

BUILDING THE CONNECTION: THE LINK BETWEEN MALPRACTICE LIABILITY AND IMPROVED HEALTH

ISSUE BRIEF

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“Malpractice reform has long been the graveyard for high hopes and good intentions. Such endeavors are not for the faint of heart or those lacking in patience and stamina.”

- D. A. Hyman (1)

“If the situation is perceived to be a crisis, legislation will be enacted. Otherwise, the debate will die down and the combatants will regroup to begin anew at the next opportunity.”

- D. A. Hyman (1)

State legislators and public policy makers are being confronted by the challenge of medical malpractice law and regulation. As suggested by the above quotes, the challenge is both ever-present and complex. It is always on the agenda, either as a priority during a crisis or just beneath the surface at other times. Its complexity stems, in large measure, from the multiple and often conflicting goals of the liability system; the lack of empirical data about the performance of the system in relation to these goals; and the differing interpretations of what information is available based, substantially, on personal and professional biases. Mimi Marchev (2), writing for the National Academy for State Health Policy, has summarized this problem as

“the challenge facing the states – to determine the causes and find a solution to this pressing and complicated problem – is made much more difficult by the crossfire of accusations and the dearth of empirical research.”

According to the National Conference of State Legislators, 34 state legislatures considered some form of malpractice liability reform during their 2003 sessions and 11 states enacted reforms. In 2001, Utah was one of the few states enacting legislation targeted at malpractice issues. Legislators from 30 states, including Tennessee, believed that malpractice reform will be at the forefront of legislative activity during the 2004 session.

The Crisis in Finance

The current malpractice crisis centers largely on the financing of malpractice liability insurance for physicians (Figure 1). In 2002, the national average increase in insurance premiums was 23%, but was much higher for some specialties and in some states; in Virginia, for example, premiums for internists, general surgeons and obstetricians increased by 144%, 127% and 88%, respectively. Rates charged by Tennessee’s largest carrier, State Volunteer Mutual Insurance Company, rose 17% for internists, general surgeons and obstetrician/gynecologists between 2001 and 2002.

The rapid rise in insurance premiums has been alleged to be a major factor in limiting access to needed care in certain parts of the nation. The American Medical Association has identified 19 states in which malpractice insurance premiums have created a “crisis” in access to

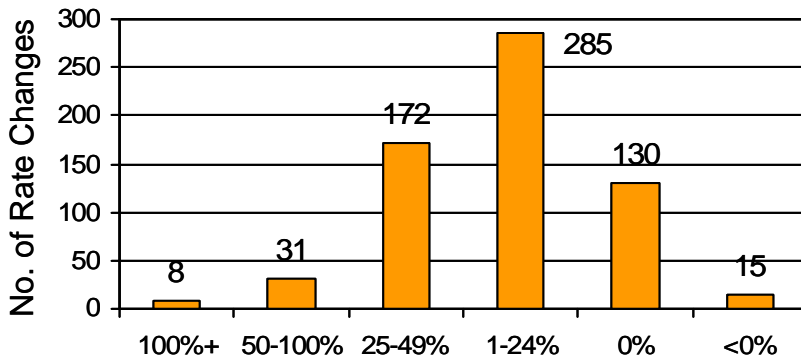


Figure 1: The number of changes in malpractice premiums in all states (total = 600 changes) between 2001 and 2002 that were greater than 100%, 50-100%, etc. Fifteen rates fell (<0%). Source: Medical Liability Monitor 2003 Annual Survey.

health care (Figure 2), and a survey of 700 group practices conducted by the Medical Group Management Association indicated that 14% of practices had physicians who would eliminate care to patients at high risk of filing suits. The U.S. General Accounting Office has documented that many but not all of the identified access concerns are, in reality, related to liability insurance issues. For example, the high costs of malpractice liability insurance were found to be the primary cause for restricted access to general surgery in Jacksonville, Florida and along the Mississippi Gulf Coast, and for the temporary closures of Level I Trauma Centers in Nevada and West Virginia. Tennessee is not at present among the AMA’s crisis states but is listed among 30 other states with a “problem”.

This Issue Brief and the Forum which it supports will focus on a different aspect of the malpractice crisis. Both will focus on the ability of the malpractice liability system to achieve one of its major goals - deterring future negligent acts.

The role of malpractice liability suits to deter future negligent events and to thereby improve the quality of health care has advanced on the public policy agenda because of developments in understanding the nature of medical errors. Substantial progress has been made in documenting the prevalence and understanding the causes of adverse outcomes and errors in health care, and in developing methods to

The Crisis In Deterrence

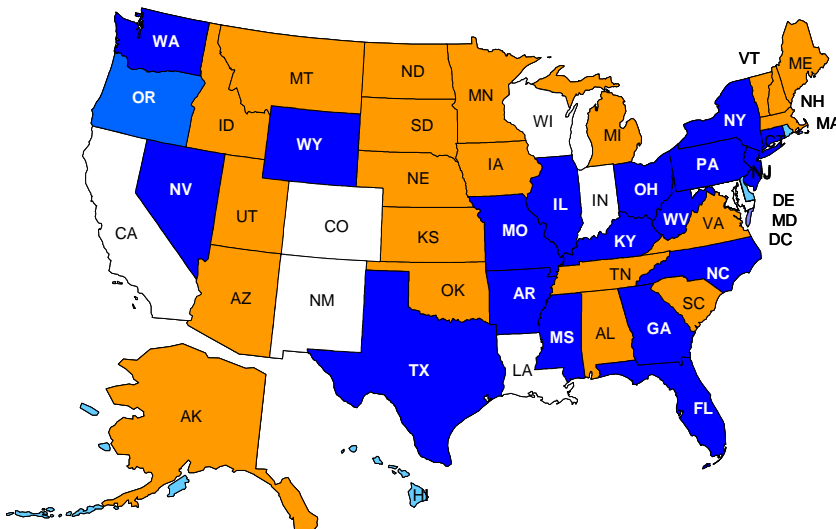


Figure 2: Map identifying states deemed by the American Medical Association to have medical malpractice crises (blue) or problems (orange). Modified from American Medical Association, www.ama-assn.org, accessed January 30, 2003.

“At issue is whether we should adopt short-term, stopgap solutions to slow the growth in premiums, or use the recent experience to more fundamentally evaluate and perhaps reform the liability system.”

- Kenneth Thorpe (3)

This Issue Brief

Differences between adverse events, medical errors and negligence

improve overall patient safety. These advances change, in fundamental ways, how malpractice and negligent care are viewed; how the adequacy of the current malpractice liability system is assessed; and how liability reforms are devised and implemented. They have highlighted the common goal of the liability system and patient safety programs to improve health and, at the same time, have called attention to the fundamental conflicts between them. Understanding these issues is essential for developing long-term as well as short-term public policies that effectively promote the basic goals of the tort system and the health care system.

It is the purpose of this Issue Brief to provide background information about these concerns. It will address the following general questions:

- *What are medical errors, how often do they occur, what are their causes, how do they relate to negligence and how can they be prevented?*
- *Does the tort liability system effectively deter errors and promote improved health care?*
- *What changes in public policy have been proposed that would build the link between malpractice liability and improved health care?*

What are medical errors, how often do they occur, what are their causes, how do they relate to negligence and how can they be prevented?

Much of the growing interest in assessing and preventing medical errors follows the 1999 report from the Institute of Medicine entitled “To Err is Human. Building a Safer Health Care System” (4). Important findings stressed in the report include:

1. *Adverse events, medical errors and negligent events are not the same.* The distinctions among these categories of undesirable outcomes of health care are important in understanding the relation between liability and patient safety issues. An adverse event is defined, according to the Institute of Medicine, as any injury caused by medical management rather than caused by the underlying disease processes. An error is “the failure of a planned action to be completed as intended (i.e., an error of execution) or the use of a wrong plan to achieve an aim (i.e., an error of planning)”.

Based on these definitions, not all bad outcomes are adverse events and not all adverse outcomes are due to errors. An allergic reaction to an antibiotic in a patient not known to have a drug allergy is an adverse event but does not represent an error. The adverse event would represent an error if the patient had been known to be allergic to the antibiotic. Similarly, an error may or may not result in an adverse event. For example, if a physician prescribed an antibiotic to a patient with a known allergy but a pharmacist identified and intervened before the antibiotic was administered, an error occurred but an adverse event did not.

Negligent events represent a subgroup of errors that satisfy the legal criteria for negligence, that is, the care provided “failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question” (4). For example, a physician may have prescribed an appropriate antibiotic but a different antibiotic to which the patient is allergic was administered. This occurred because of an error in transcribing the doctor’s order, and the wrong drug was administered despite the normal functions of the hospital’s generally accepted checking systems, an error occurred without clear negligence.

2. *Adverse events and medical errors are common.* Perhaps the most startling revelation of the Institute of Medicine report was the frequency with which adverse events and medical errors occur. Studies of hospitalized patients in New York, Colorado and Utah cited in the report found that adverse events occurred in 2.9% to 3.7% of hospital admissions (5,6). Most resulted in only temporary disability but 13.6% resulted in death and 2.6% caused permanent disability.

A large proportion of adverse events are the result of errors (Figure 3). In the studies referred to above, 53% to 58% of adverse events were due to identifiable errors. When these statistics are considered in the context of the number of persons admitted to hospitals each year, it has been estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. These numbers are higher than the number of deaths due to motor vehicle accidents or breast cancer. These numbers include only events that occurred in hospital settings; the extent of the problem in outpatient care is not known.

A Kaiser Family Foundation poll also demonstrated that errors are common. It revealed that 42% of the general public and 35% of physicians had experienced a medical error in their own care or in the care of a family member. Of those who had experienced an error, 24% of the public and 18% of physicians experienced an error with serious health consequences.

Adverse events and errors are common.

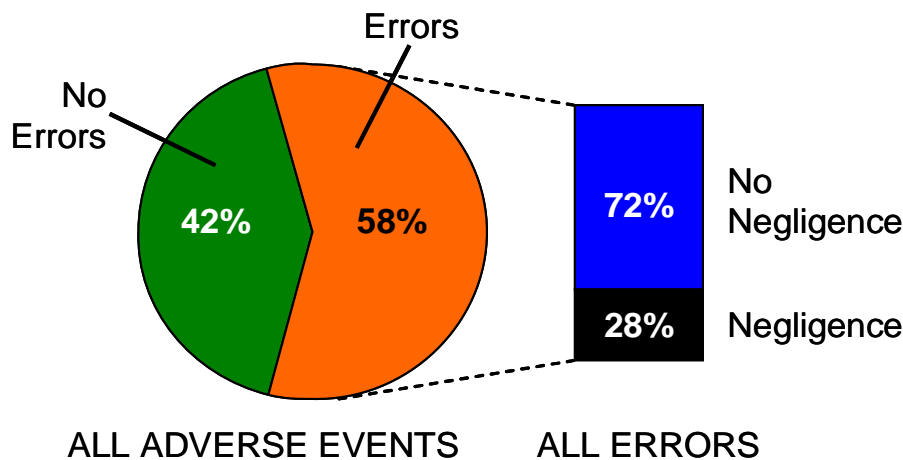


Figure 3: The proportion of adverse events that were due to medical errors (left) and the proportion of medical errors that were caused by negligent care, based upon the Harvard Medical Practice Study (5). Errors caused 58% of all adverse events and 28% of adverse events were due to negligence.

Adverse events and errors are not due to negligence.

Most errors are due to underlying system failures.

“...even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors

Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors.”
- Institute of Medicine (4)

Improvement is possible.

3. *Most adverse events and errors are not due to negligence.* As in the examples above, only some adverse events reflect errors and only some errors reflect negligence. For example, in a review of over 30,000 randomly selected medical records in New York State, 1278 adverse events were detected by professional review (7). Less than one-fourth (24%) of the errors were due to negligence (Figure 3). In a similar review of 15,000 records in Colorado and Utah (8), approximately one-third (27.4% to 37.6%) of adverse events were due to negligence. The proportion of adverse events and errors that are due to negligence does increase as the severity of the injury increases and varies with the type of injury. For example, in the New York study, 51% of injuries resulting in death were due to negligence while only 23% of injuries resulting in temporary impairment were due to negligence.
4. *Most medical errors are induced by system problems rather than mistakes by individual practitioners.* The Institute of Medicine report emphasizes the lessons learned from studies of errors in other systems - including the Challenger and the Three-Mile Island disasters – that system problems rather than mistakes of individual people are primarily responsible for medical errors. The delivery of health care is the product of a very complex system and when systems fail it is commonly due to the combination of “multiple faults that occur together in unanticipated interaction, creating a chain of events in which faults grow and evolve” (4). This has been described as the “Swiss cheese” model - when the holes in error defense systems line up, errors occur.

In this model, an overt or “active” error that may be traced to an individual reflects, on deeper examination, one or more latent and unobserved system failures. In the example used by the Institute of Medicine (4), the inappropriate administration of drugs during surgery was overtly due to the actions of a nurse but reflected numerous latent problems such as the use of multiple types of equipment used to administer the drugs and the complex scheduling of personnel in operating rooms. Although human error is the largest contributor to medical errors and there are some individuals who are incompetent or impaired or who may have criminal intent, most human errors are induced by system failures that “set up” people to fail.
5. *Interventions that effectively improve quality of care and patient safety can be developed and implemented based upon these concepts.* As many as 70% of medical errors can be prevented according to the Institute of Medicine. As anticipated from the finding that systems rather than individual mistakes contribute to medical errors, efforts that have been effective in reducing errors have focused on enhancing the performance of health care systems. Because the causes of most errors lie at the system level, the causes and consequences of errors cannot be understood or corrected by focusing on the behavior of individuals. The report emphasized that the punitive approach

reduces the willingness of people to provide information needed to identify and correct systems defects, and if latent system issues are not addressed, they remain and will lead to errors again.

Does the tort liability system effectively deter errors and promote improved health care?

A primary goal of the malpractice liability system is to provide economic and noneconomic incentives to health care providers to avoid substandard care, that is, to provide incentives to improve the quality of care. The economic incentives include, in principle, the payments to injured parties and the costs of defense. It has been estimated that negligent medical care costs \$183,500 (in 1994) per malpractice claim that involves negligence (9). The Joint Economic Committee of the U.S. Congress has reported that defense costs, usually not covered in the final judgment or settlement, range from \$16,000 for cases that are dropped or dismissed to over \$80,000 for cases in which the trial verdict is for the defense. Noneconomic incentives include the personal and professional consequences of malpractice suits, including loss of professional prestige and personal stress.

The high economic and noneconomic costs of negligence would appear to represent “substantial penalties that send a very clear message to medical providers” (9). Evidence that this deterrence is, in reality, effective in reducing subsequent negligent care is, however, controversial (1,10,11).

The widespread practice of “defensive medicine” may be used as evidence of deterrence – clinicians provide more services in an effort to avoid malpractice claims. Defensive medicine occurs when clinicians order tests, procedures or treatments (or avoid high-risk procedures) primarily, although not necessarily exclusively, to reduce their risk of malpractice liability. While the precise extent of defensive medicine is unknown, surveys indicate that it is a common practice. In a Harris Poll conducted in 2003, 38% of physicians reported that excess care was given “very often” because of fear of litigation; 79% reported ordering more tests than needed and 51% had performed more invasive procedures than otherwise needed. Defensive practices may be declining as managed care systems restrain the use of “unnecessary” tests and treatments.

While some defensive practices improve the quality of care, most do not. However, since these practices have minimal marginal medical benefit, they may not represent real avoidance of substandard care. They do, like all medical actions, entail a degree of risk. Thus, the ratio of risk to benefit is easily tipped in favor of risk to the patient. In addition, empirical evidence has shown that the extent of defensive practices do not correlate with prior malpractice experience.

Explicit evidence that malpractice liability deters substandard care is scant. Studies of obstetric care have not demonstrated a relation between malpractice actions and future deviations from standards of care or with later improvements in a wide range of birth outcomes. Studies of malpractice risk among hospitals in New York State did demonstrate that higher malpractice risk was associated with a lower proportion of

Defensive medicine

Barriers to deterrence

Externalization of costs

“Thus, unlike motorists who fear getting into an accident because it is virtually certain to mean higher insurance premiums for years to come, health care providers do not feel the full economic consequences of their mistakes.”

*- M Mello and
T Brennan (11)*

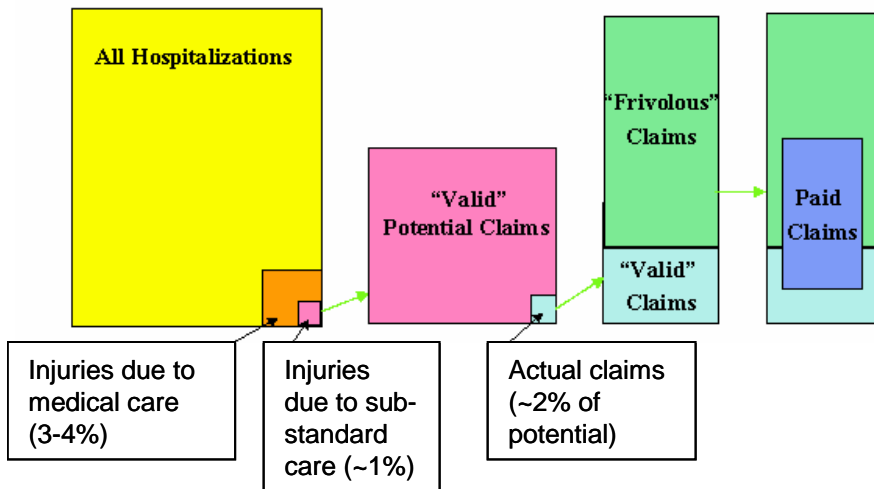
Limited relation between negligence and malpractice claims

adverse events related to negligence but other analyses of these studies failed to document a significant deterrent effect. From a review of these studies, experts such as Mello and Brennan (10) conclude that “the overall picture that emerges from these studies of the relationship between malpractice claims experience and medical errors is that evidence of a deterrent effect is (a) limited and (b) vulnerable to methodological criticism.”

Why does the current tort system not promote health? The economic and noneconomic incentives to avoid substandard care appear to be substantial. Many barriers to improving health have been identified in the tort system. These may be grouped into two broad categories – the problems with the current implementation of the tort model and the basic discordance between the tort model and what is known about medical errors.

Problems with the current tort system reflect the “externalization” of the costs of substandard care and the poor fit between negligent practice and malpractice claims.

- 1. Externalization of the costs of negligence reduces the economic incentive to change provider behavior.* Deterrence is dependent upon the negligent provider bearing enough of the cost of negligent care to create a sufficient incentive to change behavior. However, in the current system, most of the awards to plaintiffs is covered by liability insurance and the additional medical care costs are paid by health insurance carriers. (In fee-for-service systems, the physician responsible for the negligent event may be paid additionally for care required to treat the iatrogenic condition.) Because individual premiums are not now experience-rated, liability insurance costs to individual practitioners do not reflect their personal history of care. Thus, the individual practitioners directly bear little of the direct economic costs of personal negligence and there is little economic incentive for them to modify their behavior.
- 2. The poor fit between negligent practice and malpractice claims results in inconsistent incentives to providers to improve care.* The comprehensive studies by investigators from the Harvard School of Public Health relating negligent care and malpractice claims provide an empirical basis for assessing the relation between negligent practices and malpractice claims. These investigators reviewed over 100,000 medical, legal and insurance records in New York, Colorado and Utah (5-9). The findings included the following:
 - Of 280 patients in 51 randomly selected hospitals in New York state who suffered adverse outcomes with independent evidence of negligence, only 8 (2.9%) filed a malpractice claim.
 - Of 18 malpractice suits filed by the 14,700 patients in Colorado and Utah who were included in the studies, three-fourths (14 or 77.7%) revealed no evidence of negligence and over half (10 or 55%) revealed no adverse event in independent reviews.



*Figure 4: The relationships between injuries due to medical care, injuries due to negligence, malpractice claims and paid claims. See text for explanations. Modified from *Malpractice Issues and Non-Traditional Solutions*, Randall R. Bovbjerg, National Conference of State Legislatures, June, 2003.*

- Of 46 malpractice cases in New York state that were followed to closure, payments to the plaintiff were ordered in only 55% (5 of 9 cases) with evidence of negligence, but also in 43% (16 of 37 cases) of cases with no evidence of negligence.

Thus, as depicted in Figure 4, most errors are not caused by negligence, most acts of negligence do not result in claims (creating what has been called “the litigation gap”), claims are more often filed in the absence of (“frivolous claims”) than in the presence of negligence (“valid claims”), less than half of claims are paid, and many of the claims that are paid have no evidence of negligence upon professional review. These findings are in accord with public opinion; a 2003 Harris Poll reported that 66% of adults believe that patients “very often” bring claims against physicians whether or not malpractice had occurred.

Studies of malpractice claims in several settings have shown that factors such as the degree of disability, the quality of doctor-patient communication and courtroom skills are more powerful determinants of suits and their outcomes than is quality of care. The net result is that similar cases result in dissimilar outcomes and that a lack of a consistent stimulus exists to practitioners to improve care. In addition, because claims against an individual physician are relatively infrequent, individual providers will not experience a potent incentive to improve care.

Others attribute greater associations between malpractice claims and true negligence in the tort system. In some other studies, as many as 46% of claims are associated with negligence (vs. 27% in the Harvard studies). Analyses summarized by Michelle White (10) also report that the probability of payment (16-47% vs 66-89%) as well as the amount of payment (\$41,000 vs \$200,000) are higher in cases that are found to involve true negligence than in those that do not.

The second set of barriers to deterrence reflect fundamental differences between the tort system and what is known about the origins of medical errors and effective methods to reduce these errors. Critics of

Conflicts between the tort system and efforts to improve patient safety

the current liability system argue that the conflicts between the two models include:

1. *The tort system is based on blame and assigning blame is a prerequisite to compensation, whereas effective approaches to improving patient safety are based on cooperation and collaboration among groups to identify causes and implement change.*
2. *The tort system focuses on individual providers as the source of errors and as the target for punishment, whereas improving patient safety focuses on the role of organizations as the primary source of errors and as the appropriate focal point for intervention.*
3. *The tort system relies upon negative incentives to change behavior, whereas efforts to enhance patient safety are based on positive incentives to motivate behavioral change.*
4. *The tort system focuses on only the small proportion of adverse events that result in suits, whereas efforts to enhance patient safety are dependent upon a full reporting of adverse events so that trends and causes can be analyzed to determine the underlying or latent system causes of errors.*
5. *Reforms of the tort system are primarily aimed at reducing costs, not at reducing errors.*

Limited reporting of information about errors

Critics among the legal and the medical professions argue that the current liability system establishes a set of incentives that decrease the effectiveness of methods to enhance patient safety. One example is the under-reporting of adverse events that limits the ability to detect, assess and correct systems problems. The Institute of Medicine concluded that the most important barrier to reducing errors is the lack of information about the extent and causes of errors, and that there is a lack of information because “the vast majority of errors are not reported because personnel fear they will be punished.”

Focus on “active” problems

A second effect is the focus on overt or “active” problems, that is, the adverse event itself, and the role that individual providers have in committing these errors. As described above, the Institute of Medicine report emphasizes the role of underlying or “latent” systems defects that often underlay the overt event. If these latent issues are not addressed, the report asserts that they remain to create future adverse events so that patient safety is commonly not enhanced.

Chilling of communication

Another effect of the tort culture is the chilling of communication among and between clinicians and patients about adverse events. For example, hospitals with major concerns about malpractice liability are only half as likely to disclose preventable errors to patients as are hospitals with less malpractice concern. The result may then be a weakening of doctor-patient communication that, in turn, may lead to more rather than fewer suits. In addition, clinicians are less likely to openly discuss errors and opportunities for improvement do not emerge.

What changes in public policy have been proposed that would build the link between malpractice liability and improved healthcare?

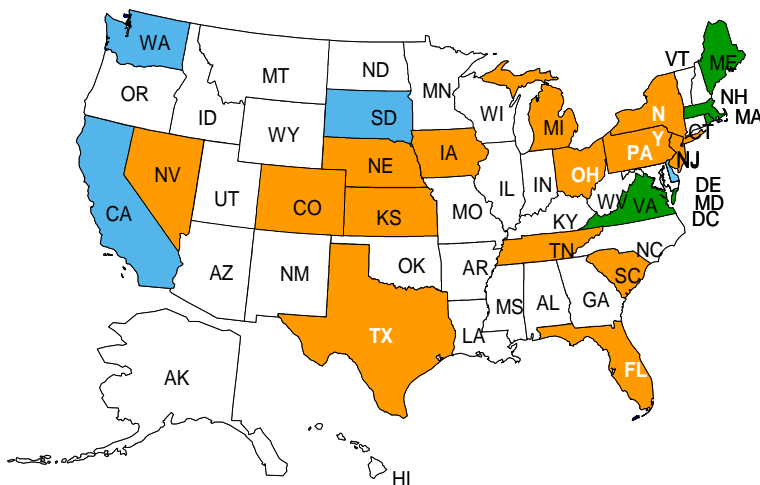
Numerous changes to existing medical practice law and regulation have been proposed to address the current malpractice crisis. The public policy goals of these reforms are, in general terms, aimed at reforming malpractice and insurance policies to implement a liability scheme that provides efficient compensation for injuries that do occur; effective incentives to reduce preventable injuries; and just means to hold health care providers accountable for negligent or incompetent behaviors, all without reducing access to or the quality of overall care.

The common tort reforms (“first generation reforms”) are aimed at assuring access to affordable malpractice insurance, reducing the number of claims or reducing the size of awards, or changing the functioning or the costs of the judicial process. Some of these reforms may have substantial effects on malpractice claims and awards (12). Caps on awards may reduce claim size by 19-39% and changes in collateral source rules may lower claim amounts by 11-50%, respectively, and reducing the statute of limitations by one year may reduce claim frequency by 8%.

Other reform proposals, referred to as “second generation reforms”, are aimed at enhancing patient safety by addressing the barriers between malpractice liability and deterrence, referred to above.

1. *Mandatory Disclosure and Reporting of Adverse Events.*

According to the Institute of Medicine report, reporting systems serve two purposes, both of which serve to deter adverse events. First, they act to hold health systems accountable for their performance. They assure the public that at least the most serious adverse events are reported and investigated, and they provide an incentive for healthcare organizations to reduce errors to avoid potential penalties and public exposure. Studies in Wisconsin demonstrated, for example, that mandatory public reporting of quality of care data did stimulate improvement activities in areas reported to be of low quality.



Goals of public policy

“First generation” tort reforms

Reporting requirements

Figure 5: States with mandatory reporting of medication-related errors (blue), mandatory reporting of adverse/sentinel events or patient safety data (orange) and mandatory reporting of general medical errors (green). States in white have no mandatory reporting requirements. Source: National Health Policy Tracking Service, December 31, 2003.

Second, reporting systems collect and aggregate data to detect trends and allow analysis of events that occur too infrequently in any one institution to provide an adequate sample for analysis. This, as described earlier, is an essential prerequisite to implementing patient safety interventions.

Reporting systems may be either mandatory or voluntary, and they may be imposed by governmental or private agencies. As of the end of 2003, 21 states (including Tennessee) had enacted mandatory reporting systems (Figure 5) and several have voluntary ones. Tennessee law (TCA 68-11-211, “The Health Data Reporting Act of 2002”) requires that health care “facilities shall report unusual events, and certain defined incidents...” with the intent of assisting “health care providers and the Department of Health to work together to collect meaningful health care data so as to minimize the frequency and severity of unexpected events and improve delivery of health care services.” The law also requires that “the affected patient and the patient’s family, as may be appropriate, shall be notified of the event or incident by the facility”. Mandatory reporting systems have also been implemented by federal agencies, including the requirement that many types of disciplinary actions against a practitioner and medical malpractice payments on behalf of a practitioner be reported to the National Practitioner Data Bank.

Privacy protections

2. *Legal Protection of Reported Events.* A critical step in the utilization of these reports to reduce errors is that the information be reported and shared in a “safe environment” without the fear of recrimination. One major fear of disclosing and reporting adverse events is that the reports may be used as a basis for malpractice claims. Although little evidence exists that mandatory reporting does, in fact, increase malpractice claims, the fear of such a relationship is the main reason for limited compliance with reporting requirements. Protections that are in statute and that are an integral part of the reporting system provide the most reliable assurances (13). Examples of protections that have been enacted include:

- Elimination of information that identifies institutions or practitioners from the reports and anonymous reporting of adverse events.
- Exemption of adverse event data from public disclosure laws.
- Confidentiality protections against subpoena, discovery and admissibility in civil or administrative proceedings.
- Expanded peer review privilege protecting peer review information from discovery, disclosure and admissibility.

Most states have enacted various combinations of these protections. In Tennessee, adverse event reports are confidential. They are not discoverable, subject to subpoena, or admissible as evidence in civil or administrative proceedings (TCA 68-11-211(a)(1)). In addition, the Tennessee Peer Review law protects peer review committees from liability for their “good faith” efforts to review, discipline and educate physicians. The statute defines “peer

review committee” broadly to include any health care organization that functions to “evaluate and improve the quality of care rendered by providers.” This law protects not only peer review committees, but any organization, institution, foundation or medical personnel who participate with or assist the peer review committee in its functions. The law provides that all information furnished to the committee or generated during committee proceedings “shall be privileged” (TCA 63-6-219(2)).

However, many of these protections are limited. As pointed out by a report from the Department of Health and Human Services, many provide protection for communications within a single institution and usually for information only from certain committees. They do not, for example, provide protection for combining many types of data from multiple providers and sources to compare results.

Counterarguments claim that these shields limit the needed uses of the data for public accountability. These protections can result in losing of public trust; shielding providers who do not meet standards of care from sanctions; limiting the ability of purchasers of health care to contract for health care services based on quality; and not, as described by William Sage of Columbia University Law School, “helping patients make better decisions about care, respecting the dignity of victims and families, and fostering the public debate about the risks and benefits of medicine” (14). As summarized by David Studdert and Troyen Brennan of Harvard University School of Public Health (15), “... no mix of mandatory/voluntary and public/confidential features can avoid trading off important interests of patients against those of providers.”

Other mechanisms have been proposed to assure that public accountability and patients’ interests are protected while much of the data are shielded. These include banning confidentiality agreements as part of settlements, direct government oversight of error reporting, external reviews of events by reputable independent groups, and promoting alternative means of resolution and compensation that do not depend on assigning blame (see below).

Tennessee law (TCA 68-11-211) permits disclosure of adverse event reports to “a disciplinary proceeding by the Department (of Health) or the appropriate regulatory board ...” or “to an appropriate regulatory agency having jurisdiction for disciplinary or licensing sanctions against the impacted facility” and requires the Department to “reveal upon request its awareness that a specific event or incident has been reported.”

3. *Promoting Clinical Pathways and Protocols.* Clinical pathways or guidelines identify diagnostic and treatment approaches for specific conditions based upon the best available scientific evidence and expert opinion. Although they may not apply to every patient, they are designed to reflect the state-of-the-art of care for most patients with a particular condition. Guidelines have been shown to be an effective method to change practice patterns to improve quality of care and, often, reduce costs.

Clinical pathways

*Enterprise liability and
experience rating*

In a legal environment, guidelines may rationalize the medical malpractice claims process by establishing a professionally-accepted standard of care (16). Adherence to guidelines may provide evidence of the standard of care and be used to exonerate a clinician. In states such as Maine and Kentucky, adherence to an established protocol has been proposed to be an affirmative defense in malpractice litigation. In other states, compliance with a professionally accepted guideline or pathway is considered relevant but not conclusive evidence of standards of care.

However, guidelines may also be used against a defendant. Failure to follow an established guideline may be used as evidence of substandard or negligent care. In one large obstetrics practice, nonadherence to a clinical pathway was associated with a six-fold increase in the odds of a malpractice claim and noncompliance was the major allegation of the claim of negligence.

Substantial obstacles exist to the reliance on practice guidelines in the current litigation process. These include the existence of multiple guidelines for the same condition that may conflict, the frequent limitation of guidelines to apply to particular patients such as those with multiple diseases and the limited acceptance of many guidelines by practitioners.

4. *Implementation of “Enterprise Liability” with Experience Rating.* One set of proposals transfers liability for injuries from individual practitioners to health care organizations such as practice plans and hospitals (17, 18). In its simplest form, enterprise liability would mean that “the enterprise” would be liable for paying the liability premiums for its entire affiliated staff, that is, the costs and liability are “channeled” to the organization. Such systems are in place in, for example, the Harvard Medical Institutions in Boston and the Federation of Jewish Philanthropies in New York that pay the malpractice costs of their physicians through self-insurance. Hospitals in Pennsylvania also developed enterprise liability approaches to deal with that state’s current malpractice crisis.

These models have several advantages. First, by combining the experiences of many practitioners, it may be feasible to implement experience rating for malpractice liability premiums. As noted above, this is difficult for individual practitioners because of the infrequency of malpractice events at the individual level. Combining the incidence of events of a large number of practitioners affiliated with a large group or hospital allows sufficient information about risk to set different premiums for different groups with different malpractice experiences. Thus, groups with a high incidence of events would pay more than a group with a better record.

Second, the enterprise model is consistent with systems-oriented quality improvement models. As emphasized by the Institute of Medicine, most adverse events reflect problems at the system rather than at the individual practitioner level. Enterprise liability places the burden on the system, the level at which the errors occur, and provides an incentive to the enterprise to improve. Enterprise liability also may have a new role as managed care organizations play a

greater role in influencing processes of care, reducing the prerogatives and, arguably, the culpability of physicians for adverse outcomes.

Here too, there are counterarguments. It is not clear how this model would fit into solo practices in which no easily identifiable enterprise exists. In addition, small hospitals or groups may not be able to afford the increase in liability costs or the costs of reinsurance and, as in the case of workers' compensation plans, small groups may be unable to manage the yearly changes in premiums that may result from a single event. Legal issues to be managed include concerns over violating laws prohibiting the "corporate practice of medicine" if physicians are brought under the enterprise umbrella and violating federal "kick back" regulations if the hospitals subsidized the liability insurance of physicians who remained independent practitioners.

5. *No Fault Systems.* One of the most comprehensive, complex and controversial reform proposals is the implementation of a no-fault system for compensating persons injured by medical care (19). No-fault systems would provide compensation for any patient who has been injured, subject to established requirements and payment schedules, without the need to establish negligence and assign blame. Such systems have been implemented in the United States in workers' compensation plans and some forms of automobile insurance. Some forms also exist in malpractice liability. Denmark, Sweden, Finland and New Zealand have malpractice liability systems based on no-fault models. Examples in the United States include no-fault coverage for selected newborns born with neurological damage in Florida and the national no-fault compensation plan for immunization-related injuries.

The value of no-fault systems is based on the negative effects of requiring blame to secure compensation. As described above, these include compensating only a minority of patients who have been injured during care, the high economic and noneconomic costs of adversarial procedures and proceedings, and the conflict with basic concepts of improving patient safety.

Arguments against these proposals are also potent. One objection is that the elimination of blame as a punishment for providing substandard care would further reduce the deterrent effect against providing substandard care. Conversion of motor vehicle accident liability to a no-fault system did result in a modest increase in accident rates.

Proponents respond that a deterrent effect would be maintained by combining no-fault systems with experience rating, as in the workers' compensation systems in which accident rates have fallen, so that higher payments would lead to higher rates providing an enterprise-wide stimulus to reduce risk. Implementation of a no-fault system for motor vehicle accident injuries in Canada resulted in a reduction in claims for medical compensation due to whiplash injury, as the expectation for compensation decreased under the new administrative system.

No-fault systems

“Some form of crisis in malpractice seems likely to recur despite conventional tort reform, as it has in the past. Policymakers will have few if any new options to address it when it comes unless there is some experimentation with alternatives now.”

- Urban Institute Intergovernmental Health Policy Project, 1995

A second objection is that total costs would rise as more patients are compensated. Advocates argue that costs of the system would be constrained by substantial reductions in administrative and legal expenses, allowing compensation for many more injuries.

Summary.

This Issue Brief has reviewed the key features of the malpractice liability system and the recent efforts to enhance patient safety that focus on the common goal of enhancing health. Although their goals overlap, the two approaches differ in fundamental ways that lead to conflict rather than synergy. Health-related interventions have legal ramifications while legal interventions impact health system function. Malpractice reform is thus both a health and a legal issue. Some of these conflicts may be addressed through malpractice liability law reform such as outlined here.

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