Does legal fear increase the risk of medical error?

Speak Not of Error

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HE UNITED STATES IS CURRENTLY IN THE midst of its third medical malpractice crisis in 30 years. The story is all too familiar: Insurance premiums spike, prompting demoralized doctors to protest that they are unfairly being victimized by "undeserving" claimants, greedy trial lawyers, and spiraling

jury awards. The doctors organize strikes, protests, and "sickouts" to press for such malpractice reforms as limits on non-economic damages and caps on trial lawyers' contingent fees.

Yet, the past has not been prologue in all respects. This time around, physicians are conceding that medical errors and malpractice occur far too often. In a curious twist, they blame the high error rates on the legal system, charging that fear of liability discourages them from reporting errors and prevents them from making health care safer.

Patient safety advocates have made common cause with providers on this issue. The Institute of Medicine's 1999 report *To Err is Human* flatly asserts that "patient safety is hindered through the liability system and the threat of malpractice, which discourage the disclosure of errors. The discoverability of data under legal proceedings encourages silence about errors committed or observed." The charge is repeated and extended in the Institute of Medicine's 2001 report *Crossing the Quality Chasm*, which asserts that "alternative approaches to liability, such as enterprise liability or no-fault compensation, could produce a legal environment more conducive to uncovering and resolving quality problems."

The claim that liability risk discourages error reporting and quality improvements has become conventional wisdom among providers and policymakers—and has found a ready reception among those who view trial lawyers and the tort system with skepticism or disdain. But does legal fear actually encourage

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health care providers to "see no error, hear no error, and speak not of error?" Or are tort reformers and health care providers' claims of legal fear dramatically overstated? And will the most popular tort reform proposals actually address the reporting problems or exacerbate them?

HOW DANGEROUS IS HEALTH CARE?

Health care is substantially more dangerous than it should be. The findings of patient safety researchers speak for themselves:

- "One-fourth of hospital deaths may be preventable." (*JAMA*, 1996)
- "180,000 people may die" every year "partly as a result of iatrogenic injury." (*Annals of Internal Medicine*, 1988)
- "One-third of some hospital procedures may expose patients to risk without improving their health." (*Millbank Quarterly*, 1998)
- "Adverse drug events result in more than 770,000 injuries and deaths each year and cost up to \$5.6 million per hospital." (JAMA, 1997)

Unnecessary surgery kills 12,000 people each year. (JAMA, 2000)

■ 20,000 patients die from infections every year because hospital workers fail to follow proper hand washing procedures. (Centers for Disease Control, 2002)

• "The United States loses more American lives to patient safety incidents every six months than it did in the entire Vietnam War." (HealthGrades Inc., 2004)

Among hospitalized patients, there is an "epidemic of potentially preventable iatrogenic death." (*Indiana Law Review*, 2000)

• Medical error is the eighth-leading, sixth-leading, or third-leading cause of death in the United States, depending on the source.

In all, over a million people are killed or injured annually by medical treatments in the United States, according to Dr. Lucien Leape, a well known patient safety advocate. The errors that cause these harms are neither isolated nor sporadic. To the contrary, as Dr. Mark Chassin wrote in the *Milbank Quarterly*, quality problems in health care are "frighteningly common, often predictable, and frequently preventable." Errors occur because systems for delivering health care are faulty and inefficient.

For the same reason, health care providers frequently omit indicated procedures of known value and frequently perform treatments that are outmoded, unnecessary, or inefficacious. In 2004, the National Center for Quality Assurance reported that the failure to provide needed care resulted in almost \$2 billion in excess medical costs and approximately 66 million potential sick days. Services of dubious value consume hundreds of billions of dollars a year. Treatment variations are enormous as well, with patients in some areas receiving far higher and more expensive levels of care than others of similar age and physical condition who live elsewhere—with no effect on outcomes. The result is that "geography is destiny" as far as the medical treatment one receives is concerned.



Mistakes that occur during hospitalization are only part of the picture. Additional errors occur during home care, primary care, ambulatory care, and nursing home care. Researchers in one study estimated that about 51 million prescriptions filled nationwide contained some type of error, including 3 million mistakes that were potentially harmful. Another study concluded that medical errors and quality problems in outpatient care resulted in "116 million extra physician visits, 77 million extra prescriptions, 17 million emergency department visits, 8 million hospitalizations, 3 million long-term admissions, 199,000 additional deaths, and \$77 billion in extra costs (equivalent to the aggregate cost of care of patients with diabetes)." The total cost of those errors and quality problems is staggering.

HOW WELL DOES THE TORT SYSTEM Handle medical mistakes?

Overall, the liability system does a thoroughly unimpressive job of dealing with health care errors, largely because so few errors generate claims. Consider injuries that happen in hospitals. The *Harvard Medical Practice Study* found that about 1 percent of hospitalized patients are negligently injured, suffering consequences that range from complete recovery in less than a month (46 percent of those negligently injured) to death (25 percent of those negligently injured). With more than 30 million hospitalizations occurring each year, 1 percent is a large number. Yet, the study also found that only 2 percent of patients who were negligently injured filed claims. True, many patients who were not victims of negligence also filed claims, but the second problem is dwarfed by the first; for every invalid claim, seven valid claims go unfiled.

Once cases are filed, the tort system does a pretty good job of sorting the wheat from the chaff. As Professor Tom Baker notes in a forthcoming article, many studies show that payments, settlements, and jury verdicts in malpractice cases correlate strongly with experts' assessments of the quality of care. Still, good is far from perfect. The legal system reaches the "wrong" decision (or, at least, a decision that some reviewers regard as such) a fair part of the time.

The price for this imperfect sorting is high. For every dollar in patient compensation, close to two dollars are thought to be spent on claim-processing costs. Most of this expense is ultimately borne by patients in the form of higher medical fees, but there is a substantial public subsidy as well. Overall, the tort system does a miserable job of compensating victims of medical malpractice—largely because few victims sue, but also because the legal process has extremely high loading costs and a significant error rate.

Of course, compensation is not the only issue; the tort system also seeks to deter negligent treatment. In theory, the tort system imposes economic costs on negligent providers (and only on negligent providers), who respond by modifying their behavior to conform to professional standards. In practice, matters are considerably more complicated. The tort system's deterrent "signal" contains an enormous amount of noise. Because victims of malpractice rarely sue, negligent defendants are under-deterred. Because patients who are not victims of negligence do sue and sometimes obtain compensation, careful providers are over-deterred. Negligent providers also win many cases, adding to the confusion. Whatever signal emerges from this mix of non-adjudications, good adjudications, and bad adjudications is then further muddied by malpractice insurance, which is priced by state and practice specialty and not by claims experience. In practice, the tort system seems to impose similar amounts of pain on both high-quality and lowquality providers.

DOES FEAR OF LIABILITY PREVENT Health care from improving?

The frequency of medical errors in the United States does not appear to be declining. Although the Institute of Medicine caused a sensation with *To Err Is Human*, there is little evidence of improvement in the last five years. The question is why. Health care providers, tort reformers, and many patient safety advocates blame the legal system. They contend that fear of liability causes providers to hide mistakes instead of reporting them and improving their delivery systems.

INFORMATION DISCLOSURE Health care providers clearly worry about malpractice claims. If legal fear discourages error reporting and stymies quality improvement initiatives, one would expect these effects to be more significant when liability risk is high than when liability risk is low. Because liability risk varies dramatically—by specialty, by state and county, by country, by error-type, injury-type, and patienttype, and over time—a variety of natural experiments make it possible to assess whether legal fear actually impedes quality improvement.

Most discussions regarding legal risk treat all communications about medical errors as equally affected. But a typology of communication makes it clear that this is an oversimplification. There are at least three distinct types of communication to be considered: *ex ante* communication to patients, *ex post* communication to patients, and *ex post* communication to other providers. There is little concrete evidence that malpractice exposure impedes any of those types of communication, and considerable evidence that malpractice exposure actually encourages one important form of communication (*ex ante* communication to patients).

EX ANTE COMMUNICATION TO PATIENTS Many commentators have noted that physicians do not communicate well with patients, and never have. As Jay Katz noted in *The Silent World of Doctor and Patient*, physicians have never voluntarily disclosed risks to patients because they have always wanted patients to trust them blindly. Physicians have used silence about all technical aspects of care, including the associated risks, to don a "mask of infallibility." Medical historians have made a similar point: In the 19th century, physicians frequently failed to explain the limits of their knowledge and of available technologies. As Stephen Lubet has noted, "If anything, the days before the malpractice explosion were characterized by less communication from doctors, who then routinely refused to acknowledge even the possibility of uncertainty."

The rise of medical liability has encouraged better ex ante communication to patients about risks and benefits. The American Medical Association's 1847 Code of Medical Ethics required physicians to withhold information that might undermine patients' confidence, such as uncertainty about the right course of action or the existence of divergent opinions. Judicial decisions imposing legal liability for the failure to obtain informed consent led to a change in that rule and fostered greater candor. The Principles of Medical Ethics, adopted by the American Medical Association in 1980 and supplemented thereafter, now explicitly recognize the importance of obtaining informed consent and (revealingly) specify that the requirement to do so "is based on 'social policy' generated by forces outside the medical profession." The rise of malpractice litigation as a social phenomenon preceded the development of disclosure requirements and accounts for their promulgation.

From the physician's perspective, better *ex ante* communication actually lowers liability risk by giving patients more realistic expectations about the probabilities of success and the risks they assume by going forward. The higher the liability risk, therefore, the more likely there will be extensive *ex ante* communication with patients. From the perspective of both physician and patient, better *ex ante* communication has an additional benefit: it channels patients to providers whose skill level best matches the level of treatment that is required, thus lowering systemic liability risk for all involved. Thus, *ex ante* communication with patients is unambiguously increased by liability risk, not decreased. The conventional wisdom has it exactly backwards.

EX POST COMMUNICATION TO PATIENTS Physician disclosure to a patient of the occurrence of a medical error may increase liability risk. As such, ex post communication may be more likely to be chilled as liability risk increases-meaning that more expost conversations should take place when liability risks are low. In fact, there is no historical evidence that doctors routinely disclosed mistakes ex post before the rise of malpractice suits. Silence ex post seems to have been the rule always, which may explain why ethical guidelines for physicians, nurses, and hospitals require them to disclose such information. Factors other than liability risk seem to chill expost communication with patients. Legal fear merely seems to provide a convenient excuse for behavior that would occur anyway. Even if legal fear does discourage expost communication with patients, it is not clear why that should impede efforts to make health care safer. Such conversations have no obvious nexus with affirmative efforts to prevent medical errors and improve quality.

Finally, the claim that disclosing errors increases the likelihood of lawsuits is, at best, debatable. Empirical researchers increasingly believe that honest *ex post* communication with patients after an error has occurred weakens a patient's impulse to sue, by defusing the anger and resentment that motivate many patient-plaintiffs.

EX POST COMMUNICATION TO OTHER PROVIDERS Liability has mixed effects on the frequency and usefulness of *ex post* communications with other providers. On the one hand,

those communications can "leak," precipitating lawsuits or providing plaintiffs with powerful ammunition to use at trial. On the other hand, the risk of a leak is substantially attenuated by the statutory peer review protections most states have put into place—although those protections generally do not extend beyond a single institution, which does limit their potential usefulness. At the same time, many hospitals claim to have robust morbidity and mortality conferences at which errors are aired and reviewed.

There is also the long-term to consider. A conversation with a colleague may precipitate a lawsuit today, but by making future mistakes less likely, it may also avoid many more suits tomorrow. Balancing such considerations cannot be done on theoretical grounds. Empirical evidence is required to assess the tradeoffs accurately. Somewhat surprisingly, such evidence is not available. As Leape, a strong proponent of error reporting, recently observed in the *New England Journal of Medicine*, the "fear of litigation may be overblown. No link between reporting and litigation has ever been demonstrated." The claim that legal fear reduces the quality of health care by discouraging colleagues from discussing mistakes is rhetorically plausible, but that is all it is.

ANESTHESIA AND PATIENT SAFETY

Anesthesia offers a useful counterexample to the tendency to treat liability risk as an invariant negative from a patient safety perspective. Surgical anesthesia once exposed patients to serious risks of injury and death. The American Society of Anesthesiologists (ASA) took a leadership role in addressing those quality problems, with the result that anesthesia is now exceptionally safe.

The record is clear that the ASA was impelled to take action (overcoming inertia and outright resistance from some anesthetists) by the liability risks faced by its members. When patients were injured by anesthesia, the injuries were often exceptionally severe, and patients lacked pre-existing relationships with anesthesiologists that might have tempered their willingness to sue. By studying closed insurance claims and other records, anesthesiologists working under the auspices of the ASA discovered that human errors caused an extremely large fraction of anesthesia-related injuries. They then redesigned their procedures and tools so that fewer errors would occur and the errors that did occur would be less likely to harm patients. As anesthesia became safer, lawsuits against anesthesiologists became less frequent, fewer claims resulted in payouts, and liability premiums for anesthesiologists declined significantly. Simply stated, lawsuits, payouts, and insurance costs declined because fewer patients had reason to sue.

The history of anesthesia safety thus documents the existence of a feedback loop running between liability and health care quality. When errors are frequent or have serious consequences for patients, lawsuits are brought, saddling providers with higher costs in the form of judgments, settlements, legal fees, and (mainly) higher insurance premiums. Providers tolerate the costs until it becomes cheaper for them to improve quality than to deal with claims. They then figure out what is wrong with their delivery systems and improve them. As quality rises and errors diminish, consumers litigate less often and insurance premiums and other liability costs fall.

This feedback loop has made anesthesia the only area of medical practice that approaches industrial standards of quality—but anesthesiologists figured out how to prevent errors from harming patients because of malpractice exposure, not in spite of it. As Dr. Fred Cheney, the former chair of the ASA Committee on Professional Liability, accurately observed, "The relationship of patient safety to malpractice insurance premiums was easy to predict. If patients were not injured, they would not sue, and if the payout for anesthesia-related patient injury could be reduced, then insurance rates should follow." This feedback loop is not unique to anesthesiology or to health care; as Professor Bill Sage has noted, "innovation that improves safety often happens in the shadow of liability."

ERROR AND ECONOMIC INCENTIVES

The potential for error in health care is unsurprising. High error rates are predictable whenever human beings provide services via complex delivery systems. Human beings routinely make mistakes, even when they exercise due care, and health care systems are exceptionally complicated. Consequently, the many frailties that afflict human behavior—including sensory limitations, flawed decision heuristics and empirical theories, information overload, emotions and other distractions, fatigue and other physical problems, defective motivations, training limitations, and forces beyond human control—have ample room to operate. The result is that "mistakes are inevitable" in the delivery of health care services.

The surprising thing in the health care sector and elsewhere is that consistent, high-quality performance ever occurs. Errors are inevitable, but error detection, correction, and prevention are not. All three activities require continuous commitment, money, and hard work. Yet, many other sectors of the economy have error rates that health care providers should envy. Why does health care lag behind?

Health care providers rely on a diverse array of strategies to ensure quality and avoid error, including education, lofty ethical standards, demanding norms of patient service, licensure, reputation, the desire for referrals, an emphasis on character and altruism, and a highly punitive culture. Other industries use some of those strategies to help ensure error-free performance, but the most salient factor differentiating health care is the absence of direct economic incentives to "do the right thing." In health care, most compensation arrangements pay health care providers for what they do, not for what they accomplish. The failure to tie compensation to variables that correlate strongly with patients' needs and desires means that providers rarely have an economic incentive to invest in quality or to prevent error. In the language of strategic planning, there is no "business case for quality."

A few concrete examples make the point clear. Anesthesiologists knew that patient monitors detected misintubations but did not use them because they were expensive. Hospitals know that computerized physician order entry systems greatly reduce the frequency of medication mistakes but do not use them because they are expensive. Doctors know that electronic medical records improve the quality of care, but do not use them because most independent practices are too small to afford the technology. Few emergency rooms have patient-protecting software because of limited resource pooling and economies of scale. Over and over again, one finds that providers fail to implement proven patient safety measures because they lack the economic incentive to bear the costs.

Remarkably enough, providers can also profit by cutting quality at patients' expense. As Newt Gingrich once acidly noted, "Health care is the only industry in America that can give you a disease and then charge you to cure the disease it gave you."

Payers share responsibility for this state of affairs. Payers have historically cared more about price than quality, so they have negotiated terms that largely delegate responsibility for quality to providers. Some payers and providers have recently become more interested in performance-based compensation arrangements, but quality-invariant compensation remains the rule.

Of course, culture matters as well, and the "shame and blame" culture of health care is well known. Yet, culture is not destiny. Firms in other sectors of the economy have created nonpunitive environments in which workers can report problems without fear of recrimination or reprisal, even though the firm is subject to external liability threats (or even because of the threats). For example, the airline industry, in concert with the Federal Aviation Administration, has had considerable success encouraging voluntary reporting of safety problems by pilots, air traffic controllers, flight attendants, and other airline personnel.

Few people like to report their own errors, or those of their friends, but some firms have concluded that the benefits of providing higher quality goods and services exceed the associated costs. Nonpunitive internal reporting systems provide the information needed to drive that outcome. Health care organizations can create such environments if they are truly committed to providing high quality care.

Not surprisingly, bad attitudes persist when they are encouraged by bad incentives. A world in which health care providers profit by making mistakes is a world in which they will find reasons for allowing high error rates to persist. No rational system of compensation rewards an agent for making a principal worse off. Unless and until the incentive problems are corrected, patients will continue to receive low quality care and medical errors will continue to beset our system of health care delivery.

TORT REFORM

Tort reform comes in many shapes and sizes, the most popular being caps on non-economic damages, sanctions for frivolous filings, screening panels, limits on contingent fees, collateral source offsets, and requirements relating to expert reports and expert witnesses. From an economic perspective, virtually all of those reforms have the effect of making malpractice cases more expensive, riskier, and less rewarding for claimants and their lawyers. The result is that patients have increasing trouble finding representation, particularly when their injuries are small or their damages are minor—which, for the elderly, poor, and unemployed may be true even when injuries are severe. Tort reforms also make malpractice claims less expensive for defendants by reducing their frequency, weakening plaintiffs' bargaining positions, decreasing the willingness of plaintiffs' attorneys to bear costs, or giving defendants credit for payments claimants receive from other sources. The supply- and demand-side effects decrease both the frequency and magnitude of liability claims and payouts made by defendants. The result is that tort reform lowers the incentive for health care providers to exercise due care and invest in measures that protect patients from harm.

A more fundamental problem with the reform initiatives is that they have no real nexus with the problems they purport to address (deficiencies in error reporting and error correction). Their purpose and primary effect is to reduce physician malpractice costs in the short run, not to improve delivery systems in ways that address low quality care or make harmful errors less common. Worse still, providers receive the reforms' benefits even if they do not improve their error reporting and error correction/prevention.

Providers who are subject to the liability system have failed to adopt patient safety measures of proven effectiveness, and they have similarly failed to use information already in their possession to protect patients from harm. Michael Millenson usefully frames the issue by transferring the setting from a medical environment to aviation safety:

Suppose that an airline's managers and pilots repeatedly resisted installing collision-avoidance systems despite solid evidence of their worth. Suppose, too, that they complained that the radar was not reimbursed adequately, required inconvenient retraining, provided no competitive advantage in attracting passengers at a time when airline profits were low, and (*sotto voce*) was an insult to pilot judgment. No one would blithely blame "airline culture" for an ensuing disaster, and no one would absolve individual pilots and managers of responsibility for that disaster simply because they never intended for passengers to be harmed.

If we wish to encourage error-free health care, the obvious strategy is to complement the existing (admittedly highly imperfect) mechanism for deterring negligent treatment with direct rewards to providers for making error reports and for doing something about the problems they identify—as well as punishing providers for hiding their mistakes and failing to address known deficiencies. More generally, a larger strategy of using carrots and sticks to align the interests of health care providers and patients will do far more to solve the problem of medical error and health care quality than one that either relies on the legal system exclusively or eliminates tort regulation and puts nothing in its place.

Finally, we offer a brief observation on professional ethics and tort reform. Professionals commit themselves to ethical codes to give clients greater assurance that the professionals will ignore their self-interest in contexts where self-interest and client welfare conflict. When it comes to tort reform, medical professionals have consistently and systematically opted for the opposite course, embracing liability reforms that reduce their own costs but that have no demonstrated connection to the welfare of current and future patients. Whether providers can square their preference for liability reform with their core ethical imperative to put patients' welfare first is far from clear.

CONCLUSION

Until recently, physicians argued that malpractice liability should be restricted because medical errors were few and far between. As the empirical literature made that position indefensible, physicians conceded that medical errors are common, but they continued to call for tort reform, arguing that the alarmingly high frequency of medical errors is the legal system's fault. The "concession" that medical errors are common thus amounted to what a tax lawyer would describe as an attempt to put "form over substance" because it did not change anything of significance. Malpractice liability is seemingly destined (at least among providers) to be always part of the problem, and never part of the solution.

Those less affected by self-interest can legitimately ask why a policy of penalizing unwanted conduct and mistakes should play no role in a comprehensive strategy to make health care safer. The view that sanctions discourage targeted behaviors is at least as plausible as the assertion that punishments make errors more common; in our view, it is more plausible. We think it exceptionally likely that providers are blaming the legal system for undesirable behaviors (i.e., errors, failures to report errors, and failures to improve delivery systems) that occur for other reasons, and those behaviors would continue to occur if the tort system were scrapped. Given the documented frequency of medical errors and their documented cost, all available forces-including market-based incentives, legal liability, and health care workers' professionalism—must be harnessed R in the cause of patient safety.

READINGS

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