

## Patient Safety and Medical Malpractice: A Case Study

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The system of tort liability for medical malpractice is frequently criticized for poorly performing its theoretical functions of compensating injured patients, deterring negligence, and dispensing corrective justice. Working from an actual malpractice case involving serious injury but no apparent negligence, the authors explore these criticisms from the perspectives of both the plaintiff-patient and the defendant-physician. They then examine the tort system through the lens of patient safety and conclude that the tensions between the system and patient safety initiatives suggest a need

to reexamine our attachment to adversarial dispute resolution in health care. They propose targeted reforms that could improve the functioning of the system and create incentives to improve safety and quality.

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For a list of questions and answers from the Quality Grand Rounds conference, see the Appendix, available at www.annals.org.

*"Quality Grand Rounds" is a series of articles and companion conferences designed to explore a range of quality issues and medical errors. Presenting actual cases drawn from institutions around the United States, the articles integrate traditional medical case histories with results of root-cause analyses and, where appropriate, anonymous interviews with the involved patients, physicians, nurses, and risk managers. Cases do not come from the discussants' home institutions.*

*The physician, Dr. Harris, was interviewed by a Quality Grand Rounds editor on 16 August 2002. The physician's defense attorney, Mr. Dean, was interviewed by a Quality Grand Rounds editor on 14 August 2002. All names are pseudonyms.*

### SUMMARY OF EVENTS

*Mrs. Taylor (a pseudonym), a 52-year-old woman with severe pneumonia and impending respiratory failure, was evaluated on the medical ward of a community hospital by Dr. Harris, an internist. Dr. Harris chose to immediately transfer her to the intensive care unit (ICU) for urgent intubation by a critical care specialist. During intubation, Mrs. Taylor had a cardiac arrest, which resulted in permanent brain damage. Dr. Harris was sued for malpractice.*

### THE CASE

*Mrs. Taylor had a 3-day history of progressive fevers, nausea, and vomiting. She presented to the emergency department at 2:30 a.m., where she appeared to be moderately ill and dyspneic. Her initial temperature was 38.3 °C, her blood pressure was 112/70 mm Hg, her heart rate was 118 beats/min, and her respiratory rate was 26 breaths/min. Her oxygen saturation was 92% on room air. The examination was remarkable for crackles at her right lung base. The examination of her cardiac, abdominal, and neurologic systems was unremarkable. Laboratory studies showed a leukocyte count of  $14 \times 10^9$  cells/L with a left shift, a creatinine level of 1.3 mg/dL (114.9  $\mu$ mol/L), and a sodium level of 129 mmol/L. A chest radiograph showed a dense right lower lobe infiltrate.*

*Bacterial pneumonia was diagnosed. The patient began receiving levofloxacin, metronidazole, and oxygen and was admitted to the medical ward of the hospital. A pulmonologist was consulted by telephone about the initial treatment choices.*

*At 7:45 a.m., a nurse found Mrs. Taylor profoundly dyspneic and diaphoretic. Her oxygen saturation had fallen to 69% on 2 L. The patient was immediately placed on a non-rebreather mask at 15 L/min, which increased the oxygen saturation to 91%. Dr. Harris, who had assumed Mrs. Taylor's care that morning, was paged and arrived within minutes.*

*Dr. Harris found the patient in marked respiratory distress. She had a temperature of 37.6 °C, a blood pressure of 140/88 mm Hg, a heart rate of 140 beats/min, and a respiratory rate of 50 breaths/min. On examination, she had diffuse rhonchi, as well as crackles, throughout the right lung field. The rest of the examination was unremarkable. An arterial blood gas showed a pH of 7.41, a  $PCO_2$  of 29, and a  $PO_2$  of 63 (on the nonrebreather mask). Portable chest radiography showed a worsening of the right lung infiltrate.*

*Dr. Harris diagnosed progressing pneumonia and impending respiratory failure. She considered intubating the patient herself on the floor but opted to immediately transfer Mrs. Taylor to the care of a pulmonologist and intensivist who was standing by in the ICU, for probable intubation and mechanical ventilation.*

*Dr. Harris:* In my mind, it was a matter of what would be safest. I really don't have a lot of experience with awake intubation, and I knew that a pulmonologist was already involved in the case, so it was a really easy decision from my standpoint to get . . . the patient transferred to the ICU for intubation.

*Dr. Harris first saw the patient at 7:57 a.m. and completed her evaluation by 8:20 a.m. It took a few minutes for the logistics to be organized and for Mrs. Taylor to be physically transported. She arrived in the ICU at 8:37 a.m. By this*

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time, her respiratory distress was more pronounced and she had become delirious. Her blood pressure was 142/65 mm Hg, her heart rate was 145 beats/min, her respiratory rate was 38 breaths/min, and oxygen saturation on the nonrebreather mask was 64%.

The pulmonologist preoxygenated Mrs. Taylor with a bag-valve-mask apparatus, administered a dose of midazolam, and attempted intubation at 8:45 a.m. Unfortunately, the attempt was complicated by ventricular fibrillation and a cardiac arrest. The physicians and nurses resumed bag-valve-mask oxygenation, and the oxygenation saturation, which had fallen to the mid-30s, rose to the 80s. Standard cardiopulmonary resuscitation was performed, including 2 to 3 minutes of chest compression, accompanied by boluses of atropine and epinephrine. The patient was defibrillated with 200 J and intubated successfully on the second attempt at 8:49 a.m. Arterial blood gas values after intubation were a pH of 7.09, a  $PCO_2$  of 72, and a  $PO_2$  of 39 on 100%  $F_{iO_2}$ .

The patient's oxygenation ultimately improved and her cardiopulmonary status stabilized, but she suffered profound and presumably irreversible brain damage. At the time of discharge, she could not recognize family members or independently perform any activities of daily living. Although the case was informally discussed among the providers involved, it was not forwarded to or reviewed by the hospital's risk management committee. The patient was discharged to a long-term care facility for total custodial care. Several months after discharge, the patient's family sought legal counsel and decided to pursue a malpractice claim. About 20 months later, Dr. Harris received notice that she had been named in Mrs. Taylor's malpractice case.

*Dr. Harris:* I was sitting in the ICU and my partner calls me up and says, "You're getting sued, and that's why I'm leaving medicine."

## ANATOMY OF A MALPRACTICE CLAIM

The lawsuit filed against Dr. Harris illustrates a conventional tort claim for medical malpractice against a physician. To recover damages, Mrs. Taylor must prove 1) that the relationship between Dr. Harris and her gave rise to a duty, 2) that Dr. Harris was negligent—her care fell below the standard expected of a reasonable medical practitioner, 3) that Mrs. Taylor suffered an injury that was 4) caused by Dr. Harris's negligence (1). The claim is seemingly that Dr. Harris did not move quickly enough to seek critical care attention for Mrs. Taylor and that the delay caused the cardiac arrest and subsequent brain damage.

We use this case to plumb the broader policy perspectives of malpractice and its effect on patient safety and deterrence of errors. Because some aspects of the litigation are still pending, we could not obtain comments from the plaintiff's attorney; however, we contribute our own thoughts about the plaintiff's likely view of the case.

## WHY SUE DR. HARRIS? THE PERSPECTIVE OF THE PLAINTIFF'S ATTORNEY

From the plaintiff's perspective, there are three reasons to sue the physician for malpractice. First, filing a lawsuit is a way to secure compensation for the injury (2). Mrs. Taylor no doubt has some uninsured costs associated with this injury; for example, it is highly unlikely that her health and disability insurance will provide coverage for years of rehabilitation or custodial care (3), compensate her family for the loss of her household services, and recompense Mrs. Taylor's and her family's suffering.

Second, suing Dr. Harris may provide a sense of corrective justice (4). An injured party is "made whole" through restitution from the injurer. Provoking feelings of remorse, shame, and guilt in the defendant is an integral part of this corrective justice.

Finally, tort litigation is meant to have a deterrence function (5). By forcing the negligent party to pay a penalty, the system creates an economic incentive to take greater precautions in the future. Presumably, being sued will cause Dr. Harris to approach acutely dyspneic patients differently in the future.

Presented as such, the tort system has theoretical appeal. It should supplement other methods of quality regulation through its deterrence function (Mello MM, Brennan TA. Regulating health care quality: the case of patient safety. Commissioned paper for the Agency for Healthcare Research and Quality; 2002). It is essentially a cost-free form of regulation for taxpayers because the regulatory vigor is provided by market incentives that direct plaintiffs' attorneys to select and bring cases. Attorneys weigh the costs of bringing a case (investigating the claim, hiring experts, and going to trial) against their expected compensation (usually a percentage of the award made to the plaintiff, referred to as a "contingency fee") (6).

This attractive theoretical account of tort law's social role is challenged, however, by the available empirical evidence about how medical malpractice law actually operates. Tort law performs its compensation function relatively poorly because most patients injured by negligence do not bring malpractice claims (7–9). In addition, the system has very high administrative costs—up to 60%, as compared with 5% to 30% for most other social compensation schemes (10) (Table). For example, workers' compensation is estimated to have administrative costs of 20% to 30% and the Social Security Disability Insurance system has costs in the 5% range. The differences are stark: For a \$400 000 malpractice award, another \$200 000 is spent on administrative costs, primarily in attorneys' fees. In contrast, a Workers' Compensation award of \$400 000 requires only about \$100 000 in administrative costs. With respect to corrective justice, the malpractice system does induce negative emotions in sued physicians (11), but it rarely inspires genuine remorse or feelings that justice has been done. Rather, most defendants find little merit in the

suits brought against them and feel that they are the victims of a random event (12, 13).

The deterrence function of malpractice litigation also seems unavailing (14). Studies of the relationship between lawsuits and subsequent quality of care have largely centered on obstetrics. Most studies have failed to correlate variations in care patterns or birth outcomes with the obstetrician's history of malpractice claims (15–18). The single broad study of hospital adverse events reported limited evidence that a greater number and severity of malpractice claims was associated with improvement in medical injury rates (12). Even defensive-medicine effects, that is, promoting higher-than-optimal levels of taking precautions, have not been conclusively reported (14, 19). Anecdotal evidence suggests that in periods of “tort crisis,” fear of being sued and the unaffordability or unavailability of liability insurance may have a different deterrent effect: It may deter physicians from remaining in practice or continuing to perform high-risk services (20, 21). Such effects, if they become widespread, affect patient access to care. Thus, much of the plaintiff's view of malpractice litigation is controversial.

### IS THE LAWSUIT FAIR? THE PERSPECTIVE OF THE DEFENSE ATTORNEY

From the facts of Mrs. Taylor's case, most readers probably have concluded that there is little evidence of negligence on the part of Dr. Harris. Within 40 minutes of the evaluation, Dr. Harris had moved Mrs. Taylor to the care of an expert in the ICU. Since this action plan was within the standard of care expected of a reasonable practitioner, the malpractice suit seems unfair.

The sense of unfairness is compounded by the fact that the lawsuit blames the individual physician. This event clearly occurred in several layers of the system: the nursing monitoring of the patient's condition; the schedule of attending coverage, as Dr. Harris “picks up” the care in the morning from another physician; the emergency response and admission to the ICU; and the issue of emergency intubation “on the floor.” It seems unreasonable to blame Dr. Harris, given the possible contributory role of these systemic factors.

Plaintiffs' attorneys routinely sue several individuals, as well as the hospital. They may not believe that all individuals are liable, but they hope that some will offer at least a small settlement to avoid the nuisance aspects of the suit and the risk for a larger jury award. These settlements enable the plaintiff's attorney to fund further litigation against other defendants in the suit.

Mr. Dean, the defense attorney, is savvy about the respective roles of patient injury and negligence in initiating and settling a malpractice claim:

*Mr. Dean:* In a case like this, involving a patient who was already in the hospital, who has an arrest

**Table. Comparison of Tort and Administrative Compensation Schemes**

Function	Tort Liability System	Administrative Schemes
<b>Compensation</b>		
Administrative costs	40%–60% of total costs	5%–30% of total costs
Accuracy	Many false-positive results and false-negative results	Fewer false-positive results and false-negative results because there is no need to prove negligence
Ability to scale damages costs up or down	Dependent on local factors, such as supply of plaintiffs' attorneys, tort reform, and jury propensity to make large damages awards	Readily adjustable by using eligibility criteria
<b>Deterrence</b>		
Public nature	All efforts made to hide fact of litigation, underlying adverse events, and litigation outcomes	Lack of emphasis on fault allows for more open approach
Reporting potential	Physicians fearful of reporting to patients and reporting facilities	Physicians reporting to patients integral to system—no fear of individual litigation
Experience rating	Not actuarially possible because of an insufficient number of suits against individual providers	Usually operates on an enterprise liability basis, enabling experience rating
<b>Corrective justice</b>	Present, but leads to provider animus toward system	Not a punishment-based system, so no traditional corrective justice

and anoxic encephalopathy, one of the very significant perceptual issues we have to consider . . . is the fact that there was a catastrophic outcome, and to some jurors, catastrophic outcomes may equate with “somebody must have messed up.”

Mr. Dean makes the important point that the degree of injury is critical to the outcome of the case. His contention is supported by empirical evidence from the Harvard Medical Practice Study, which examined rates of hospital adverse events, negligence, and malpractice claims in New York (7, 22). Negligence was determined by physician reviewers unaffiliated with the sued providers' insurance companies. The investigators followed the malpractice claims for 10 years and determined that the only statistically significant predictor of a payout to the plaintiff was the plaintiff's degree of disability—not the presence of negligence (23). Other studies have suggested that negligence does influence the size of settlements (24, 25), but these analyses have been based on insurance claims adjusters' determinations of negligence rather than independent judgments. If the main factor determining compensation is injury severity or disability even in a system that ostensibly revolves around a negligence determination, then one must ask why we cling to the tort model of compensation for medical injury.

**THE CASE, CONTINUED . . .**

*After a long pretrial period of fact-finding (“discovery”), expert witness reviews, and depositions, Mr. Dean felt that his client’s case was very strong. However, Mrs. Taylor’s horrendous adverse outcome and concerns (unrelated to Dr. Harris’s care) about her care by the hospital and other providers led Mr. Dean to recommend that Dr. Harris offer to settle the case for a relatively small amount of money.*

In explaining the decision to settle, Mr. Dean weighed three factors. First, if a jury found his client negligent, what would the plaintiff’s damages probably amount to, both in economic and noneconomic (“pain and suffering”) terms? Second, how likely is a jury to find in favor of the physician? Third, what is his gut instinct about the case’s worth? His judgment incorporates subjective factors, such as the likely composition and liberality of the jury in a given venue and sympathetic or unsympathetic characteristics of the plaintiff, her injury, and her circumstances.

*Mr. Dean:* The concern was that the jury could be so overwhelmed with sympathy for what occurred to the patient and the patient’s family that they would feel it would be impossible to say no. . . . Even if you are assessed a very small percentage of responsibility by the jury, given the huge potential damage exposure . . . it could potentially represent a judgment . . . in excess of your malpractice coverage. Mrs. Taylor and her family could come after the physician and force her into bankruptcy, resulting in financial ruin for Dr. Harris.

One would not blame Dr. Harris for feeling that the outcome of her case is unfair. Yet it is perfectly in accord with empirical research on litigation outcomes and with attorneys’ strategic decisions as they function within an imperfect tort system. For Dr. Harris, settlement is the most rational choice in a system that could produce an utterly calamitous outcome.

**THE PERSPECTIVE OF PATIENT SAFETY REFORMERS**

Those persons directly involved in this litigation—Dr. Harris, Mrs. Taylor, and their families and attorneys—feel the greatest effect of the malpractice system’s shortcomings. However, these failings also have strong implications for the nascent patient safety movement.

The traditional rule in the common law is that all available probative evidence (evidence that proves a fact) should be admitted to the court for consideration (26). But legislators have long recognized that peer reviewers would be chilled if they knew that their review would be available to a plaintiff and to his or her attorney; thus, they have granted a privilege of nondiscoverability to peer review information, which courts generally have enforced (27).

The breadth of the privilege varies from state to state (28), but generally, hospitals must confine discussions

about adverse events to small committees of insiders to retain the privilege. The need to minimize legal exposure leads them to eschew more public debate about quality issues. In the Harris case, it seems that it would have been beneficial for the hospital and staff to have openly evaluated issues of seamless cross-coverage, protocols for emergent intubation on the floor, and timely transfer to the ICU. Unfortunately, it appears that nothing of this sort occurred.

*Dr. Harris:* From a hospital standpoint, to my knowledge, it was never discussed with any of the physicians. It never came up. I guess the things that come to mind are . . . intensive care unit transfers and code blue situations . . . but if they changed things in regards to this case, that would be news to me. . . . I don’t really know the risk management people. . . . I know they exist, but who they are and their role and function in a situation like this or day to day, despite the fact that I spend up to 120 hours in the hospital, is just not discussed and I’ve never met them face to face.

The hospital cannot necessarily be blamed for failing to follow up. Perhaps the hospital concluded after an initial evaluation that there were few grounds for quality improvement. More likely, the hospital realized the extent of the resources necessary to complete a formal peer review process and decided it was not worth the effort. But Dr. Harris’s ignorance of the formal mechanics of peer review at her hospital, and its essentially hidden nature, demonstrate the tension between error prevention or quality improvement and medical malpractice. Fear of litigation either stifles injury reduction efforts or drives efforts underground.

**MALPRACTICE AND PATIENT SAFETY TRENDS**

The Institute of Medicine’s report on medical errors (29) has fomented a critical change in attitude about patient safety activism. Many risk management offices (a euphemism that obscures whether the “risk” is for a medical injury or for a successful malpractice claim) are now becoming patient safety offices or are partnering with newly created, separate patient safety offices. The use of careful root-cause analysis is becoming prevalent at the departmental level in many institutions (30). Yet malpractice fears continue to retard these salutary efforts, and many hospitals still approach error-related injuries the way Dr. Harris’s hospital did.

These apprehensions not only chill educational discussion but also exert profound pressure against initiatives to disclose adverse events to both patients and governmental reporting systems. We (31) and others (32) have long advocated greater transparency about medical errors. Codes of professional ethics, as well as the new patient safety

standards promulgated by the Joint Commission on Accreditation of Healthcare Organizations (33), support an obligation of disclosure to patients. The enormous potential for learning about errors through epidemiologic analysis argues persuasively for reporting to centralized data collection systems.

However, providers reasonably fear that greater transparency will tremendously increase the number of successful malpractice claims, with concomitant increases in malpractice premiums and decreases in the availability of insurance. Advocates of reporting counter that honesty may actually decrease physicians' malpractice risk (34): Physicians who have poor relationships with patients are the ones who get sued, and what patients really want is to be dealt with forthrightly (35, 36). The sole piece of published evidence on this issue is methodologically weak and comes from the Veterans Administration system, in which the physicians cannot be sued and institutional liability is limited (37). Researchers have yet to disprove providers' suppositions that greater disclosure will lead to more requests for compensation.

Legislation to protect centralized error reporting from legal discovery can help, but not all states have adopted such protections (38). Even in states that guarantee confidentiality, the continued public and media attention to medical errors—which provides valuable impetus and momentum for patient safety initiatives—may make injured patients more disposed to file claims.

## A NEW PARADIGM

The tensions between the tort system and patient safety demand that we reexamine our attachment to adversarial dispute resolution in health care. The options boil down to three paths. First, we can maintain the status quo and simultaneously push the safety agenda harder. It is possible that appeals to physicians' ethical commitments to patient welfare (39) and the demonstrated successes of industry-based models of systemic quality improvement may gradually yield buy-in to safety initiatives. We have our doubts, however. The conflicts between the tort system and error reduction programs are fundamental and severe, and physicians' concerns about being sued and losing their liability insurance have reached a fever pitch. Appeals to professionalism may ring hollow with physicians operating under a siege mentality.

A second option is to take legislative steps to curb the frequency and economic effect of malpractice litigation. During past "tort crises," providers successfully lobbied state legislatures to change litigation rules to make them less favorable to plaintiffs (40). Tort reform aims to decrease the expected value of a case for plaintiffs' attorneys, changing the calculus about when it is worthwhile to bring a claim. Among the most efficacious reforms are caps on noneconomic damages; changes in the amount that attorneys may take as contingency fees; reductions in the length

of time that injured patients have to bring a claim; and elimination of the "collateral source rule," which allows plaintiffs to recover medical expenses and other costs even if these have been covered by insurance (41–44).

Today we are in the throes of new tort crisis, with claims rates and average payouts rising in many states, especially those that did not institute tort reform in previous crises (45). The concurrence of the tort crisis and the attention to medical errors has not gone unnoticed by insurers. Lobbying for tort reform at both the state and federal levels is under way (47).

The tort reform strategy is problematic, not the least because of its contentiousness. Many state legislatures cannot pass meaningful reform because of the competitive gridlock interposed by health care providers and trial lawyers. Moreover, traditional tort reforms aim to reduce providers' economic exposure, not create a more efficient system. The system's fundamental flaw is not simply that it costs health care providers too much but that it tends to overcompensate some patients while undercompensating others (8, 47). Reform should strive to do more, and we believe a no-fault approach is the answer.

In a no-fault system, the injured patient would only have to demonstrate that a disability was caused by medical management as opposed to the disease process: There is no need to prove negligence. This approach comports better with the patient safety movement. Modern notions of error prevention, emphasizing evidence-based analysis of systems of care (29) and application of technological and structural methods to foster prevention (50), find little value in assessing individual moral blame. No-fault compensation for avoidable injuries is far better suited to support error prevention than a system that revolves around culpability determinations.

We believe that such an approach could produce important incentives for prevention, the so-called deterrent effect, if risk were aggregated in institutions and medical groups. Experience-rating individual physicians' insurance premiums has not been actuarially feasible because physicians are sued too infrequently and their claims experience fluctuates too radically from year to year (14). However, hospitals and integrated medical groups have a more consistent risk profile and their premiums can be experience-rated.

An even better approach may be to set up so-called channeling programs, in which hospitals and their medical staffs are insured by the same entity and all efforts to prevent medical errors are undertaken jointly. Some medical school and academic medical centers already use a channeling approach, and, as links grow between hospitals and integrated medical groups, the potential for a substantial amount of the health care system to operate under channeling approaches increases. In a channeled program, the foundation for greater safety is established by integrating the physician and hospitals or health care centers. The enterprise bears the liability for injury and has incentives to

address prevention of errors in both inpatient and ambulatory settings.

We have also noted that in practice, compensation in the current tort system turns on severity of injury more than negligence—so why maintain a system focused on determining negligence? It is expensive and administratively cumbersome to make these determinations, as it involves an adversarial “battle of the experts.” Moreover, even negligence judgments by financially disinterested expert reviewers are notoriously unreliable (48). In the context of a vigorously adversarial system, the focus on negligence also incites emotion-provoking behavior by litigants. Not only does this leave lasting psychological scars on persons involved, it pollutes what otherwise might be a useful exercise in root-cause analysis leading to quality improvements (49).

Finally, good data suggest that the no-fault approach would be less costly administratively. Similar no-fault programs in Workers’ Compensation and vaccine liability operate at less than half of the costs of tort litigation, largely by minimizing the role of the lawyers. This is where politics will play an important role: Lawyers will fight to maintain the present system.

Elsewhere we have described a limited no-fault approach to medical injury compensation that could work on an elective basis (14). We believe that no-fault compensation can 1) promote greater transparency about adverse events, 2) partner with a hospital-based, experience-rated insurance system that does not remove incentives for error prevention, and 3) lead to more equitable and efficient compensation (Table).

There are people who doubt no-fault proposals; they highlight the historical absence of effective self-policing, the possibility that the present malpractice system has improved safety by promoting vigilance and better documentation, and the uninspiring example of other no-fault systems, such as Workers’ Compensation (51). Mr. Dean’s view of the matter reflects the prevailing uncertainty about its probable outcomes:

*Mr. Dean:* If we reinvent the system and take lawyers completely out of the equation . . . is that going to result in safer medical care? One argument is that if physicians know that their care is not going to be subject to scrutiny . . . that can actually decrease patient safety. On the other hand, I think that a reasonable argument can be made that if a physician or health care provider knows that every judgment is not going to be subjected to intense microscopic scrutiny under the “retrospectoscope,” they are going to be more liberated and free to practice what they see as good medicine, and not be subject to second-guessing at every turn, and that can improve patient safety. It seems to me that until we have some hard data comparing safety in a pure no-

fault system, we are not going to know the answer.

We acknowledge this uncertainty, but believe the proposal is worthy of experimentation.

The Harris case illustrates how difficult it is to move forward with an error prevention agenda in a heated malpractice environment. It is not surprising that providers are reluctant to buy in. Patients deserve innovative approaches that will reduce their chances of being injured by errors and lead to fair compensation if an avoidable injury occurs; providers deserve an environment in which participating in patient safety and compensation initiatives does not put them at risk for financial and professional ruin.

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## APPENDIX

### Questions and Answers from the Conference

*Dr. Robert M. Wachter, Quality Grand Rounds Editor:* Where do you think the locus of action for improving patient safety should be? How would the malpractice system or the no-fault system play into creating incentives for institutions to improve safety?

*Dr. Brennan:* The only place where we find any real evidence of the deterrent effect of malpractice on errors is at the level of the institution. That makes sense because it is very difficult for individual practitioners to institute systematic approaches to reducing the number of medical injuries. In our most recent proposal for a no-fault system, we suggested that individual hospitals could choose to check out of the tort system and into a voluntary, no-fault program. The only places that can do that are those with integrated medical groups, which you find mostly in so-called channeling institutions. That's an insurance company term for a place where a single insurer covers both the doctors and the hospitals. Doctors who see patients in a primary care setting could have them sign a waiver saying that they understand they can't sue because the organization is in a no-fault compensation scheme. What I find attractive about this is that it could afford a competitive advantage in today's environment. We can tell patients that we can compensate them through the administrative system and that the compensation is going to be fair. We also have very strong incentives to report any injury to patients and to the administrative system. The average community hospital is going to have a harder time because physicians are separately insured and separate entities from the point of view of patient safety. From our point of view, the no-fault system creates an environment that encourages reporting, analyzing these reports, and publicizing the results. Many patients are going to find that attractive.

*A physician:* In a no-fault system that has no negligence, who decides what an adverse event is?

*Dr. Brennan:* An adverse event is defined as something that results in a prolongation of hospitalization or disability at the time of discharge, as a result of medical management as opposed to the disease process. That is actually a lot easier to define reliably than is the negligence judgment. What people are being compensated for today is their injury, not the negligence. Trying to identify the negligence is eating up a lot of administrative cost and poisoning the system with the morality play. Determining if an avoidable adverse event occurred would be easier in an administrative compensation scheme and would run similarly to the way things are adjudicated by insurance companies today, with expert testimony and decision-making along those lines. I am fairly confident that the system would work.

*Dr. Mark Smith, President and Chief Executive Officer, California HealthCare Foundation, and Quality Grand Rounds Editor:* Perhaps as a result of the rise of managed care, much of the most heavily publicized litigation in California has been at the health plan; not targeting physicians or hospitals, but, for instance, about coverage for bone marrow transplantation for breast cancer. Are there implications in a no-fault approach for liability when a health plan declines to cover treatment?

*Dr. Brennan:* Probably not. These cases occur infrequently, and the protections afforded insurance companies, because of the Employee Retirement Income Security Act (ERISA), make them relatively difficult cases to bring. These two factors tend to overwhelm a need for a no-fault approach there.

*A physician:* Under the no-fault program, the physician has a strong incentive to report adverse events to the patients and the hospital. Hopefully we all do that, but in a busy physician's schedule, I would think that they would find it easier not to report.

*Dr. Brennan:* You can build in some penalties for failure to report. Some insurance companies already charge an extra malpractice premium if a claim comes in and you haven't forewarned the insurance company. We would do the same thing in a no-fault program. Although we're trying to avoid a sense of penalty, there nonetheless have to be inducements to report.

*Dr. Wachter:* Informing patients of errors in their care is ethically the right thing to do. Increasingly, people cite evidence that full disclosure also will not increase the risk of a lawsuit. Is this correct?

*Dr. Brennan:* There are no good studies on that point, unfortunately. There are seasoned risk managers who will tell you that a lot of what people get upset about, and bring suits about, is the feeling that someone lied to them. Nonetheless, those same seasoned risk managers are not necessarily in favor of full reporting. The literature that people cite is a 1999 article in the *Annals of Internal Medicine* (37), which observed that at a couple of hospitals in a VA [Veterans Administration] system that promoted reporting errors to patients, claim rates were no higher than in other hospitals. However, there was absolutely no case-mix adjustment, and the VA system is a lot different from other hospital systems. First of all you have the Federal Tort Claims Act, which provides protection from suit, and second, you can't sue the individual doctors. So there is really no evidence right now.

*A physician:* Can you comment from the charts that you've reviewed about the quality of documentation and the role that it plays in the merits of the suit or on the outcome?

*Dr. Brennan:* In general, the quality of documentation is helpful in terms of nailing down whether or not a medical injury occurred or whether or not there was negligence. A few might take from this that if you don't document well, it's going to be more difficult to bring a case against the doctor, but crummy documentation actually plays very poorly in litigation. From the point of view of preventing medical injury, it is probably best to do the documentation.

*Dr. Wachter:* I can't let you leave without talking about the estimate of 44 000 to 98 000 yearly deaths due to medical errors in the Harvard Medical Study practice, which you led. These numbers, more than anything, captured the public's attention when they were touted in the 1999 IOM [Institute of Medicine] report. Yet, you have been circumspect about their accuracy. Could you comment?

*Dr. Brennan:* These are statistical analyses and I think we did them about as well as they can be done. But the reliability of these judgments from a statistical point of view is fairly poor with



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a kappa statistic of 0.4 to 0.5 for adverse events and even lower for negligence. What that means is that one person may say an event is a negligent adverse event, while another would say it's not. The other issue is that the IOM took our state-level data on adverse events and upweighted them to generate national mortality estimates. Whenever you extrapolate from relatively small samples, you have concerns about the statistical precision of the estimates. We always tried to point out the sponginess of these numbers in our public statements, but the IOM made a specific decision to go with them. The IOM performed a very important service in terms of putting patient safety back into the common vernacular of the American medical system and for that we owe

them a debt of gratitude. Although we don't know exactly how many people die from medical errors, there is no doubt that it is at least 50 000 per year in hospitals and many additional outpatients. In the end, the actual number doesn't make much difference. Whatever the numbers, we have a tremendous burden of morbidity and mortality caused by errors and relatively little attention being paid to trying to prevent them.

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