year.

A number of states now have mandatory error reporting systems of various types.³² One of the most active, the New York State Patient Occurrence Report and Tracking Systems (NYPORTS), logged approximately 30,000 reports in 2003.³³ A new reporting system in Pennsylvania captures reports of near-misses as well as actual errors. Reporting systems can capture enormous volumes of data, but without the requisite resources to analyze the data and translate it into useful information, their potential is far from being fully realized. Other types of external reporting systems include voluntary reporting systems tailored to specific health care segments and medical specialty-based reporting systems.³⁴

There remains a substantial lack of clarity as to whether error analyses reported to a third-party, such as a state agency or the Joint Commission, are afforded legal privilege protections. This lack of certainty of protection continues to hamper reporting efforts that could otherwise yield essential information for making breakthrough improvements in health care safety.

II.E ENACT FEDERAL PATIENT SAFETY LEGISLATION THAT PROVIDES LEGAL PROTECTION FOR INFORMATION REPORTED TO DESIGNATED PATIENT SAFETY ORGANIZATIONS

Patient safety legislation – under consideration by the Congress for several years and currently pending reintroduction in the current Congress – proposes legal protection for information reported to any Patient Safety Organization, as defined in the legislation. Passage of patient safety legislation of this nature would provide the cornerstone for effective reporting systems that assure confidentiality and encourage the sharing of lessons learned from the analyses of adverse events.



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RECOMMENDATION III. CREATE AN INJURY COMPENSATION SYSTEM THAT IS PATIENT-CENTERED AND SERVES THE COMMON GOOD

Only a small percentage (2-3 percent) of patients who are injured through medical negligence ever pursue litigation, and even fewer ever receive compensation for their injuries.³⁵ Those who are awarded compensation wait an average of five years to receive it.³⁶ Clearly, the current tort system falls short in compensating injured patients. As for exacting justice, there is often little correlation between court findings of negligence and actual negligence.³⁷ And rather than deterring negligence, there is a common refrain among physicians that the current tort system “keeps us from doing things that we, as good professionals, would naturally do.”³⁸

A central question is how the medical liability system can be restructured to actively encourage physicians and other health care professionals to participate in patient safety improvement activities.³⁹ The goal of any such restructuring should be to reduce litigation by decreasing patient injury, by encouraging open communication and disclosure among patients and providers, and by assuring prompt and fair compensation when safety systems fail.

III.A CONDUCT DEMONSTRATION PROJECTS OF ALTERNATIVES TO THE MEDICAL LIABILITY SYSTEM THAT PROMOTE PATIENT SAFETY AND TRANSPARENCY, AND PROVIDE SWIFT COMPENSATION TO INJURED PATIENTS

Numerous proposals have been suggested for improving the medical liability system over the past several years. These proposals center on three broad approaches: 1) creation of alternative mechanisms for compensating injured patients, such as through early settlement offers; 2) resolving disputes through a so-called “no-fault” administrative system or through health courts; and 3) shifting liability from individuals to organizations.⁴⁰ Though these approaches are distinct, they are not in conflict. One could imagine an injury resolution system that incorporates the characteristics of all three.

Inherent in any alternative to the current tort system must be a high priority for disclosure -- an acknowledgement of the error or injury, an apology, and assurances that steps will be taken to avoid such an error in the future.



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A 2003 IOM report calls for demonstration projects to test the feasibility and effectiveness of alternative injury compensation systems that are patient-centered and focused on safety.⁴¹ Such demonstration projects are needed to begin the process of mitigating the periodic medical liability crises that, aside from economic factors, result from the delivery of unsafe care, unreliable adjudication of claims, and unfair compensation for injured patients.

III.B ENCOURAGE CONTINUED DEVELOPMENT OF MEDIATION AND EARLY-OFFER INITIATIVES

Some states and liability insurance companies are already pursuing reforms to reduce reliance on litigation as a means to resolve injury claims.

In 2002, Pennsylvania became the first state to require hospitals to disclose, in writing, adverse events to patients or their families.⁴² Nevada and Florida have since followed Pennsylvania's lead.⁴³ Pennsylvania is also the site of a Pew-sponsored demonstration project that encourages mediated dispute resolution.⁴⁴ As part of this model, physicians are encouraged to disclose adverse events to their patients and to apologize.⁴⁵ Patients or their families are provided with an early and fair offer of compensation, and the opportunity for mediation to resolve disputes.⁴⁶ It is too soon to know the full ramifications of the Pew-sponsored project, but early indications are that it has been successful in mitigating litigation.⁴⁷

COPIC Insurance Company, a physician-owned liability insurer in Colorado, initiated its "3Rs" (respect, respond and resolve) program in 2000. Under this program, each insured physician is encouraged to communicate openly with the patient if an adverse event occurs, and to offer an apology when warranted.⁴⁸ COPIC pays for patient expenses, and also reimburses for lost wages.⁴⁹ Importantly, patients are not asked to waive their rights to litigation.⁵⁰ Since its inception, none of the cases addressed through the 3Rs program has gone to litigation.⁵¹

Comprehensive medical liability reform is the long-term solution for resolving the issues inherent in today's system, but there are actions that can be taken in the intermediate term that would bring greater integrity and transparency to the process.



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III.C PROHIBIT CONFIDENTIAL SETTLEMENTS — SO-CALLED “GAG CLAUSES” — THAT PREVENT LEARNING FROM EVENTS THAT LEAD TO LITIGATION

Medical liability claims are often settled before they reach trial, or before the trial ends in judgment. Terms of these settlements typically include a “gag clause” that requires the confidential sequestering of all information related to the case. Such confidential settlement offers may encourage quick resolution, but this is achieved at the cost of forever barring access to potentially important information that could be used to improve the quality and safety of care.

III.D REDESIGN OR REPLACE THE NATIONAL PRACTITIONER DATA BANK

Physicians named in medical liability judgments and settlements, as well as disciplinary actions, are reported to the National Practitioner Data Bank (NPDB). The primary reason for the existence of the NPDB is to permit hospitals and licensing boards to track physician performance issues. Since its inception, questions have continued to be raised about the validity and reliability of the NPDB.⁵² A 2000 GAO report cited a multitude of NPDB problems, including underreporting of disciplinary actions, which, the report states, is a far better expression of physician competence than medical liability claims.⁵³ In fact, medical liability claims data constitute 80 percent of the information

contained in the NPDB.⁵⁴ The information the data bank contains is also characterized in the GAO report as substantially incomplete – lacking, for example, any information as to whether the standard of care was considered when a claim was settled or adjudicated⁵⁵

There is a need for a centralized information or sources that reliably capture important inputs about the performance of physicians and other practitioners, but other options than the NPDB exist. For instance, the Federation of State Medical Boards (FSMB) regularly makes information on disciplinary actions taken against physicians publicly available. It has now been five years since the release of the GAO report critical of the NPDB, and no substantial progress has been made to implement its recommendations. Given the relative ineffectiveness of the NPDB, it either needs to be substantially redesigned or its responsibilities need to be reassigned to other more reliable information repositories.



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III.E ADVOCATE FOR COURT-APPOINTED, INDEPENDENT EXPERT WITNESSES TO MITIGATE BIAS IN EXPERT WITNESS TESTIMONY

Accountability for health care professional competency lies with the individual and his or her licensing and certification boards, and employers. This accountability should increasingly extend to the conduct of physicians who act as expert witnesses in medical liability cases. As many who have participated in a medical liability case can attest, expert opinion is subject to substantial potential bias when that opinion is paid for by either the defendant or the plaintiff in a case.⁵⁶ According to the Federation of State Medical Boards, expert witnesses who give false or misleading testimony are subject to disciplinary action.⁵⁷ In the long term, court-appointed experts that are independent of either plaintiffs or defendants are more likely to provide objective support to the litigation process.

CONCLUSION

It is clearly time to actively explore and test alternatives to the medical liability system.

The goal of such alternatives is not to legally prescribe “blame-free” cultures. Rather, the goal is to stimulate the creation of “just cultures,” that is, health care environments that foster learning – including learning from mistakes – but that also emphasize individual accountability for misconduct. Inherent in any viable alternative for addressing medical liability claims should be the potential for fairly compensating greater numbers of injured patients, while allowing health care practitioners and providers the opportunity to reveal error, learn from such errors, and ensure that they are not repeated.

Redesigning the medical liability system will necessarily be a long-term endeavor. Meanwhile, more and continued efforts aimed at fostering transparency among provider organizations, practitioners, and patients; seeking alternatives to litigation; leveraging the development of patient safety cultures; treating health care providers fairly; and honoring patients are both noble goals and practical necessities that must be actively pursued.



INHERENT IN ANY VIABLE ALTERNATIVE FOR ADDRESSING MEDICAL LIABILITY CLAIMS SHOULD BE THE POTENTIAL FOR COMPENSATING GREATER NUMBERS OF INJURED PATIENTS, WHILE ALLOWING HEALTH CARE PROVIDERS THE OPPORTUNITY TO REVEAL ERROR, LEARN FROM SUCH ERRORS, AND ENSURE THAT THEY ARE NOT REPEATED.



I. PURSUE PATIENT SAFETY INITIATIVES THAT PREVENT MEDICAL INJURY

FIVE YEARS HENCE

When the Institute of Medicine released its landmark report, *To Err Is Human*,⁵⁸ the frequent occurrence of medical error went public. Now, five years after the IOM report, error remains ubiquitous in health care delivery. To be sure, activities and initiatives aimed at improving patient safety have been and continue to be pursued. The health care industry has embraced the safety efforts of other industries, such as aviation and manufacturing, though it has not yet been able to emulate the successes realized in these industries. There are obstacles within health care organizations that stymie improvement – most notably, lack of will, resources and knowledge. These can be overcome with hard work and commitment, or, in the words of Paul O'Neill, “when safety becomes a precondition for all other priorities.” But the medical liability system provides a far more formidable obstacle to meeting patient safety improvement goals than the obstacles that exist within health care organizations.

The axiom, “you learn from your mistakes” is too little honored in health care. Near-miss and error reporting is an essential component of safety programs across safety-conscious industries. Within health care, though, many physicians are often reluctant to engage in patient safety activities and be open about errors because they believe they are being asked to do so without adequate assurances of legal protection.⁵⁹ The stifling specter of litigation results in the under-reporting of adverse events by physicians and avoidance of open communications with patients about error.⁶⁰

The IOM report suggests that 90 percent of medical errors are the result of failed systems and procedures that are poorly designed to accommodate the complexity of health care delivery. If properly designed, these systems and procedures could better prevent inevitable human errors from reaching patients. But understanding the root causes of errors requires their divulgence in the first place. In sharp contrast to the systems-based orientation of the patient safety movement, tort law targets individual physicians.⁶¹

TAKING ACCOUNT

All doctors, even the nation's best doctors, make mistakes.⁶² Despite its high-tech progress, health care delivery remains very much a human endeavor. Statistics suggest the strong likelihood that every surgeon will be named in a suit during his or her career.⁶³ The tort system's blunt weapon seems ill-suited when it is potentially directed at every person practicing medicine. As the IOM reports make clear, multiple broken systems can be identified in the majority of cases in which a serious adverse event has occurred. However, there remains today too little effort to unveil the specific contributory factors to such occurrences. That said, a systems-based approach to quality improvement does not preclude individual accountability. Accountability mechanisms – licensure, certification, and peer review – also need to be strengthened to ensure an optimally qualified health care workforce. The tort system should not be the net to snare incompetent physicians, and it cannot be effective, when it is cast so wide.



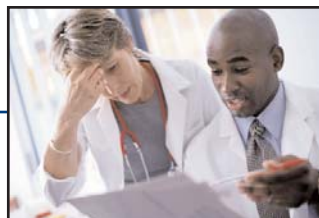
The American Board of Medical Specialties (ABMS) is now in the process of implementing encompassing new requirements for the maintenance of board certification for the 24 medical specialties it represents. Specialty boards already must provide recertification programs and time-limited certificates.⁶⁴ Additionally, physicians will be expected to continuously meet core competency requirements respecting patient care, medical knowledge, practice-based learning and improvement, interpersonal and communications skills, professionalism, and systems-based practice.⁶⁵ These requirements would eventually apply to over 90 percent of practicing physicians.

Following suit, the Federation of State Medical Boards is also pursuing an agenda for the maintenance of physician licensure. But efforts to strengthen the stringency of medical licensure requirements are not necessarily embraced by the field of medicine. In 2004, the Federation of State Medical Boards instituted a clinical and communication skills assessment as a requirement of physician licensure. This change was met with a firestorm of resistance, despite its potential benefits for physicians and the public, mainly on the grounds that such skills assessment should be the responsibility of medical schools and not tied to licensure. Physicians are most often sued, not for bad care, but for inept communication.

Physicians who communicate poorly with patients and families, and who otherwise have a bad “bedside manner,” are sued more often than physicians who communicate effectively.⁶⁶

While the legal system is often maligned by physicians, some physicians do not hesitate to use it to stave off loss of hospital privileges and licensure. Hospitals and state medical boards that pursue the removal of a physician’s right to practice often find themselves in the middle of intense legal battles. These legal maneuvers consume hospital and medical board resources. And, for hospitals, the drain on resources, plus the loss of income the physician otherwise generates, can stifle motivation to take action.

Going forward, to avoid the quagmire in which hospitals often find themselves when they attempt to curtail or remove privileges, these institutions need to be thorough and deliberate in their initial granting of privileges, to consider granting new privileges for shorter periods of time, and to apply objective measures of performance before renewing privileges. This approach would be synchronous with the movement of certification boards to grant time-limited board certification, and to undertake rigorous competency assessment on a continuing basis.



THE AXIOM, “YOU LEARN FROM YOUR MISTAKES” IS TOO LITTLE HONORED IN HEALTH CARE. NEAR-MISS AND ERROR REPORTING IS AN ESSENTIAL COMPONENT OF SAFETY PROGRAMS ACROSS SAFETY-CONSCIOUS INDUSTRIES.



Administrative and clinical leaders must also take greater initiative to ensure the competency of their nurses. Nurse staffing shortages have made the hiring of new nurses a priority, but newly graduated nurses typically receive far too little training before assuming clinical responsibilities, and the monitoring of clinical performance is uneven at best. The growing use of external staffing agencies to fill the staffing gaps only makes this problem worse. According to Joint Commission data, insufficient staffing has been implicated in 24 percent of reported sentinel events; inadequate orientation and training has been identified in 58 percent of these occurrences. Conversely, several studies have shown the positive impacts on quality and outcomes when nurse staffing is optimized – fewer complications, fewer adverse events and lower mortality.⁶⁷

REVELATIONS

One of health care's principal patient safety success stories is anesthesiology. In the 1980s, in the midst of a separate medical liability crisis, the rate of anesthesia-related deaths was one in 10,000; 6,000 people per year who had undergone anesthesia died or suffered brain damage, and anesthesiologists' liability insurance premiums had sharply escalated.⁶⁸ Following a national news magazine broadcast which pilloried the field for these outcomes, the American Society of Anesthesiologists (ASA) decided to seize the opportunity presented by the crisis to improve anesthesiology safety.

It started with the hiring of a systems engineer. Through close scientific examination of 359 anesthesia errors, every aspect of anesthesia care – equipment, practices, and caregivers –

was analyzed. Eventually, with the commitment of leadership and resources towards the task, the many system failures revealed by the study were re-engineered, and anesthesia-related death rates fell to one in more than 200,000 cases.⁶⁹

The ASA continues to use case analysis to identify liability risk areas, monitor trends in patient injury, and design strategies for prevention. Today, the ASA Closed Claims Project – created in 1985 -- contains 6,448 closed insurance claims. Analyses of these claims have, for example, recently revealed patterns in patient injury in the use of regional anesthesia, in the placement of central venous catheters, and in chronic pain management. Results of these analyses are published in the professional literature to aid practitioner learning and promote changes in practices that improve safety and reduce liability exposure.

Closed claims data analysis is the one way in which the current medical liability system helps to inform improvements in care delivery. However, reliance on closed claims for information related to error and injury is cumbersome at best. It may take years for an insurance or medical liability claim to close. These are years in which potentially vital information on substandard practices remains unknown. Providing patient safety researchers with access to open claims, now protected from external examination, could vastly improve efforts aimed at identifying worrisome patterns in care and designing appropriate safety interventions.



In addition to anesthesiology's early work in identifying the human factors and system failures that cause error, anesthesiology has also promoted reliance on standards and guidelines to support optimal anesthesiology care. Anesthesiology has also been at the forefront in the use of patient simulation for research, training and performance assessment. With simulation, no patients are at risk for exposure to novice caregivers or unproven technologies.⁷⁰

Anesthesiology is still far from perfect. But, its "institutionalization of safety,"⁷¹ continues to serve the field well as it tackles the continuing threats to patient safety that are endemic to modern medicine.

PATHS TO PROTECTION

Adherence to clinical guidelines has long been touted as an effective way in which to improve quality, reduce variation in care, and improve financial performance.⁷² In court, clinical guidelines are increasingly invoked to prove or disprove deviations from the standard of care. But there is a more significant relationship between medical liability and clinical guidelines. A new study has shown that adherence to clinical guidelines can have a significant role in reducing legal risk.⁷³ The study, which focused on obstetrical patients, found a six-fold increase in risk of litigation for cases in which there was a deviation from relevant clinical guidelines.⁷⁴ Further, one-third of all obstetric claims analyzed in the study were linked to non-compliant care.⁷⁵

Some clinicians have not embraced clinical guidelines on the grounds that they intrude on the physician's autonomy, and discourage the appropriate individualization of care that

would best serve particular patient needs. However, the demonstrated impact of clinical guideline adherence on reducing liability exposure provides ample incentive for physicians to rethink the autonomy proposition. Clinical guideline adherence is also an increasingly important factor in the defense of medical liability cases. The Maine, Florida and Kentucky legislatures have experimented with legislation that establishes clinical guideline adherence as an affirmative defense in medical liability litigation.⁷⁶

TEAM PLAYERS

Teamwork -- indeed, team training -- has been identified by patient safety experts as an essential factor in reducing the risk of medical error. In aviation, "Crew Resource Management" (CRM) is the methodology used to guide team development among pilots, flight attendants and other crew. In this context, predefined roles and responsibilities for various scenarios help to assure the safety of every flight. Consistently applying such an approach to health care delivery could increase the timeliness and accuracy of communications -- breakdowns of which are commonly implicated sources of serious adverse events. This could also help to enlist clinicians and support staff in committing to a common goal -- safe and effective care -- in the often high-pressure and chaotic environments of health care delivery. Unfortunately, health care professionals are not educated and trained to work as teams or even team members. Recreating the culture of health care delivery to value team-based care must begin at the earliest point of intervention -- health care professional education -- and be continuously reinforced in practice.



Clinical units that successfully foster strong team-based approaches to health care delivery do exist. In their research, Nelson, Batalden *et al* identified high-performing, front-line clinical units called microsystems.⁷⁷ A microsystem is further defined as a small group of people who regularly work together to provide care to discrete sub-populations of patients, and share business and clinical aims, linked processes, and a common information environment. Microsystems are often embedded in larger organizations – the “macrosystem.”⁷⁸

The high-performing microsystems identified in this study produce superior outcomes and cost-effective care, and at the same time, provide positive and attractive working environments.⁷⁹ These units are also characterized by the high value placed on patient safety, as well as compliance with policies and other requirements. The clinical units studied were involved in different types of care – rehabilitation, orthopedic oncology, hospice care, family medicine, and emergency care, that was provided in a variety of settings, including hospitals, nursing homes, clinics and even the home.⁸⁰ Across this continuum, the microsystems had nine common characteristics that interacted to contribute to their success. These included leadership, culture, organization support, patient focus, staff focus,

interdependence of the care team, information and information technology, process improvement, and performance patterns.⁸¹

If microsystems are the “building blocks”⁸² of the macro-organization, potential promise lies in replicating the characteristics of those that are high performing to create high-performing, safe health care environments. In fact, Nelson, Batalden *et al*, write, “A seamless, patient-centered, high-quality, safe and efficient health system cannot be realized without this transformation of the essential building blocks that combine to form the care continuum.”⁸³

PEER PRESSURE

A study recently published in *Health Affairs* by Devers *et al* concludes that the major driver for hospital patient safety initiatives is Joint Commission requirements.⁸⁴ The majority of hospitals surveyed as part of the study explicitly noted that they were working to meet Joint Commission requirements – developing better processes for reporting, analyzing, and preventing sentinel events; meeting patient safety standards, including acknowledgement of leadership’s accountability for patient safety and the creation of a non-punitive culture; and meeting the specific National Patient Safety Goals.⁸⁵



RECREATING THE CULTURE OF HEALTH CARE DELIVERY TO VALUE TEAM-BASED CARE MUST BEGIN AT THE EARLIEST POINT OF INTERVENTION -- HEALTH CARE PROFESSIONAL EDUCATION -
- AND BE CONTINUOUSLY REINFORCED IN PRACTICE.



More than half of the Joint Commission's accreditation standards for hospitals are directly related to patient safety. These include standards relating to infection control, medication use, and surgery and anesthesia, among others. In addition to standards, the Joint Commission also annually issues, and requires compliance with, its National Patient Safety Goals. These goals are formulated by an expert panel comprising a variety of clinicians, management experts, and national leaders in patient safety, and set forth specific requirements for improving the safety of care delivery. The goals address fundamental performance issues such as surgical site marking, patient identification, and communications among caregivers that can result in error, including the use of abbreviations in medical orders and the use of verbal orders.

To address wrong-site, wrong-person, wrong-procedure surgery, the Joint Commission has taken that particular safety goal a step further by issuing the Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery.TM The Universal Protocol calls for a pre-operative verification process; marking of the operative site; taking a 'time out' immediately before starting the procedure; and adapting the requirements to non-operating room settings, including the bedside where procedures are also performed.

The Joint Commission's Sentinel Event Policy requires organizations that experience a sentinel event to complete a thorough and credible root cause analysis, implement improvements to reduce risk, and monitor the effectiveness of those improvements.

The root cause analysis is expected to drill down to underlying organization systems and processes to identify opportunities for redesign that could reduce the likelihood of failure in the future. Health care organizations are encouraged to report sentinel events and root cause analysis findings to the Joint Commission to permit trend analysis, and to identify lessons learned and patient safety solutions that can be disseminated to accredited organizations.

Since 1996, more than 2500 sentinel events have been reviewed by the Joint Commission. Among these, patient suicide, operative/post-operative complications, wrong-site surgery, medication error, and delay in treatment are the most common types of sentinel events that have been reported. The top five contributory factors to sentinel events include communication issues, inadequate orientation and training of staff, incomplete or inaccurate patient assessments, staffing levels, and unavailability of patient information.

In the Devers *et al* study, the description of hospital patient safety initiatives also highlights the influence of other third parties in driving patient safety improvements. The Leapfrog Group was frequently mentioned by study participants, particularly with regard to its influence in driving the adoption of Computerized Physician Order Entry (CPOE) systems. In fact, information technology implementation – specifically including electronic medical records (EMRs) --is expected to have major positive impacts on patient safety.



The Joint Commission and other standard setters, and third-party review organizations clearly must work to assure that their standards, other requirements, and review mechanisms are continuously updated to optimize their impact in driving patient safety improvement.

MAN VS. MACHINE

Where human error is inevitable, health care is now, finally, turning to automation. Much of the delay in widespread deployment of health care information technology has been the failure of its proponents to make the value proposition. The benefits over costs = value equation, until recently, had not achieved the requisite level to create impetus for acquisition. Lack of standardization and integration, and the absence of significant drivers to make the investment – which is substantial – have long held back potential purchasers and users. Recently, the prospects for advancement and application of information technology have improved.

In its *Crossing the Quality Chasm* report, The Institute of Medicine underscores the importance of information technology as a key factor in meeting several of its quality aims. Since then, the momentum toward widespread adoption of information technology has accelerated. Leading proponents include the National Alliance on Healthcare Information Technology, the Markle Foundation's Connecting for Health initiative, and now the Department of Health and Human Services itself, with the appointment of a national coordinator for IT initiatives last year.

Information technology solutions have the potential to address many of the factors in health care delivery that have proven to be major risk points for error. Communications between caregivers, availability of patient information, medication prescribing and use, and adherence to clinical guidelines can all be improved through reliance on IT capabilities. However, even with the evidence-base for IT becoming well established, health care organizations and practitioners are still pondering over how to secure adequate funding to support appropriate and necessary IT purchases.

Despite their obvious patient safety benefits, EMRs and CPOE systems are often met with much resistance by clinical staff, particularly physicians. Some initial implementations of CPOE actually served to increase error because of poor systems design and inadequate user training. It is essential that physician support be mobilized to ensure successful IT adoption. Among the ways physician support can be gained is for organization leaders to reinforce their commitment to patient safety and patient safety solutions; involve physician leaders in choosing systems; identify champions to spur others to use them; and, most importantly, ensure that the systems support and enhance physician workflow.⁸⁶

Financial and performance incentives could speed the adoption of IT. For instance, liability insurers could offer premium discounts to organization and individual users of CPOE and other IT solutions. And new pay-for-performance models could tie performance criteria such as reduced adverse drug events – a derivative of the use of CPOE – to incentive pay arrangements.



Top Down

The pressures on health care leaders today are great. Increasing costs, increasing demand for services, and unfavorable reimbursement policies mean that patient “throughput” – the time in which patients move into, through, and out of the health care setting – must be accelerated to maintain revenues. This acceleration of the care process heightens the risk of medical error, and compromises effective patient-practitioner communications.⁸⁷ Yet, in this environment, a culture of patient safety must be created and emulated from the top down. This responsibility lies both with individual health care organizations and practitioners, and with those who set health care policy in this country.

Where federal leadership and accountability for the quality of health care is lacking, the liability system is tapped to replace regulation.⁸⁸ State-based patient safety authorities have been established in such states as Massachusetts and Pennsylvania to support activities aimed at improving safety, and these are promising developments.

Despite the launching of a number of quality initiatives by the Department of Health and Human Services over the past few years, there is neither a focused approach to, nor advocacy for, health care quality and patient safety within the federal government. Until this country both elevates the importance of quality and safety problems and engages in a coordinated approach to solutions, it will be difficult to make significant strides in addressing the foundational patient safety problems that persist today. Creation of an Office of Health Care

Quality in the Department of Health and Human Services could provide a powerful platform for setting priorities and direction for improving patient safety and health care quality. Such an office could also coordinate and enhance the efforts of established private and public sector bodies already engaged in patient safety and quality improvement activities.

New public and private sector payer initiatives designed to “pay for performance” may provide a new opportunity to align incentives for increasing safety and improving quality and patient outcomes. In 2003, CMS launched a demonstration project in partnership with Premier Inc. to test the effectiveness of paying hospitals more for better performance according to selected measures. In 2005, a new demonstration project was initiated for large medical group practices. Small but symbolically significant bonuses are to be based on results in the management of specific clinical conditions and procedures. The pay-for-performance concept essentially envisions rewards for desired behaviors and outcomes.

Other than selected CMS demonstration projects, hospitals and physicians are generally paid the same federal dollar whether the level of care is truly exemplary or clearly substandard. This obviously offers little incentive for pursuing much needed improvements in the safety and quality of health care that is being delivered today. This is one of the most important foundational issues that enhanced federal leadership could and should address.



RECOMMENDATIONS TO PURSUE PATIENT SAFETY INITIATIVES THAT DETER MEDICAL NEGLIGENCE:

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none">• Strengthen oversight and accountability mechanisms to better ensure the competencies of physicians and nurses• Allow health care researcher access to open liability claims to permit early identification of problematic trends in clinical care• Encourage appropriate adherence to clinical guidelines to improve quality and reduce liability risk• Support teamwork development through team training, “Crew Resource Management,” and high-performing microsystem modeling• Continue to leverage patient safety initiatives through regulatory and other quality oversight bodies• Encourage the adoption of information and simulation technology by building the evidence-base of their impacts on patient safety, and pursue proposals to offset implementation costs• Leverage the creation of cultures of patient safety in health care organizations• Establish a federal leadership locus for advocacy of patient safety and health care quality• Pursue “pay-for-performance” strategies that provide incentives to focus on improvements in patient safety and health care quality	<ul style="list-style-type: none">➔ State medical boards, American Board of Medical Specialties, state nursing boards, health care provider organizations➔ insurers➔ medical staff leaders, medical professional societies, health care administrators, health care purchasers and payers➔ health care educators, health care administrators, medical and nursing staff leaders, chiefs of medicine➔ accrediting, licensing and regulatory bodies, patient safety organizations, purchasers and payers➔ information technology task forces, i.e. Connecting for Health, DHHS Office of Information Technology, health care providers organizations and technology vendors➔ health care administrators, medical and nursing staff leaders➔ DHHS➔ CMS and private-sector health care purchasers and payers



II. PROMOTE OPEN COMMUNICATION BETWEEN PATIENTS AND PRACTITIONERS

PATIENT CENTEREDNESS

“...we have had the unique opportunity to gain insight into the American health care system and its lenient oversight; the general disregard of the patient when a medical error occurs; the lack of quality-of-care standards; the lack of integrity and the code of silence, as the IOM put it, present at hospitals; the absence of accountability and consequences when medical error occur; the legal system and its distortion; and the general complexity of the system whose responsibility it is to ensure patient safety.”⁸⁹ These words are Susan Sheridan’s, a wife and mother whose newborn son suffered preventable, permanent and devastating injury and whose husband lost his life as a result of medical error. Ms. Sheridan, now a patient safety advocate, endured lengthy trials and dueling expert testimony, in her family’s attempt to learn what went wrong. Unfortunately, her story is like that of many others who have been injured within the health care system.

Lack of disclosure and communication is the most prominent complaint of patients, and their families, who together have become

victims of medical error or negligence. Years of expensive and wounding litigation often ensue when families are sometimes only seeking answers.

In seeking something good from tragedy, Ms. Sheridan has educated many about the continued occurrence of kernicterus, the condition that left her son severely disabled. Kernicterus results from untreated jaundice in newborns and is readily responsive to treatment if properly diagnosed. In part through her efforts, new guidelines for the diagnosis and treatment of children born with kernicterus were recently promulgated by the American Academy of Pediatrics.

In fact, health care consumers are playing an important role in the patient safety movement – as educated advocates for change based on their own experiences. When individuals’ stories reach the right audiences, listeners pay heed. Health care consumers can specifically help to prevent adverse events by being active, informed and involved members of the health care team.



HEALTH CARE CONSUMERS CAN SPECIFICALLY HELP TO PREVENT ADVERSE EVENTS BY BEING ACTIVE, INFORMED AND INVOLVED MEMBERS OF THE HEALTH CARE TEAM.



SOUND OF SILENCE

For patients and family members, the physical and emotional devastation of medical error cannot be easily overcome. What they want most out of their ordeal is honest and open dialogue about what went wrong, and a “legacy” – having their experience serve as a lesson for prevention in the future.⁹⁰ Seldom are such communications and assurances forthcoming.

In their book, *Wall of Silence*, authors Rosemary Gibson and Janardan Prasad Singh describe the ways in which information on medical error is kept under cover. An unintended consequence of the tort system is that it inspires suppression of the very information necessary to build safer systems of health care delivery. When it comes to acknowledging and reporting medical error, according to Gibson and Singh, there is too often silence between practitioners and patients; practitioners and their peers; practitioners and the organizations in which they practice; and health care organizations and oversight agencies.

In addition to the fear of litigation, the wall of silence is amplified by the fears of physicians and health care organizations about the loss of reputation, accreditation or licensure, and income. The wall of silence severely undermines efforts to create a culture of safety within health care organizations and across the health care system. Indeed, patients will not

be safe until caregivers feel safe to talk about and act on medical error.

SO TRANSPARENT

One of the basic principles of patient safety is to talk to and listen to patients.⁹¹ Several elements are fundamental to any disclosure effort. These include a prompt explanation of what is understood about what happened and its probable effects; assurance that an analysis will take place to understand what went wrong; follow-up based on the analysis to make it unlikely that such an event will happen again; and an apology.⁹²

The Joint Commission’s accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients, and to their family members when appropriate. A recent study confirms that many hospitals – half of those surveyed -- are reluctant to comply with this standard for fear of medical liability suits.⁹³ If disclosure is taken a step further to the offer of an apology, hospitals and physicians are even more likely to gravitate to traditional “defend and deny” behaviors. But there is increasing awareness that openness has the potential to heal, rather than harm, the physician-patient relationship. A growing number of hospitals, doctors and insurers are coming around to the idea that apologies may save money by reducing error-related payouts and the frequency of litigation.⁹⁴



YEARS OF EXPENSIVE AND WOUNDING LITIGATION OFTEN ENSUE WHEN
FAMILIES ARE SOMETIMES ONLY SEEKING ANSWERS.

Charles Utley, a patient who, after surgery, was left with a surgical sponge festering in a body cavity, decided not to pursue litigation because his doctor and the hospital administrator took responsibility and apologized to him.⁹⁵ “They honored me as a human being,” he said.⁹⁶ In turn, Mr. Utley settled for less compensation for his injuries than he could have potentially been awarded if the case had been adjudicated.⁹⁷

The VA Medical Center in Lexington, Kentucky has an established “apology policy” that has helped it to reduce levels of litigation; however, the relevancy of this approach to private sector health care institutions -- where the prospects of suits are much greater -- has been questioned. Nevertheless, now prominent medical centers, such as the Dana-Farber Cancer Institute and Johns Hopkins Hospital, have policies that urge doctors to disclose their mistakes and to apologize.⁹⁸ Insurers, too, are increasingly urging apologies.⁹⁹ And, increasingly, states, such as Colorado and Oregon, are passing laws that protect an apology from being used against a doctor in court.¹⁰⁰ More such protections will be needed in order for most caregivers and organizations to feel comfortable with apologies, despite the ethical imperatives underlying such disclosure.

ONLY THE BRAVE

Few caregivers and health care organizations voluntarily break through the wall of silence to report life-threatening medical errors beyond the walls of their institutions. The Joint Commission has had a voluntary reporting system since 1996, but its Sentinel Event Database receives only about 400 new reports of events each year – well below the 44,000 to 98,000 medical error-related deaths estimated by the IOM to occur each year.

The Joint Commission requires organizations reporting a sentinel event – defined as an unexpected occurrence involving death or permanent loss of function – to conduct an analysis to determine the underlying causes of such events. Root cause analysis and risk reduction information from the Sentinel Event Database form the basis for *Sentinel Event Alerts* – error prevention advice that is regularly disseminated to the health care field.

A number of states now have mandatory error reporting systems of various types.¹⁰¹ One of the most active, the New York State Patient Occurrence Report and Tracking Systems (NYPORTS), logged approximately 30,000 reports in 2003.¹⁰² A new reporting system in Pennsylvania captures reports of near-misses as well as actual errors.



WHEN IT COMES TO ACKNOWLEDGING AND REPORTING MEDICAL ERROR, THERE IS TOO OFTEN SILENCE BETWEEN PRACTITIONERS AND PATIENTS; PRACTITIONERS AND THEIR PEERS; PRACTITIONERS AND THE ORGANIZATIONS IN WHICH THEY PRACTICE; AND HEALTH CARE ORGANIZATIONS AND OVERSIGHT AGENCIES.



Reporting systems can capture enormous volumes of data, but without the requisite resources to analyze and translate data into useful information, their potential is far from being fully realized.

Other types of external reporting systems include reporting systems tailored to specific health care segments, such as the Veterans Administration's (VA) nascent Patient Safety Reporting System, and medical specialty-based reporting systems.¹⁰³ One such specialty-based system developed by the Neonatal Intensive Care Quality (NICQ) Collaborative and sponsored by the Vermont Oxford Network, encourages Internet-based, anonymous, voluntary reporting by health care professionals working in neonatal intensive care units (NICU). The system has logged 1230 reports in a 27-month study period that have identified a broad range of errors.¹⁰⁴ Reported information is analyzed by a team of experts who provide feedback and recommendations to participating NICUs.¹⁰⁵ The robust participation in the system is attributed to the natural allegiance participants have to their medical specialty peers and their confidence in expert opinion leaders.¹⁰⁶

There remains a substantial lack of clarity as to whether error analyses reported to a third-party, such as a state agency or the Joint Commission, are afforded legal privilege protections. This lack of certainty of protection continues to hamper reporting efforts that could otherwise yield essential information for making breakthrough improvements in health care safety.

Patient safety legislation – under consideration by the Congress for several years and currently pending reintroduction in the current Congress – proposes legal protection for information reported to any Patient Safety Organization, as defined in the legislation. Passage of patient safety legislation of this nature would provide the cornerstone for effective reporting systems that assure confidentiality and encourage the sharing of lessons learned from the analyses of adverse events.

FLY SAFELY

Many safety experts point to the reporting model used by the Federal Aviation Administration (FAA). The Aviation Safety Reporting System (ASRS) was developed by the FAA to “increase the flow of information regarding actual or potential deficiencies in the aviation system.”¹⁰⁷ The launch of the ASRS was prompted by a plane crash near Dulles Airport in 1974. Some of the reasons for the crash – poorly defined altitude markers at Dulles and unclear instructions from air control – were widely known (in the case of the markers) and bound to be repeated (unclear instructions).¹⁰⁸

The ASRS captures “near miss” reports (actual airline events typically do not go unnoticed) and is administered by a third-party, NASA, for two reasons. First, an airline industry employee is more likely to report an error resulting in a near-miss to someone outside of his or her “chain of command,” and second, NASA has the resources to analyze the incoming data and disseminate lessons learned.

Reporting is mandatory, confidential and protected – no punishment is meted out for those who report a near miss within ten days of its occurrence, but failure to report removes such immunity. And since there has never been a breach of confidentiality, trust in the system among flight and ground crews is high.

The ASRS has five traits that have made it “the linchpin” of modern aviation’s impressive safety record – ease of reporting, confidentiality, third-party administration, timely analysis and feedback, and regulatory action.¹⁰⁹ These traits, applied to a medical error reporting system, could help health care achieve a similarly impressive safety record.

RECOMMENDATIONS TO PROMOTE OPEN COMMUNICATION BETWEEN PATIENTS AND PRACTITIONERS:

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none"> • Involve health care consumers as active members of the health care team • Encourage open communication between practitioners and patients when an adverse event occurs • Pursue legislation that protects disclosure and apology from being used as evidence against practitioners in litigation • Encourage non-punitive reporting of errors to third parties that promotes sharing of information and data analysis as the basis for developing safety improvement strategies • Enact federal patient safety legislation that provides legal protection for information reported to designated patient safety organizations 	<ul style="list-style-type: none"> ➔ health care practitioners and provider organizations ➔ health care administrators, risk managers, clinical leaders, liability insurers ➔ health care organizations and practitioners, trade and professional organizations ➔ health care organizations and medical and nursing staff leaders, oversight and regulatory bodies ➔ U.S. Congress



III. CREATE AN INJURY COMPENSATION SYSTEM THAT IS PATIENT-CENTERED AND SERVES THE COMMON GOOD

IF IT'S BROKEN...

Only a small percentage (2-3 percent) of patients who are injured through medical negligence ever pursue litigation, and even fewer ever receive compensation for their injuries.¹¹⁰ Those who are awarded compensation wait an average of five years to receive it.¹¹¹ Clearly, the current tort system falls short in compensating injured patients. As for exacting justice, there is often little correlation between court findings of negligence and actual negligence.¹¹² And rather than deterring negligence, there is a common refrain among physicians that the current tort system “keeps us from doing things that we, as good professionals, would naturally do.”¹¹³

A central question is how the medical liability system can be restructured to actively encourage physicians and other health care professionals to participate in patient safety improvement activities.¹¹⁴ The goal of any such restructuring should be to reduce litigation by decreasing patient injury, by encouraging open communication and disclosure among patients and providers, and by assuring prompt and fair compensation when safety systems fail. Reform proposals, such as caps on non-economic damages, while important temporizing measures, are unlikely to accomplish these objectives by themselves. Rather, according to Columbia Law Professor William Sage, “patient safety may be the trigger that finally propels ideas such as accelerated compensa-

tion for clearly avoidable events, less adversarial forms of dispute resolution, non-judicial compensation mechanisms, encouragement of private contracting, and assumption of legal responsibility by medical institutions from the academic literature into the real world.”¹¹⁵

...FIX IT

Numerous proposals have been suggested for improving the medical liability system. These proposals center on three broad approaches: 1) creation of alternative mechanisms for compensating injured patients, such as through early settlement offers; 2) resolving disputes through a so-called “no-fault” administrative system or through health courts; and 3) shifting liability from individuals to organizations.¹¹⁶ Though these approaches are distinct, they are not in conflict. One could imagine an injury resolution system that incorporates the characteristics of all three.

An administrative system approach -- similar to the mechanisms generally in use today to address worker's compensation claims -- would eliminate negligence as the basis for compensation and provides for a no-trial, administrative resolution process.¹¹⁷ However, because the term “no-fault” implies the absence of responsibility for injury or untoward outcomes, “strict liability” may be a more appropriate and accurate term.¹¹⁸



In the design of an administrative system, proponents have proposed that compensation be based on determination of avoidability, rather than on negligence.¹¹⁹ Such preventable events could be defined through Avoidable Classes of Events (ACEs) categories that are expert-based and can be used to trigger an early offer of compensation.¹²⁰

Safety experts and systems engineers have demonstrated that non-punitive approaches encourage the detection of errors, and improvement, which, according to the IOM, “...suggests that resolving malpractice cases without a determination of fault will help rather than harm quality.” An administrative approach also makes sense in light of the poor track record of the tort system in consistently determining negligence.

An early settlement – or compensation offer – can be an important component of a strict liability model, as it is for many mediation programs that institutions rely on as an alternative dispute resolution mechanism. Early-offer programs meet the needs of patients, providers and practitioners for swift resolution of claims. Compensation values could be based on a fee schedule that has predetermined rates based on the avoidable event and its concomitant injury. Such fee schedules would essentially

eliminate the random variability of award judgments. The predictability of pay-outs could also help to stabilize insurance premium rates, although it is likely that more patients would rightly receive compensation under such a model.¹²¹

While there is no designation of negligence under a strict liability approach, designation of responsibility is one of its key features. If there were a shift to enterprise liability, the health care organization would have a new and strong incentive to foster a culture of patient safety, and to identify and redesign vulnerable systems. Experience-rating the enterprise’s liability premiums could further induce greater investments in improving patient safety.

Another way in which to foster cultures of patient safety and accountability would be to require individual physicians or provider organizations to “earn” their way into alternative dispute resolution systems. The bases for earning into the system could include the meeting of specified standards and other performance thresholds. Given the leadership of the Centers for Medicare and Medicaid Services (CMS) in developing pay-for-performance quality improvement models, the agency could become the lead sponsor of an “earn-in” model for alternative dispute resolution.¹²²



A CENTRAL QUESTION IS HOW THE MEDICAL LIABILITY SYSTEM CAN BE RESTRUCTURED TO ACTIVELY ENCOURAGE PHYSICIANS AND OTHER HEALTH CARE PROFESSIONALS TO PARTICIPATE IN PATIENT SAFETY IMPROVEMENT ACTIVITIES.



Access to alternative dispute resolution, and potentially, medical liability insurance subsidies, could be closely tied with pay-for-performance and other measurement-based performance monitoring initiatives.¹²³

Based on the precedents of the U.S. Tax Court system and worker's compensation administrative law, the concept of specially appointed health courts is another potential alternative to the current tort system model. The Robert Wood Johnson Foundation recently awarded a grant to Common Good, a national bipartisan legal reform coalition, and the Harvard School of Public Health to design a prototype of the health court system.¹²⁴ In addition to specially designated health courts for resolving disputes, the concept incorporates reliance on expert guidelines for compensation of avoidable events.¹²⁵ For straightforward cases, an expedited process would allow injured patients to apply for compensation without the necessity of legal representation. Such individuals -- based on the application of malpractice standards (avoidable events) -- would receive awards based on a schedule of damages. For complex cases, a health court judge would hear arguments from lawyers, as well as testimony from court-appointed, independent

experts. The health court judge -- having special knowledge regarding the assessment of scientific evidence and medical practice -- would base rulings on determinations of the standard of care. Damages would be awarded based on the predetermined fee schedule. Under the health court system, all settlements and adjudications would be made publicly available.

Inherent in any alternative to the tort system must be a high priority for disclosure -- an acknowledgement of the error or injury, an apology, and assurances that steps will be taken to avoid such an error in the future.

A 2003 IOM report calls for demonstration projects to test the feasibility and effectiveness of alternative injury compensation systems that are patient-centered and focused on safety.¹²⁶ Such demonstration projects are needed to begin the process of mitigating the periodic medical liability crises that, aside from economic factors, result from the delivery of unsafe care, unreliable adjudication of claims, and unfair compensation for injured patients.



INHERENT IN ANY ALTERNATIVE TO TORT REFORM MUST BE A HIGH PRIORITY FOR DISCLOSURE -- AN ACKNOWLEDGEMENT OF THE ERROR OR INJURY, AN APOLOGY, AND ASSURANCES THAT STEPS WILL BE TAKEN TO AVOID SUCH AN ERROR IN THE FUTURE.



TAKING INITIATIVE

Absent action by the Federal government, some states and liability insurance companies are already pursuing – for better or worse -- reforms to reduce reliance on litigation as a means to resolve injury claims.

In the 2004 election, Florida voters adopted a proposition that limits lawyers' contingency fees in medical liability cases, and entitles patients to 70 percent of damages awarded that are \$250,000 or less, and 90 percent for damages exceeding \$250,000. Lawyers otherwise typically receive 30 to 40 percent of damages. However, Florida voters also passed a measure that expands public access to medical records and adverse event reports – essentially nullifying peer review protections in that state. Florida has also passed a ballot initiative mandating the revocation of physicians' licenses to practice medicine if they have received three or more adverse medical liability judgments, as opposed to settlements. There are substantial questions as to whether either or both of the latter two actions will constructively advance the patient safety agenda.

In Wyoming, voters last year defeated a proposal to cap non-economic damages on medical liability claims, but passed a measure to allow the use of alternative dispute resolution, including medical panel reviews of potential claims against providers and practitioners before they can be filed.

In 2002, Pennsylvania became the first state to require hospitals to disclose, in writing, adverse events to patients or their families.¹²⁷ Nevada and Florida have since followed

Pennsylvania's lead.¹²⁸ Pennsylvania is also the site of a Pew-sponsored demonstration project that encourages mediated dispute resolution.¹²⁹ As part of this model, physicians are encouraged to disclose adverse events to their patients and to apologize.¹³⁰ Patients or their families are provided with an early and fair offer of compensation, and the opportunity for mediation to resolve disputes.¹³¹ It is too soon to know the full ramifications of the Pew-sponsored project, but early indications are that it has been successful in mitigating litigation.¹³²

COPIC Insurance Company, a physician-owned liability insurer in Colorado, initiated its "3Rs" (respect, respond and resolve) program in 2000. Under this program, each insured physician is encouraged to communicate openly with the patient if an adverse event occurs, and to offer an apology when warranted.¹³³ COPIC pays for patient expenses, and also reimburses lost wages.¹³⁴ Importantly, patients are not asked to waive their rights to litigation.¹³⁵ Since its inception, none of the cases addressed through the 3Rs program has gone to litigation.¹³⁶

THE MENU

The following tables outline the different alternatives for liability system reform and delineate the potential impact of each on deterring negligence and supporting engagement in patient safety activities, providing swift compensation to injured patients, supporting transparency in the patient-practitioner relationship, and addressing claims fairly.



TABLE I: ALTERNATIVE SYSTEM REFORMS AND THEIR IMPACT

	STRICT LIABILITY (NO-FAULT) ADMIN. SYSTEM	PREVENTABLE- EVENTS (ACES)	MEDIATION- EARLY OFFER	HEALTH COURTS	ENTERPR. LIABILITY
DETERRENCE EFFECT — PATIENT SAFETY IMPACT	<ul style="list-style-type: none"> - supports creation of a just patient safety culture - encourages reporting of adverse events 	<ul style="list-style-type: none"> - represents consensus on what constitutes an avoidable event - encourages prevention of avoidable events 	<ul style="list-style-type: none"> - alternative dispute resolution mechanism to litigation can potentially “warm” reporting of adverse events 	<ul style="list-style-type: none"> - more reliable judgments have the potential to send clearer messages for deterrence 	<ul style="list-style-type: none"> - provides incentive for prioritization of enterprise-wide safety
SWIFT COMPENSATION	<ul style="list-style-type: none"> - no-trial, administrative process - compatible with “early offer” compensation system 	<ul style="list-style-type: none"> - can trigger eligibility for early compensation offer 	<ul style="list-style-type: none"> - provides prompt settlement and compensation 	<ul style="list-style-type: none"> - swifter address of claims - could provide more reliable and standardized compensation 	
OPEN DISCLOSURE	<ul style="list-style-type: none"> - removal of litigation threat supports open disclosure 	<ul style="list-style-type: none"> - makes “avoidability” and therefore, eligibility for compensation, transparent to providers and patients alike 	<ul style="list-style-type: none"> - offers non-judicial dispute resolution that encourages communication between parties 		
CORRECTIVE JUSTICE	<ul style="list-style-type: none"> - provider is accountable for all avoidable medically related losses 	<ul style="list-style-type: none"> - restitution can be sought in conventional tort system or alternative system - potential to compensate greater number of injured patients 	<ul style="list-style-type: none"> - health care provider or organization is accountable - settlements are often sequestered 	<ul style="list-style-type: none"> - provides the potential for more reliable and credible adjudication and restitution of claims - makes fault determinations 	<ul style="list-style-type: none"> - holds enterprise accountable for the safety and quality of health care practice and practitioners

**TABLE 2: AN OVERVIEW OF ALTERNATIVES**

	STRICT LIABILITY (NO-FAULT) ADMIN. SYSTEM	PREVENTABLE- EVENTS (ACES)	MEDIATION- EARLY OFFER	HEALTH COURTS	ENTERPR. LIABILITY
KEY FEATURES	<ul style="list-style-type: none"> - eligibility based on avoidability rather than negligence - no trial, holds providers strictly responsible for medically related losses 	<ul style="list-style-type: none"> - pre-determination of events that should not occur in quality health care delivery - triggers eligibility for compensation 	<ul style="list-style-type: none"> - prompt, private settlement offers 	<ul style="list-style-type: none"> - appointment of special expert courts to hear medical cases or administer compensation based on avoidable events 	<ul style="list-style-type: none"> - shifts liability from individual provider to provider organization
PROS	<ul style="list-style-type: none"> - promotes prevention & transparency - widens eligibility for compensation - faster resolution of claims 	<ul style="list-style-type: none"> - standardizes eligibility for compensation - quicker identification of meritorious cases 	<ul style="list-style-type: none"> - can avoid litigation - lowers costs - swift & assured compensation for patients - promotes transparency 	<ul style="list-style-type: none"> - could improve the reliability of judgments - quicker resolution of claims - provides public access to settlement and adjudication findings 	<ul style="list-style-type: none"> - promotes institutional safety - potential to stabilize liability insurance fees
CONS	<ul style="list-style-type: none"> - perception that “no-fault” means “no accountability” 	<ul style="list-style-type: none"> - comprehensive ACE list currently non-existent - development of the list requires an array of expert consensus 	<ul style="list-style-type: none"> - intensifies pressure on patients to settle 	<ul style="list-style-type: none"> - requires judges who have special knowledge or training 	<ul style="list-style-type: none"> - legal provisions (Stark laws) may prohibit liability insurance coverage of non-employee physicians
COMPATIBILITY	<ul style="list-style-type: none"> - compatible with current system if based on “earn-in” model- providers meet criteria for admin. system; others are in conventional system 	<ul style="list-style-type: none"> - a basis to determine eligibility for alternative and conventional compensation systems - can be paired with standardized compensation fee schedule 	<ul style="list-style-type: none"> - used with current tort system - can be used with admin. systems, ACEs 	<ul style="list-style-type: none"> - is paired with ACEs and standardized compensation schedule - adds trial option to an administrative system 	<ul style="list-style-type: none"> - works with alternatives and current tort system
REAL-WORLD APPS.	<ul style="list-style-type: none"> - worker’s compensation laws - Fla. & Va. injury-specific demonstrations 		<ul style="list-style-type: none"> - Liability insurer models - Health plan models - Provider models 	<ul style="list-style-type: none"> - Special court precedents – tax and patent courts -- and worker’s compensation laws 	<ul style="list-style-type: none"> - precedents in product liability law



OPEN THE BLACK BOX

While comprehensive medical liability reform is the long-term solution for resolving the issues inherent in today's system, there are actions that can be taken in the intermediate term that would bring greater integrity and transparency to the process.

Medical liability claims are often settled before they reach trial, or before the trial ends in judgment. Terms of these settlements typically include a “gag clause” that requires the confidential sequestering of all information related to the case. Such confidential settlement offers may encourage quick resolution, but this is achieved at the cost of forever barring access to potentially important information that could be used to improve the quality and safety of care. Such settlements are of course encouraged by insurers to save court costs, and physicians are often amenable because the gag clauses preclude the sharing of information that could be damaging to their reputations. But gag clauses are antithetical to patient-centeredness – they deprive injured patients the opportunity to provide a legacy, and they provide a disservice to the provider and practitioner communities by preventing learning.

Physicians named in medical liability judgments and settlements, as well as disciplinary actions, are reported to the National Practitioner Data Bank (NPDB). Information contained in the NPDB is only accessible to hospitals and other health care organizations, licensing boards, and professional societies. Individual practitioners can only access information about themselves. Medical liability insurers, advocacy groups and members of the general public cannot access the data bank. The NPDB was established through federal statute and is managed by the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS).

The primary reason for the existence of the NPDB is to permit hospitals and licensing boards to track physician performance issues. Since its inception, questions have continued to be raised about the validity and reliability of the NPDB.¹³⁷ A 2000 GAO report cited a multitude of NPDB problems, including under-reporting of disciplinary actions, which, the report states, is a far better expression of physician competence than medical liability claims.¹³⁸ In fact, medical liability claims data constitute 80 percent of the information contained in the NPDB.¹³⁹



WHILE COMPREHENSIVE MEDICAL LIABILITY REFORM IS THE LONG-TERM SOLUTION FOR RESOLVING THE ISSUES INHERENT IN TODAY'S SYSTEM, THERE ARE ACTIONS THAT CAN BE TAKEN IN THE INTERMEDIATE TERM TO BRING MORE INTEGRITY AND TRANSPARENCY TO THE PROCESS.



The information the data bank contains is also characterized in the GAO report as substantially incomplete -- lacking, for example, any information as to whether the standard of care was considered when a claim was settled or adjudicated.¹⁴⁰

Because of its operational unsoundness, the NPDB represents a significant threat to physicians concerned about their reputations and ability to practice medicine. As previously discussed, medical liability judgments and settlements do not necessarily reflect medical negligence. Settlements, in particular, are often business decisions made by insurers who consider the potential cost of trial to outweigh the benefit of fighting a claim, without regard to the merits of the claim. The NPDB is also philosophically dissonant with patient safety theory -- all errors and actions it contains are tracked and related to individuals. It provides no information about, or insights into, related systems failures. And finally, its access limitations are antithetical to the goal of transparency in the patient-physician relationship.

There is a need for a centralized information source or sources that can reliably capture important inputs about the performance of physicians and other health care practitioners, but options other than the NPDB exist. For instance, the Federation of State Medical Boards (FSMB) regularly makes information on disciplinary actions taken against physicians publicly available. It has now been five years since the release of the GAO report critical of the NPDB, and no substantial progress has been made to implement its recommendations.

Given the relative ineffectiveness of the NPDB, it either needs to be substantially redesigned or its responsibilities need to be reassigned to other more reliable information repositories.

Accountability for health care professional competency lies with the individual and his or her licensing and certification boards, and employers. This accountability should extend to the conduct of physicians who act as expert witnesses in medical liability cases. As many who have participated in a medical liability case can attest, expert opinion is subject to substantial potential bias when that opinion is paid for by either the defendant or the plaintiff in a case.¹⁴¹

According to the Federation of State Medical Boards, expert witnesses who give false or misleading testimony are subject to disciplinary action.¹⁴² In Massachusetts, the medical society has established a series of standards that require, among others, that experts who testify in court be state-licensed, board-certified, and actively practicing in the field in which they represent themselves as experts. More aggressive oversight of expert witnesses by state licensing boards and professional societies would be an important short term and continuing contribution to ensuring more ethical expert testimony. In the long term, court-appointed experts that are independent of either plaintiffs or defendants are more likely to provide objective support to the litigation process.



RECOMMENDATIONS TO CREATE AN INJURY COMPENSATION SYSTEM THAT IS PATIENT-CENTERED AND SERVES THE COMMON GOOD:

TACTICS	ACCOUNTABILITY
<ul style="list-style-type: none">• Conduct demonstration projects of alternatives to the medical liability system that promote patient safety and transparency, and provide swift compensation to injured patients	➔ CMS, state-based initiatives
<ul style="list-style-type: none">• Encourage continued development of mediation and early-offer initiatives	➔ liability insurers, health care organizations, health plans
<ul style="list-style-type: none">• Prohibit confidential settlements – so-called “gag clauses” – that prevent learning from events that lead to litigation	➔ legal system
<ul style="list-style-type: none">• Redesign or replace the National Practitioner Data Bank	➔ DHHS Health Resources and Services Administration
<ul style="list-style-type: none">• Advocate for court-appointed, independent expert witnesses to mitigate bias in expert witness testimony	➔ medical professional societies, state medical boards



CONCLUSION

The current national tort reform discussion affords an opportunity to extend the focus on caps on non-economic damages to pursue fundamental, far-reaching changes to the health care system that would benefit patients, providers, practitioners, and the general public. But these significant benefits can only be achieved if the debate is informed by the voices of those who understand the inverse relationship between the impacts of the current medical liability system and efforts to improve patient safety. Instituting a federal cap on non-economic damages, while having the potential to slow the rise in liability premiums, will not alter the fundamental unfairness to patients and physicians and the deleterious impact on patient safety that are inherent in the existing tort system.

Now, five years after the seminal Institute of Medicine (IOM) report on patient safety, *To Err is Human*, too little progress has been made in identifying, learning from, and ameliorating medical error. While there are multiple reasons for this disappointing progress, no one can deny that the vulnerabilities for practitioners and provider organizations created by the medical liability system – fear

of litigation, loss of liability coverage, and professional reprisals among them – are driving underground information vital for learning and solution development.

It is clearly time to actively explore and test alternatives to the medical liability system. The goal of such alternatives is not to legally prescribe “blame-free” cultures, but rather, to stimulate the creation of “just cultures.” “Just cultures” foster learning – including learning from mistakes – but also emphasize individual accountability for misconduct. Inherent in any viable alternative for addressing medical liability claims should be the potential for fairly compensating greater numbers of injured patients, while allowing health care practitioners and providers the opportunity to reveal error, learn from such errors, and ensure that they are not repeated.

It is now two years since the IOM released another relevant report -- *Fostering Rapid Advances in Health Care*.¹⁴³ In addressing the medical liability system, the report calls for demonstration projects of alternatives for resolving medical liability claims. To date,



IT IS CLEARLY TIME TO ACTIVELY EXPLORE AND TEST ALTERNATIVES
TO THE MEDICAL LIABILITY SYSTEM.



no such demonstration projects have been initiated. This lapse is increasingly unacceptable in the face of the emergence of the medical liability system's problems as a pressing public policy issue. Both the federal and state governments need to put this issue at the top of their public policy "to do" lists.

Redesigning the medical liability system will necessarily be a long-term endeavor. Meanwhile, more and continued efforts aimed at fostering transparency among provider organizations, practitioners, and patients; seeking alternatives to litigation; leveraging the development of patient safety cultures; treating health care providers fairly; and honoring patients are both noble goals and practical necessities that must be actively pursued.

The ultimate goal is to make health care as safe as it can be, while also assuring appropriate redress for patients when it is warranted. Such public policy would truly serve the common good.

A VISION FOR TORT RESOLUTION & INJURY PREVENTION:

- All health care organizations acculturate patient safety – making it a precondition of all other priorities – with the goal of reducing incidences of malpractice.
- When a medical error occurs, the injured patient is promptly informed of the error and receives an apology, and analysis of the error informs the prevention of such error in the future.
- An early offer of compensation for losses is promptly provided to the patient.
- If a claim of injury remains in dispute, an alternative dispute mechanism is employed to bring the claim to a swift, fair and efficient resolution.



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ENDNOTES

- ¹ USA Today, September 14, 2004
- ² Randy Bovbjerg, speaking at the Joint Commission Roundtable meeting, July 28, 2004
- ³⁻⁴ Studdert, David M., Mello, Michelle M., Brennan, Troyen A., "Medical malpractice," NEJM 350:3, January 15, 2004
- ⁵ Iglehart, John, "The malpractice morass: Symbol of societal conflict," *Health Affairs*, July/August 2004
- ⁶ Harris poll
- ⁷ General Accounting Office, *Medical malpractice insurance: Multiple factors have contributed to the increased premium rates*, GAO-03-702, June 2003
- ⁸ Gibson, Rosemary, Singh, Janardan Prasad, *Wall of Silence: The Untold Story of the Medical Mistakes that Kill and Injure Millions of Americans*, Lifeline Press, May 2003
- ⁹ Sage, William, "Medical liability and patient safety," *Health Affairs*, July/August 2003
- ¹⁰ Institute of Medicine, *To Err is Human: Building a Safer Health System*, National Academies Press: 2000
- ¹¹⁻¹³ Studdert et al
- ¹⁴⁻¹⁷ Ransom, Scott R., Studdert, David M., et al, "Reduced medicolegal risk by compliance with obstetric clinical pathways: A case-control study," OB/GYN, 101:4, April 2003
- ¹⁸⁻²⁰ Nelson, Eugene C., Batalden, Paul B., et al, "Microsystems in health care: Part 1. Learning from high-performing front-line clinical units," *The Joint Commission Journal on Quality Improvement*, September 2002: 472-493
- ²¹⁻²² Devers, Kelly J., Pham, Hoangmai H., Liu, Gigi, "What is driving hospitals' patient-safety efforts?" *Health Affairs*, 23:2, March/April 2004
- ²³ Sage
- ²⁴ Gibson, Singh
- ²⁵⁻²⁶ Mohr, Julie J., Barach, Paul, et al, "Microsystems in health care: Part 6. Designing patient safety into the microsystem," *Joint Commission Journal on Quality and Safety*, 29:8, August 2003
- ²⁷ Devers et al
- ²⁸⁻³¹ Zimmerman, Rachel, "Doctors' new tool to fight lawsuits: Saying I'm sorry," *Wall Street Journal*, May 18, 2004
- ³²⁻³³ Wachter, Robert M, Shojania, Kaveh, *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes*, Rugged Land, February 2004
- ³⁴ Suresh, Gautham, Horbar, Jeffrey D., Plesk, Paul et al, "Voluntary anonymous reporting of medical errors for neonatal intensive care," *Pediatrics*, June 2004
- ³⁵⁻³⁷ Studdert, et al
- ³⁸ Comment at roundtable meeting
- ³⁹ Sage
- ⁴⁰⁻⁴¹ Studdert, et al
- ⁴²⁻⁴⁷ Liebman, Carol B., Hyman, Chris Stern, "A mediation skills model to manage disclosure of errors and adverse events to patients," *Health Affairs*, July/August 2004
- ⁴⁸⁻⁵¹ COPIC's 3Rs Program, Volume 1, Issue 1, March 2004, viewed on the website, copic. com
- ⁵²⁻⁵⁵ General Accounting Office, *National Practitioner Data Bank: Major improvements are needed to enhance Data Bank's reliability*, GAO-01-130, November 2000
- ⁵⁶ Posner, Karen L., Caplan, Robert A., Cheney, Frederick W., "Variation in expert opinion in medical malpractice review," *Anesthesiology*, 1996; 85: 109-54
- ⁵⁷ James Thompson, speaking at the Joint Commission Roundtable meeting, July 28, 2004



ENDNOTES

⁵⁸ IOM, *To Err is Human*

⁵⁹⁻⁶¹ Studdert et al

⁶²⁻⁶³ Gawande, Atul, *Complications: A Surgeon's Notes on an Imperfect Science*, Picador USA, April 2003

⁶⁴⁻⁶⁵ Brennan, Troyen A., Horwitz, Ralph I., Duffy, F. Daniel, "The role of physician specialty board certification status in the quality movement," *JAMA*, Sept. 1, 2004, vol. 202, no. 9

⁶⁶ Hickson, Gerald B., Federspiel, Charles F. Pichert, James, W., "Patient complaints and malpractice risks," *JAMA*, 2002: 2951-3297

⁶⁷ Needleman, Jack, Buerhaus, Peter I., et al., "Nurse staffing and patient outcomes in hospitals," February 38, 2001; Pronovost, Peter J, Dang, Deborah H., Dorman, Todd et al., "Intensive Care Unit Nurse Staffing and the Risk for Complications after Abdominal Aortic Surgery," *Effective Clinical Practice*, September/October 2001

⁶⁸⁻⁶⁹ Gawande

⁷⁰⁻⁷¹ Gaba, David M., "Anesthesiology as a model for patient safety in health care," *British Medical Journal*, vol. 320, March 18, 2000

⁷²⁻⁷⁶ Ransom, Scott R., Studdert, David M., et al, "Reduced medicolegal risk by compliance with obstetric clinical pathways: A case-control study," *OB/GYN*, 101:4, April 2003

⁷⁷⁻⁸³ Nelson, Eugene C., Batalden, Paul B., et al, "Microsystems in health care: Part 1. Learning from high-performing front-line clinical units," *The Joint Commission Journal on Quality Improvement*, September 2002:472-493

⁸⁴⁻⁸⁵ Devers, Kelly J., Pham, Hoangmai H., Liu, Gigi, "What is driving hospitals' patient-safety efforts?" *Health Affairs*, 23:2, March/April 2004

⁸⁶ Poon, Eric G., Blumenthal, David, et al, "Overcoming barriers to adopting and implementing computerized physician order entry systems in U.S. hospitals," *Health Affairs*, July/August 2004

⁸⁷⁻⁸⁸ Sage

⁸⁹ Testimony of Susan E. Sheridan before the National Summit on Medical Errors and Patient Safety, September 2000

⁹⁰ Gibson, Singh

⁹¹⁻⁹² Mohr, Julie J., Barach, Paul, et al, "Microsystems in health care: Part 6. Designing patient safety into the microsystem," *Joint Commission Journal on Quality and Safety*, 29:8, August 2003

⁹³ Devers et al

⁹⁴ Zimmerman, Rachel, "Doctors' new tool to fight lawsuits: Saying I'm sorry," *Wall Street Journal*, May 18, 2004

⁹⁵⁻¹⁰⁰ Zimmerman, Rachel, "Medical contrition," *Wall Street Journal*, May 18, 2004

¹⁰¹⁻¹⁰² Wachter, Shojania

¹⁰³⁻¹⁰⁶ Suresh, Gautham, Horbar, Jeffrey D., Plesk, Paul et al, "Voluntary anonymous reporting of medical errors for neonatal intensive care," *Pediatrics*, June 2004

¹⁰⁷⁻¹⁰⁹ Wachter, Shogania

¹¹⁰⁻¹¹² Studdert, et al

¹¹³ Comment at roundtable meeting

¹¹⁴⁻¹¹⁵ Sage

¹¹⁶⁻¹¹⁷ Studdert, et al

¹¹⁸⁻¹¹⁹ Sage



ENDNOTES

- ¹²⁰ Bovbjerg, Randall R., Raymond, Brian, *Issue Brief: Patient safety, just compensation, and medical liability reform*, Kaiser Permanente Institute for Health, Summer 2003
- ¹²¹ Institute of Medicine, "Liability: Patient-Centered and Safety-Focused, Nonjudicial Compensation," *Fostering Rapid Advances in Health Care: Learning from Systems Demonstrations*, National Academies Press, 2002
- ¹²²⁻¹²³ Bill Sage, presentation at the Joint Commission conference, Medical Liability: New Solutions to an Old Dilemma, November 11-12, 2004
- ¹²⁴ Common Good/Harvard School of Public Health press release, January 10, 2005
- ¹²⁵⁻¹²⁶ Udell, Nancy, Kendall, David B., *Health Courts: Fair and Reliable Justice for Injured Patients*, draft report: 1.12.05
- ¹²⁷⁻¹³² Liebman, Carol B., Hyman, Chris Stern, "A mediation skills model to manage disclosure of errors and adverse events to patients," *Health Affairs*, July/August 2004
- ¹³³⁻¹³⁶ COPIC's 3Rs Program, Volume 1, Issue 1, March 2004, viewed on the website, copic.com
- ¹³⁷⁻¹⁴⁰ General Accounting Office, National Practitioner Data Bank: *Major improvements are needed to enhance Data Bank's reliability*, GAO-01-130, November 2000
- ¹⁴¹ Posner, Karen L., Caplan, Robert A., Cheney, Frederick W., "Variation in expert opinion in medical malpractice review," *Anesthesiology*, 1996; 85: 109-54
- ¹⁴² James Thompson, speaking at the Joint Commission Roundtable meeting, July 28, 2004
- ¹⁴³ Institute of Medicine, "Liability: Patient-Centered and Safety-Focused, Nonjudicial Compensation," *Fostering Rapid Advances in Health Care: Learning from Systems Demonstrations*, 2002

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