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POLICY FORUM

Medical Malpractice Reform—Historical Approaches, Alternative Models, and Communication and Resolution Programs

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Legal responsibility for medical malpractice is not a new concept, with a history that can be traced back to the Code of Hammurabi in 2030 BCE [1]. Roman law recognized medical malpractice as a legal wrong, and this concept was expanded and introduced to continental Europe around 1200 CE [1]. English common law, from its medieval origins, "provide[s] an unbroken line of medical malpractice decisions, all the way to modern times" [2]. Derived from English common law, United States medical malpractice law—grounded in the legal concept of tort law—has evolved through decades of state and federal court decisions and been modified by legislative intervention [1]. As *Black's Law Dictionary* defines it, "A tort is a legal wrong committed upon the person or property independent of contract" [3]. It is an umbrella concept encompassing myriad categories such as negligence, gross negligence, professional negligence, recklessness, and acts of intentional harm (referred to as intentional torts). Medical malpractice is a form of professional negligence, since professionals discharging their professional duties are expected to act with a higher standard of care than nonprofessionals.

To prevail in a medical malpractice claim against a physician, the injured party (the patient or patient's family) must demonstrate that it was more likely than not (this requirement is known as the "preponderance of the evidence" standard) that the following four elements were present: (1) the physician had a duty to the patient; (2) the physician was negligent in his or her execution of the duty, (i.e., by breaching the standard of care); (3) the physician's negligent action was the proximate cause of the patient's injuries; and (4) the patient's injury resulted in damages, whether economic or other [4]. A breach of a physician's duty to patients can take many forms. For example, injuries may result from misdiagnosis, errors in the choice or technical execution of procedures, improper administration of medications, failure to follow up appropriately with a patient, and failure to obtain adequate informed consent [5]. The standard of care requirement means that the finder of fact, typically the jury, must hear testimony from both sides of the litigation about what the standard of care is and then evaluate that information to decide if the physician breached it, i.e., whether a reasonably prudent physician confronting similar circumstances would not have acted as the defendant physician did.

Studdert, Mello, and Brennan state that "[t]here are three social goals of malpractice litigation: to deter unsafe practices, to compensate persons injured through negligence, and to exact corrective justice" [6]. Thus, patients might reasonably expect medical malpractice law to serve as a deterrent to the improper practice of medicine and to compensate—through a negotiated settlement or a trial—patients who are victims of physician negligence. However, only a small number of harmed patients receive compensation, and a large number of compensated patients appear not to be victims of actual negligence [7, 8]. As Kessler [9] asserts, "[w]hile it is more difficult to assess the extent to which the malpractice system has provided incentives for appropriate care, a variety of evidence suggests that it has not" [10].

A significant literature suggests that physicians believe that pressure to avoid malpractice litigation <u>leads to</u> "defensive medicine" [9, 11]. Defensive medicine is medical practice performed primarily to limit future risk of a successful lawsuit against the physician and only secondarily to adhere to the medical standard of care. Defensive medicine can lead to a broad set of consequences: providing care that is "unproductive, not cost effective, or even harmful" or "declining to supply care that could be beneficial" [10]. Additionally, defensive medicine can also inflict moral harm on the physician and damage the patient-physician relationship. Defensive medicine is problematic ethically because it moves the focus of medical care away from the best interests of the patient toward the best interests of the physician. The ethical consequences of this change in focus are considerable. As Rentmeester and George write,

when a practitioner orients herself to a patient defensively, for example, the scope of her moral perception narrows and she draws her concern away from her patient toward herself. This kind of physician-centered practice suggests a physician's narrowed moral outlook toward her patients: what constitutes a reason to respond with care to a patient is defined narrowly (instead of broadly), exclusively (instead of inclusively), and meagerly (instead of generously) [12].

Studies measuring the effect of malpractice pressure on malpractice premiums, claims frequency, or claims severity tend to find evidence of defensive, unproductive care [7, 13, 14]. The costs of defensive medicine to the health care system, which a Cleveland Clinic study estimated to be \$6 billion—in addition to the economic and noneconomic costs of malpractice litigation itself—have driven advocacy for malpractice reform [15]. Furthermore, it appears that medical malpractice tort reform does have a positive impact on the health care bottom line. For example, the Congressional Budget Office concluded in 2009 that "the weight of the empirical evidence now demonstrates a link between tort reform and the use of healthcare services" [16].

This article examines this country's historical approach to medical malpractice, traditional reform models, proposals based on alternative models, and the role of mediation and ethics consultation in medical malpractice cases.

Background: Malpractice Reform Attempts

In the United States, medical malpractice claims began to appear in the 1800s [17], but it was not until the 1960s that a surge of medical malpractice claims appeared in the courts [18]. This surge was likely driven by a number of factors: new and more complex treatments with higher risks of iatrogenic harm, a changing legal landscape that removed barriers to lawsuits and changed liability rules that had previously shielded charitable institutions from suit, and changes in satisfaction with the health care system, among others [19]. The rising incidence and costs of malpractice litigation led organized medicine to lobby for state and federal interventions to curb the burdens of the current malpractice liability system [9].

Medical malpractice reform is the product of political processes, whereby groups with different interests attempt to push their agendas. Physicians and physician organizations have tended to view most medical malpractice claims as spurious and injurious to the medical system, whereas patient advocates view the malpractice system as both a deterrent against the practice of dangerous medicine and an avenue for much-deserved compensation for injured patients [9].

In 2011, the National Conference of State Legislatures (NCSL) compiled an analysis of medical malpractice reform goals and initiatives [20]. The NCSL sought to address the challenges of cost containment while acknowledging that medical malpractice reform (i.e., tort reform) needs to address three major areas: limiting the costs associated with medical malpractice, deterring medical errors, and ensuring fair compensation for patients who are harmed [20].

Traditionally, reforms have attempted to change the medical malpractice climate in one of three ways: (1) allowing fewer lawsuits by creating barriers to filing, such as a prefiling certification or review of the medical merits of the case [20]; (2) limiting plaintiffs' compensation by imposing damage caps for noneconomic damages such as pain and suffering [21]; or (3) changing how awards are paid out to plaintiffs (payments over time versus large lump-sum settlements) [22]. Caps on noneconomic damages are the most common types of reforms and have been implemented in over half the states in various forms [23].

Hyman and colleagues used claim-level data to estimate the effect of Texas's 2003 cap on noneconomic damages on jury verdicts, post-verdict payouts, and settlements in medical malpractice cases closed during 1988-2004. The investigators found that the cap affected 47 percent of verdicts favoring plaintiffs and reduced mean allowed

noneconomic damages by 73 percent and mean total payout by 27 percent. The noneconomic damages cap affected 18 percent of cases settled without trial and reduced predicted mean total payout by 18 percent [24]. In addition to affecting indemnity payments, it appears that damage caps also modestly reduce the rise in malpractice insurance premiums [25].

Although malpractice reform in the form of caps on noneconomic damages may reduce the actual payouts to plaintiffs, the broader impact of these reforms on reducing defensive medicine is less clear. Waxman and colleagues attempted to gauge the impact of these reforms on emergency department care in three states with malpractice reform—Texas, South Carolina, and Georgia—as compared to neighboring states without reforms [26]. Using a 5 percent random sample of Medicare fee-for-service beneficiaries, the investigators identified all emergency department visits to hospitals in the three reform states and in neighboring (control) states from 1997 through 2011. They examined pre- and post-reform changes in the use of computed tomography or magnetic resonance imaging, per-visit emergency department charges, and the rate of hospital admissions and they did not find any policy-attributable reduction in care intensity: no significant reduction in the rates of CT or MRI utilization or hospital admission in any of the three reform states and no significant reduction in charges in Texas or South Carolina was found. Georgia, however, did see a modest 3.6 percent reduction in per-visit emergency department charges [26].

Alternative Dispute Resolution Methods

While traditional malpractice reform efforts could reduce the number and success of malpractice lawsuits in some states, they do little to help patients injured by physician negligence obtain what research suggests they truly desire: (1) an account of why the harm occurred; (2) an apology from the health care professionals involved; (3) information about how similar harms can be avoided in the future; and (4) appropriate restitution for an avoidable harm [27].

Society as a whole has an interest in cultivating a medical system in which medical practitioners do not practice defensive medicine but rather engage in process improvement at both the individual level and the system level. Therefore, to be effective, medical malpractice reform must balance the needs of all parties. The health care system must promote a culture of open communication between clinicians and patients that persists even after a patient has experienced a negative outcome (regardless of who or what is to blame), allows for robust process improvement, and offers compensation to injured parties. A possible beneficial effect of such a culture may be that patients trust their physicians when physicians truthfully explain that a poor outcome was due to the natural history of disease rather than the negligent practice of medicine. Such a system would be adversarial only as a last resort, and even under those circumstances it should

build on mediation-based models such as communication and resolution programs, discussed in more detail below.

A 2013 study estimated that between 210,000 to 400,000 people die annually in the US due to medical error [28]. Ethically, a reformed medical malpractice system must address the fact that medical errors do injure patients and are at play in a significant number of malpractice cases. For example, Studdert and colleagues analyzed 1,452 closed malpractice claims from five liability insurers and concluded that 63 percent of the claims did, in fact, involve injuries due to medical error [29].

Alternative dispute resolution (ADR) models, which allow physicians and the health systems in which they operate to acknowledge openly when errors have occurred and offer reasonable compensation to the injured parties, balance the needs of clinicians—to act ethically by being truthful and engaging in vigorous quality improvement—and of patients—to receive compensation for negligence-induced iatrogenic harm. Alternative dispute resolution allows litigants to move out of a "battle" mentality and into a facilitated conversation to achieve resolution of the conflict.

Alternative dispute resolution typically includes either mediation or arbitration. These two approaches are quite different, but both can be quite effective in resolving disputes in a less adversarial and less costly manner than traditional litigation [30]. A number of health care institutions have experimented with a unique twist on ADR by developing communication and resolution programs (CRPs), novel approaches to addressing medical error that have paid off in terms of the costs associated with malpractice litigation [31-34]. These programs encourage open communication and transparency with patients and their families and facilitate restitution for injured parties when appropriate. They also support physicians in disclosure conversations with patients.

The Lexington, Kentucky, Veterans Affairs (VA) Medical Center was a pioneer in this area. In 1987, the Lexington VA implemented its CRP, which provided a full disclosure of the occurrence that led to harm as well as an expression of regret on behalf of the institution and its personnel [33]. Under this system, patients and their families are invited to bring attorneys to discuss offers of compensation early in the process. Although ADR in a health care situation likely provides a number of benefits to both the health care provider (by promoting honesty and ethical behavior) and to the patient and patient's family (by providing an honest accounting of what happened, including a statement of regret and possibly an offer of compensation), the empirical literature discussing ADR typically emphasizes quantitative, economic measures in the form of payouts as a measure of success. With the implementation of this program, the Lexington VA became the VA hospital with the lowest payouts. Between 1990 and 1996, the average settlement per claim in Lexington was approximately \$15,622 [33], whereas in other VA institutions it

was \$98,000. Additionally, the average duration of cases decreased from 2-4 years to 2-4 months [35].

CRPs also exist outside the VA system and come in two varieties: early settlement and limited reimbursement [36]. The University of Michigan Health System (UMHS) was the first non-VA health system to adopt a CRP, implementing an early settlement model in 2001. UMHS self-insures [37]; all its physicians are employed and insured by the university rather than by commercial malpractice carriers, thereby simplifying buy-in to the CRP. This model has four components: (1) acknowledging when patients are injured due to medical error; (2) compensating fairly (commensurate with degree of harm) and quickly when there is a deviation from the standard of care; (3) aggressively defending against meritless cases; and (4) studying all adverse events to determine how health care delivery can be improved. Because the payments are made on behalf of the institution only, they are not reported to the National Practitioner Data Bank (NPDB) [36]. This operational detail is significant because the NPDB, which was created by Congress, "contains information on medical malpractice payments and certain adverse actions related to health care practitioners, entities, providers, and suppliers" [38]. It is publically available information that may affect a physician's reputation and follows a physician throughout his or her career. By not reporting this information to the NPDB, UMHS reduces an important barrier to physician participation in this CRP.

In a retrospective chart review of UMHS claims reported in the eight years before and the five years after full implementation of the CRP in 2003, investigators compared the number of new claims for compensation, the number of claims compensated, the time to claim resolution, and claims-related costs from 1995-2007 [31]. After full implementation of the CRP, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100,000 patient encounters, the average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters, and the median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Moreover, the average monthly cost rates decreased by at least 50 percent for total liability, patient compensation, and noncompensation-related legal cost [31].

The model employed by COPIC Insurance Company, a large medical liability insurer in Colorado, is an example of a limited-reimbursement model, the second type of CRP. In 2000 COPIC developed its 3Rs program—Recognize, Respond, and Resolve—to address situations in which their enrollees' patients were unsatisfied with their health outcomes [32, 39]. When patients suffer adverse outcomes they receive a disclosure of what occurred and compensation for out-of-pocket expenses not covered by insurance (up to \$25,000) and for lost time (up to \$5,000). Disclosure and compensation occur without a determination of physician fault. Patients retain the right to sue, and payments are not reportable to the NPDB. Physician participation is voluntary, and participating physicians undergo disclosure training. Exclusion criteria include death, clear negligence, attorney

involvement, a complaint to the state board, and a written demand for payment. From October 2000 to October 2007, there were 4,800 qualified events, with 1,026 patients receiving payments averaging \$5,286. Seven paid cases were litigated, and only two resulted in tort compensation. Sixteen unpaid cases were litigated, and six resulted in tort compensation. Anecdotal evidence and survey data suggest to the COPIC leadership that the system is successful. The majority of physicians and patients find the system effective and only a small fraction of cases that go through the 3R system evolve into litigated and compensated claims. Because of the open disclosure and compensation, the animosity between the injured patient and the physician appears to be reduced, and many patients maintain their therapeutic relationship with their physician [32].

Facilitating CRPs: Apology Laws

CRPs are one innovative approach to medical malpractice reform that address both patient and institutional needs. CRPs require, however, a culture shift in the medical community and a management of expectations on the part of injured patients who may be anticipating larger payouts than they are offered in this type of system. CRPs also require a favorable legal environment; they work best if "apology laws" explicitly protect clinicians and health institutions from penalty for discussing adverse events openly and honestly with patients and their families. Currently, apology and disclosure laws in the majority of states do not go far enough in fostering open communication after a medical error has occurred.

A 2010 study of state apology laws found that the laws of 34 states and the District of Columbia were not written in ways that foster open and honest communication between the physician and the injured party [40]. Of these jurisdictions, 25 states and the District of Columbia had "sympathy only" laws. This type of law prevents an expression of sympathy (e.g., "I'm sorry") from being entered into evidence as proof of malpractice. However, an explanation of the cause of the error and admission by the person at fault *could* be used at trial as evidence of malpractice. Only six states have laws protecting expressions both of sympathy and of fault; only three protect expressions of sympathy and an explanation of why the error occurred [40]. Furthermore, only nine states even require physicians to disclose an error to the patient, although hospital accrediting bodies such as the Joint Commission do in general terms require disclosure to patients. The Joint Commission Standard RI.2.90 states: "Patients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes" [41].

The interplay between CRPs and a given state's legal landscape surrounding malpractice reform (e.g., damage caps) and evidentiary standards (e.g., apology laws and protection of peer review), is complex and a full discussion of the many ways in which individual state laws affect CRP implementation is beyond the scope of this article. However, in general terms, certain state laws are believed to threaten CRP implementation. Sage and

colleagues aver, "Consequently, changes to malpractice law and procedure might play a useful role in convincing providers and insurers to adopt CRPs.... Lack of motivation is a greater risk in states such as Texas and Washington that have less malpractice litigation; risk aversion is a bigger problem in states with more and more costly litigation, such as New York, Alabama, and Illinois" [42]. CRPs provide a system for physicians to discharge their ethical obligation to communicate honestly with patients. Even outside the context of a CRP, physicians should understand that patients are less likely to sue when they believe they have been dealt with honestly. Furthermore, attorneys, as a practical matter, rarely introduce apology-related information as evidence during trial because doing so contradicts the narrative of the physician as uncaring. However, these trends are not absolutes, and limited evidentiary protection of physician disclosure likely stymies open and honest conversation (thereby necessitating the development of CRPs) [42].

While CRPs require buy-in from an entire health system, a grass roots effort to encourage open communication after an adverse event began in 2005, inspired by the Lexington, Ky, VA approach. This advocacy organization, called Sorry Works!, aims

to encourage physicians, hospitals, and insurers to think differently about the medical malpractice crisis... [and] want[s] healthcare, insurance, and legal professionals to realize the solution was in their hands (as opposed to a legislature) by simply developing disclosure and apology programs that pro-actively heal everyone injured by an adverse event [43].

Sorry Works! has developed commercially available toolkits to train health professionals about disclosure. However, buy-in from the medical community is still a challenge outside an organized CRP. For example, in 2015 Medscape polled 4,000 physicians, including oncologists, about their experience with medical malpractice lawsuits, asking them if apologizing "would have helped avoid or mitigate a malpractice claim" [44]. Only 2 percent of male physicians and no female physicians reported feeling that an apology would have helped. However, the survey did not ask about experiences with disclosure and apology training [44].

Although most medical malpractice litigation takes place in the context of state law, the federal government's desire to expand alternative approaches to traditional litigation in medical malpractice cases is expressly delineated in the Affordable Care Act (ACA), section 280g-15(a): "The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations" [45]. The Agency for Healthcare Research and Quality (AHRQ) awarded a number of demonstration grants to institutions [46], which implemented novel ways of dealing with physician malpractice [29]. To date, the effects

of these novel approaches is unknown, and little has changed in the realm of medical malpractice under the ACA. However, the focus of many AHRQ demonstration grants is the development of CRPs.

Conclusion

Transparency and open communication with patients and families about medical errors allow medical practitioners to fulfill their ethical obligations to their patients even when outcomes are poor. These ethical obligations are grounded in the principles of autonomy, beneficence, and nonmaleficence and the virtues of compassion, courage, and honesty. Alternative dispute resolution models mitigate stress on clinicians, de-emphasize tendencies of health systems to try to hide fault, and help avoid dragging clinicians, patients, and others through time-consuming, costly, and reputation-damaging litigation. They can also mitigate the stress on patients and allow injured parties to receive reasonable compensation in a reasonable timeframe without the emotional and financial toll of the arduous litigation process. Creating a cultural, legal, and economic environment where communication and resolution programs can thrive may be an effective approach to creating a win-win situation for patients, physicians, and therefore society as a whole.

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