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Closing Death's Door: Legal Innovations to End the Epidemic of Healthcare Harm

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Program Materials for Celesq

Closing Death's Door:
Legal Innovations to End the Epidemic of Healthcare Harm

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Description

This program addresses the massive problem of iatrogenic injury and death, the inadequacy of the law's conventional response, and several of the more innovative approaches the law might be taking in the future to raise the level of patient safety. Those more innovative approaches will be more regulatory than litigative. Three areas to be discussed are: new incentives for investment in safety, error reporting, and engaged surveillance.

Contents

Introduction

More deaths and injuries result from healthcare gone awry than all other causes of accidental harm in the United States added together.

In addition to the physical and psychological harm experienced by victims, the economic burden externalized from the healthcare industry to patients, their families, insurers, and government is enormous.

We might assume that tort law is our society's answer to that problem. But malpractice liability has never been sufficient to create a business case for sufficient investment in patient safety to bring those numbers down from the stratosphere. Tort reforms of recent decades have succeeded in reducing the number of malpractice claims by more than half.

In this CLE, we discuss the studies that reveal the magnitude of the problem of iatrogenic harm and the inadequacy of conventional malpractice liability. We then discuss several innovative alternatives, some of which have already been instituted by American law and a few which could become law in the future.

Terminology

Iatrogenic: Illness or injury caused by medical examination or treatment. From the Greek: healer + produced by.

Medical errors are defined as failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning). An "unintended act (either omission or commission) or an act that does not achieve its intended outcome." (Leape). A "failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance." (Reason). Errors do not always lead to harm.

Medical error, iatrogenic harm, adverse events, medical accidents, etc., cover much overlapping territory, and we will use them synonymously.

Additional Resources

Broader and deeper information on the subject, as well as more extensive sources, can be found in Saks & Landsman, CLOSING DEATH'S DOOR: LEGAL INNOVATIONS TO END THE EPIDEMIC OF HEALTHCARE HARM (Oxford, 2021).

The Problem of Iatrogenic Injury and Death

"In almost no other field would consumers tolerate
the frequency of error that is common in medicine."
–Dr. Donald Berwick, former administrator,
Centers for Medicare and Medicaid Services

Before the 1970s, it could still be claimed that serious harms from medical error were few and far between. But once efforts were undertaken to systematically count instances of the problem, the reality became apparent. That reality was vastly larger than had been assumed. The massiveness of the problem stunned researchers and policy-makers and anyone else who learned of it.

Heathcare errors are the third leading cause of death in the U.S. (after heart disease and cancer). And they are the #1 cause of *accidental* death and injury – exceeding all other causes of accidental death and injury combined.

In this section we provide thumbnail summaries of some of the major studies of the problem.

Hospital Records Review Studies

The earliest and most common approach to studying patients who had been harmed by medical adverse events was to systematically review hospital medical records.

Department of Health, Education & Welfare

Source: Leon S. Pocincki et al., U.S. Dept. Health, Educ. & Welfare, The Incidence of Iatrogenic Injuries: Report of The Secretary's Comm'n on Medical Malpractice 50 (1973) (Pub. No. (05) 89).

The HEW project found that hospital medical care caused injuries to about 6% of patients, and that about one third of those (2% of all patients) were harmed negligently.

California Medical Association / California Hospital Association

Sources: D.H. Mills et al., Report on the Medical Insurance Feasibility Study (1977); D. H. Mills, *Medical Insurance Feasibility Study: A Technical Summary*, 128 WESTERN J. MEDICINE 360 (1978).

The researchers drew a random sample of 20,864 patient charts from 23 representative California hospitals. They discovered that 4.65% of inpatients in California hospitals at the time suffered what they termed a "potentially compensable event" (PCE), that is, harm "caused by health care

management." With 3,011,000 admissions to California hospitals per year, that meant 140,000 people suffered from harms caused by the care they were receiving.

The researchers calculated that all but 28,000 of those injuries were temporary, but 5400 involved serious permanent disability and 13,600 were deaths. The researchers also concluded that only 17% of the 140,000 California hospital patients who suffered harm had cases strong enough and serious enough that they would be taken on by plaintiffs' lawyers and in which legal liability could properly have been found. That translated to only .08% of all patients, or about 23,800 California hospital patients per year.

Harvard Medical Practice Study – New York State

Source: PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION (1993).

Researchers drew a representative sample of the medical records of approximately 31,000 patients treated in 51 New York hospitals in 1984.

The essential findings were that 3.7% of New York hospital patients (nearly 99,000 people) suffered adverse events, nearly 28% of which were due to negligence. In other words, slightly over 1% of the patients, more than 27,000 individuals, appear to have been victims of medical malpractice. The table below indicates the degree of harm found in these cases, as well as the proportion judged (by medical reviewers) to be attributable to negligence.

Disability caused by adverse events New York State, 1984					
			Negligent adverse events		**Adverse events due to negligence**
	Adverse events				
Disability	**N**	**%**	**N**	**%**	**%**
Minimal (recovery 1 month)	56,042	57	12,428	46	22
Moderate (recovery 6 months)	13,521	14	3,302	12	24
Moderate (recovery >6 months)	2,762	3	817	3	30
Permanent (1%– 50% disability)	3,807	4	869	3	23
Permanent (>50% disability)	2,550	3	877	3	34
Death	13,451	14	6,895	25	51
Not determinable	6,477	7	1,989	7	31
Total	98,610	100	27,177	100	28

Harvard Medical Practice Study – Utah & Colorado

Source: Eric J. Thomas et al., *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 MED. CARE 261 (2000).

The Harvard researchers carried out further studies in two other states: Utah and Colorado. In those states, combined, they found 2.9% of hospital patients suffered adverse events and, of those, 27.5% were due to negligent care.

Report of the Inspector General, Department of Health & Human Services

Source: Office of Inspector General, Department of Health and Human Services, Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries (2010).

Using the same records review approach, in 2010 the Office of the Inspector General of the U.S. Department of Health and Human Services reported a study limited to Medicare beneficiaries in hospitals. The research found that 13.5% of those patients suffered *serious* adverse events, with 1.5% resulting in death — meaning about 180,000 Medicare patient deaths a year from adverse events. The cost of treatment for adverse events added 3.5% to inpatient costs — or $4.4 billion over the year. The physician reviewers judged 44% of the harmful events to have been clearly or likely preventable.

Limitations

According to the Institute of Medicine's landmark report, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000), looking for victims of iatrogenic harm in hospital medical records is likely to yield conservative picture of the overall problem. Among the reasons are these. The studies can include only errors that are documented in the medical record. Some of the studies, notably the HMPS, counted only those injuries above a specified level of harm. The studies, by definition, examine only hospital care. Some researchers, therefore, tried other approaches.

Participant Observer Studies

Some studies arranged to obtain information from caregivers on hospital wards, in addition to what could be gleaned from medical records.

Steel et al.

Source: Knight Steel et al., *Iatrogenic Illness on a General Medical Service at a University Hospital*, 304 N. ENG. J. MED. 638 (1981).

Stee et al.'s research was carried out in a general medical service of a university teaching hospital in Boston. In addition to a careful review of each patient's record, "identification of

iatrogenic issues was supplemented with staff questioning of clinical personnel who cared for the patient and with information obtained from utilization review coordinators who were evaluating the patients' needs for continued hospitalization." They found that 36% of patients suffered an injurious adverse event; 9% were victims of "major" iatrogenic harm; and 2% of such cases resulted in death. Note that this approach found ten times as many instances of iatrogenic injury or death than were found from reviewing medical records alone.

Andrews et al.

Source: Lori B. Andrews et al., *An Alternative Strategy for Studying Adverse Events in Medical Care*, 349 LANCET 309 (1997); Lori B. Andrews, *Studying Medical Error* in Situ: *Implications for Malpractice Law and Policy*, 54 DEPAUL L. REV. 357 (2004).

Similar to the Steele et al. research, this hospital observation study, conducted in Chicago, found that errors were made in the care of nearly half of all patients, and of those about a fifth suffered serious injuries. These findings suggest that errors are quite common and that almost 10% of patients suffer a serious injury or death.

Global Trigger

Sources: David C. Classen et al., *"Global Trigger Tool" Shows that Adverse Events in Hospitals May Be Ten Times Greater Than Previously Measured*, 30 HEALTH AFF. 581 (2011); Christine Sammer et al., *Developing and Evaluating an Automated All-Cause Harm Trigger System,* 43 JOINT COMM. J. QUAL. PATIENT SAF. 155 (2017); Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 N. ENGL. J. MED. 2124 (2010).

Yet another approach to finding adverse events uses patient medical records, but researchers proceed somewhat more like detectives seeking out facts that might not be made explicit in the medical record but which can be found by putting together certain medical facts that are associated with iatrogenic harm. More automated approaches finding such "triggers" have been in development.

As the researchers explain:

> The [Institute for Healthcare Improvement's] Global Trigger Tool [for Measuring Adverse Events] uses specific methods for reviewing medical charts. Closed patient charts are reviewed by two or three employees — usually nurses and pharmacists, who are trained to review the charts in a systematic manner by looking at discharge codes, discharge summaries, medications, lab results, operation records, nursing notes, physician progress notes, and other notes or comments to determine whether there is a "trigger" in the chart. A trigger could be a notation indicating, for example, a medication stop order, an abnormal lab result, or use of an antidote medication. Any notation of a trigger leads to further

investigation into whether an adverse event occurred and how severe the event was. A physician ultimately has to examine and sign off on this chart review.

In one study, the Global Trigger Tool was applied to the records of adult patients admitted during a single month at three large U.S. tertiary (specialized) care centers that had "well-established patient safety programs" "focused on improved detection of safety incidents and adverse events through patient safety reporting programs, and special tools built around advanced electronic health record systems used within all three organizations…." In fact, the three hospitals had won awards or other recognition for their patient safety initiatives. We learn that one was an academic hospital and two were community-based teaching hospitals; one was in a midsize city in the West, one in a large city in the Midwest, and the third in a large city in the Northeast.

The study found an overall adverse event rate of 33.2%. The most serious harms and deaths accounted for a little over 8% of all adverse events.

Another application of the Global Trigger Tool was aimed at determining whether progress was being made in patient safety. The researchers sampled and analyzed records from ten hospitals in North Carolina over a six-year period. The overall adverse event rate was found to be 25.1%, with only a hint that patient care was becoming safer over time. Of all the harms identified, 13.8% were permanent or life-threatening or caused death.

In sum, the Global Trigger approach identified ten times as many adverse events as did records reviews, and about fifteen times as many cases of major permanent disability or death.

Beyond Hospitals

Healthcare is delivered in various settings other than hospitals: doctors' offices, ambulatory surgical and other treatment centers, pharmacies, labs, imaging facilities. There are thirty times as many such outpatient visits as there are hospital admissions.

Research on iatrogenic harm outside of hospitals is more limited, but they provide a fragmented mosaic of what is happening in those settings. First, the annual number of outpatient surgical visits in the U.S. currently is more than four times the number of hospital patients admitted for surgeries. Though surgeries in hospitals would, in the aggregate, be for more serious conditions and more risky procedures, the sheer number of surgeries outside of hospitals offers ample opportunity for preventable errors to occur. Second, approximately 1.8% of patients in skilled nursing facilities died as a result of the care they received (or needed but did not receive). This alone adds another 90,000 or more deaths to the total. Third, an IOM study of medication-related injuries concluded that three times as many harmful medication errors occur in healthcare delivered outside of hospitals as inside them. Moreover, medication errors accounted for one out of every 131 deaths in the outpatient setting, but only one out of 854 inpatient deaths. Fourth, research using data in the National Practitioner Data Bank found that nearly as many payments to compensate patients for iatrogenic harm were made for injuries incurred in outpatient settings as in hospitals. Two-thirds of those payments were for major injury or death.

The error profile in the outpatient setting is different, more often involving medication adverse events or diagnostic errors.

A conservative totaling of these various studies suggests approximately as many serious errors leading to injury and deaths occur in-patient research as have been found inside hospitals.

Summing Up

Based on the medical records review approach to counting adverse events, it appears that somewhere between 3 and 5% of hospital patients suffer from harm caused by their medical care. Of these adverse events, about 28% are due to negligence. This means that about one hospital patient out of 100 suffers from harm that would qualify as medical malpractice (negligently caused harm). Applied to the 35 million annual hospital patients in the U.S. currently, that would work out to between 1,053,000 and 1,755,000 victims of adverse events, of whom between 147,420 and 245,700 die and another 28,000 to 46,000 suffer permanent total disability.

Martin Makary and Michael Daniel, *Medical Error — The Third Leading Cause of Death in the* U.S., 353 BMJ (2016), combining major studies conducted after the IOM report (from 1999 to 2013), calculated "a mean rate of death from medical error of 251,454 a year…."

John T. James, *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, 9 J. Patient Saf. 122 (2013), reviewing the major Global Trigger studies available, concluded in 2013 that deaths from "preventable adverse events" numbered somewhere between 210,000 and 440,000.

All those studies and reviews of studies limited themselves to what happens to hospital inpatients.

Additional patients were receiving diagnoses, treatments, and surgeries in various non-hospital settings: doctors' offices, outpatient clinics, free-standing surgical centers, skilled nursing facilities, rehabilitation hospitals, and nursing homes.

A conservative count from the more limited research on those settings suggests that about as many preventable deaths and serious injuries occur in healthcare settings outside of hospitals as occur inside of hospitals.

As to the economic costs of iatrogenic harm, if we double the IOM Report's conservative calculations, to take into account injuries and deaths occurring outside of the hospital care setting, we would be looking at between $34 to $58 billion in annual economic loss to patients, families, insurers, and taxpayers. A more recent study, John C. Goodman et al., *The Social Cost of Adverse Medical Events, and What We Can Do About It*, 30 HEALTH AFFAIRS 590 (2011) (employing estimates totaling 187,000 deaths and 6.1 million injuries annually in and out of hospitals), found the likely cost of harmful adverse events to be somewhere between $393 billion

and $958 billion. That amount equaled between 18% and 45% of total U.S. health care spending in 2006.

Inadequacy of the Traditional Legal Response (Malpractice Liability)

Whatever the tort system has done to reimburse patients, families, first party health insurers, and government for the externalities generated by avoidable iatrogenic harm, and thereby encouraged the healthcare industry to invest in safety, it has fallen far woefully short. We base that conclusion on the sheer fact that iatrogenic harm is so widespread, so frequent, so massive, and so continuous. Malpractice liability clearly has not had the safety-promoting impact that, in theory, it was imagined to have.

The California Medical Association / California Hospital Association research concluded that for every 10 malpractice suits that could properly have been brought on behalf of an injured patient, only one actually materialized into a legal complaint.

The research had been conducted to explore the expected advantages to the industry of advancing legislation that would abolish traditional malpractice liability and replace it with an administrative no-fault system. The research led the CMA and CHA to realize that their members faced only one case under the existing system for every 60 that would have been eligible for compensation under a no-fault system.

The Harvard Medical Practice Study findings led, similarly, to the conclusion that the existing tort system protected the healthcare industry from the vast bulk of the claims it could have been facing. Of the approximately 351,000 meritorious malpractice suits that could have been brought (around the time the study was conducted), only about 10,000 actually materialized.

At the same time, it needs to be realized that, given the transaction costs of malpractice litigation, substantially stepping up the number of claims brought on behalf of victims is not a feasible solution, either. The total cost of the system would become intolerable to the economy.

The extent of the tort system's protection of the healthcare industry from compensating its victims is evident from insurance data. As noted earlier, the healthcare industry causes more accidental injuries and deaths than all other activity in our society added together. Considering that fact, one would expect the industry to be paying something greater than 50% of the liability insurance costs in the nation. Yet it pays only 2.4% of all the liability insurance premiums paid in the U.S. (Adding any reasonable estimate of the costs of self-insurance for those entities that self-insure leave the basic conclusion unchanged.)

The Harvard Medical Practice Study matched the cases of negligent injury they found in hospital medical records to the claim files opened by the relevant insurance carriers. The following table shows what the results of that inquiry.

Negligent adverse events and claims, New York State			
	Claim filed?		
	No	**Yes**	
Negligent adverse event	**272**	**8**	280
No negligent adverse event	**29,802**	**39**	29,841
	30,074	47	30,121

Of the 280 instances of negligent adverse events, only 8 (or 2.9%) became insurance company files. Of the 29,802 patients who, in the view of the medical reviewers, had not suffered a negligent injury, 39 (or 0.13%) became insurance company open files. (Some of those 39 no doubt involved injuries that were not the result of negligence. But some that ultimately were classified as non-negligent had been debated among the Harvard review team. Note that we call them "files" rather than "claims" because some insurance files are opened not because a lawsuit was initiated but instead because a doctor or hospital notified an insurer of an adverse event that could become a claim. So, the actual number of suits needing to be defended is smaller than appears.) The main take-away from the data is that far fewer cases become malpractice claims than could properly have been filed.

Studies exploring the flow of cases from iatrogenic injury occurrence to ultimate disposition illuminate why the tort system is inadequate for the purpose of creating incentives for investment in patient safety.

The tort system is non-self-starting. Victims of iatrogenic harm need to take the first steps to initiate a potential complaint. But great majority of such persons do not take the first step necessary to pursue a malpractice complaint. One study examined how nearly 200 patients dealt with medical care they considered to be harmful and seriously unsatisfactory. Of that sample, only 9% contacted lawyers, though none of them ultimately filed suits.

Lawyers who are contacted screen out most of the cases offered to them, and they screen malpractice case more vigorously than other torts. In a study of attorney screening practices involving tens of thousands of contacts with potential clients seeking representation, attorneys rejected 80% of prospective malpractice claims compared to 70% for other kinds of tort cases. Another study that examined plaintiffs' attorneys' responses to requests from prospective medical malpractice clients reached similar findings. Of 730 total calls received by these lawyers' offices over ten randomly selected days, medical records were obtained for 90, most of which were then reviewed by a consulting expert. The physicians' reviews led to 53 more rejections because they "were felt to have had insufficient damages (42%) or lacked negligence on the part of the health care provider (26%)." For various reasons, additional cases were rejected. In all, 97% of the original 730 inquiries were declined.

Thus, filings are a shadow of the original population of injured, or negligently injured, patients. For every 100 adverse events, four malpractice insurer claim files are opened; for every 100 negligent adverse events, seventeen claim files are opened.

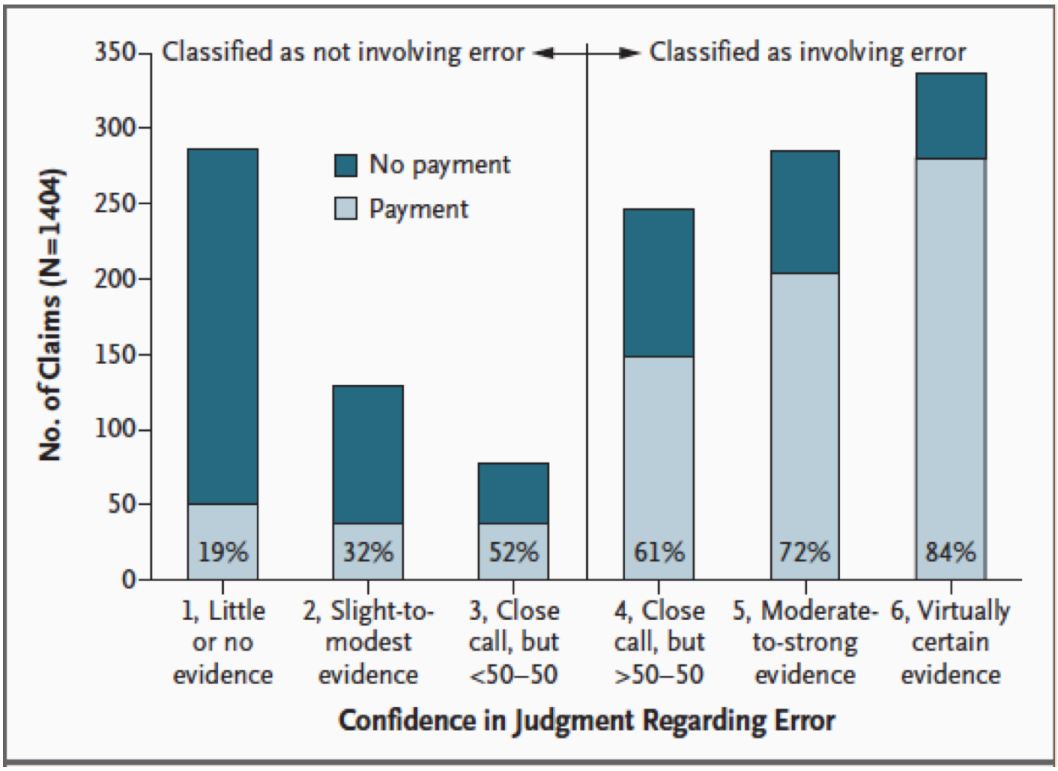
The following table reflects the findings of a variety of studies applied to a state with a population of 10 million, having about 1.1 million annual hospital admissions.

Iatrogenic Harm and Legal Response in a State with 10 Million Population			
State population	10,000,000		
Hospital admissions	1,108,750		
Total adverse events	36,504		
Negligent adv events	11,076		
Mod to severe	5,538		
Deaths	2,769		
Total med mal filings	755	13.6%	of mod-severe NAAs
Settled, dropped, dismissed	694		
Trials	61	8.1%	of filings
Verdicts for plaintiffs	15		
Total number of payments	282		
Mean payment (2020$)	$415,000		

Out of approximately 5,500 moderate-to-severe negligent adverse events, only 13.6% become tort claims, 4.8% (267/5538) are settled for a payment, and 0.3% (15/5538) become verdicts favoring plaintiffs. (Note: several of the settlements will have taken place without the formal filing of a malpractice claim.) The medical injuries that come before juries are almost always severe – 90% of them deaths or injuries that are serious and permanent.

Thus, for every case in which a victim of negligent iatrogenic injury receive some compensation, 20 other cases of moderate-to-more-severe negligent injuries (half of them deaths) never materialized or were disposed of without payment.

As can be seen in the diagram that follows, based on a study of insurance closed claims, David M. Studdert et al., Claims, Errors, and Compensation Payments in Medical Malpractice Litigation, 354 New England J Medicine 2029 (2006), the more confident physician reviewers were that a negligent error had occurred causing the injury, the more likely it was that some compensation was paid, and in quite a rational manner: from 19% to 32% to 52% to 61% to 72% to 84%).



Settlements and awards are, on average, smaller than the amounts of damages suffered by the plaintiffs. This occurs not only because a portion goes to legal fees, but because of discounting for settlements, because of a phenomenon whereby increasingly large losses are compensated with progressively shrinking under-awarding, post-verdict re-negotiation, caps on general damages or total damages resulting from tort reform, and a de facto cap that is equal to the insurance policy limits.

But, in the larger picture, compensation awards, are insufficient to incentivize adequate investments in safety because, overall, there are so few claimants (relative to negligent injuries and deaths) and too few claims. Tort reforms of recent decades have made a weak liability system weaker, cutting the number of filed malpractice claims by one half to two-thirds.

At the end of the day, the malpractice liability system has failed to create a business case for the healthcare industry to invest in patent safety. In the aggregate, only a few percent of all of the costs suffered by medical injury victims (somewhere between <1% and 3.8%) are returned by the tort system.

If the level of iatrogenic harm that our society has been living with for decades is not to remain a permanent feature of the healthcare system, and the law is to play a part in prompting those improvements, more innovative approaches are needed. We suggest some in the remaining sections of these materials. Others can be found in SAKS & LANDSMAN, CLOSING DEATH'S DOOR (2021).

New Incentives for Investment in Safety

In theory, the tort system was supposed to create incentives sufficient to stimulate a roughly optimal level of safety in any and all dangerous activities. See, GUIDO CALABRESI, THE COST OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS (1970); Richard Posner, *A Theory of Negligence*, 1 JOURNAL OF LEGAL STUDIES 29 (1972). As we saw in the preceding section, the system is not accomplishing that goal, at least not in the realm of medical accidents.

In addition to the malpractice system providing inadequate incentives for investment in patient safety, the healthcare system is riddled with perverse incentives. These drive behavior in directions inconsistent with patient safety. Consider some examples.

- Thin staffing ratios save money but provide less attentive care and increase the risk of errors.

- Overworking medical residents is economically beneficial to hospitals but puts patients at risk. Imagine being the patient who needs an emergency surgical procedure to be performed by a resident in the 25th hour of her 28-hour shift.

- Surgeon and author Atul Gawande has observed that, "our systems are incredibly optimized for sending bills. I can send the bill in like three keystrokes. But recording an allergy can be four different screens. So it's not built to set a goal for care and then accomplish it."

- Paradoxically, newborns with medical needs tend to get better care when they have poor or no insurance and poorer care when they are covered by good insurance. Here's how that happens. Newborns with congenital anomalies but without good health insurance represent losses to hospitals. So, when they can do it, general hospitals transfer those babies to children's hospitals, thereby shifting the cost to the children's hospital. But afflicted newborns with good insurance will be retained by the general hospital, so it can collect fees for delivering its lower-quality care to the infant. By over-burdening children's hospitals with an excess of costly, low-or-no-fee-paying cases, the ability of the children's hospitals to provide the best care to children with the greatest need for specialized care, is reduced.

- The existing system is "supply-sensitive," meaning that the patient population magically expands as needed to consume the available resources: hospital beds will be filled, operating rooms will be occupied, doctors will keep themselves busy. This leads to great waste as well as increased risks to patients. But it keeps revenue flowing in. (Supply-sensitive care, more generally, is one of the reasons Americans pay the most to obtain some of the lowest quality healthcare overall among modern, wealthy nations.)

Most perversely, when errors occur and harm results, the most likely consequence for the healthcare industry is that it makes more money. First, note that any harm a patient has suffered – be it a serious illness, a car accident, or a medical accident – means healthcare services are needed and revenue will flow to the healthcare system (so long as there is some insurance to pay for it). At the same time, as we saw in the preceding section, hospitals are largely insulated from the financial costs of patients' injuries, including those caused by the hospital's negligence. So errors mean more income.

We do not suggest any kind of intentional injury to patients. We do suggest that the system perversely incentivizes sluggishness in the pursuit of safety, not offset by other incentives to invest in safety. Noted medical researchers: "Effective methods for reducing surgical complications have been identified. However, hospitals have been slow to implement them." News reporting indicated that only about 1% of hospitals had installed inexpensive sponge-tracking systems that could reduce foreign-body-left-during procedure rates to nearly zero. Multiply such decisions across the industry, and one sees the effects of the lack of disincentives (weak malpractice system) and the perverse incentives for tolerating iatrogenic injuries.

Investment in safer systems and practices is costly. And the consequence of successfully improving safety is to see future revenues decline. Sunil Eappen, the head of one team of researchers who studied this problem concluded: "We found clear evidence that reducing harm and improving quality is perversely penalized in our current health care system." Co-researcher Atul Gawande, commented, "The more effective their quality control department is, the more they lose. We're talking about massive amounts of losses if they improve quality."

One thing the law (and health insurers as well) do is search the healthcare system to locate perverse incentives and then restructure the reimbursement architecture to make investments in patient safety more attractive than they are now. Obviously, some perverse incentives are easier to address than others. And some changed incentives would have a more dramatic impact on safety than others. Two CMS (Centers for Medicare and Medicaid Services) programs in particular reflect efforts to incentivize investments in patient-safety: the Hospital-Acquired Conditions Reduction Program (HACRP) and the Hospital Readmission Reduction Program (HRRP).

HAC Reduction Program

Hospital-Acquired Conditions are injuries suffered by patients while being cared for in hospitals, injuries that are thought to be "reasonably preventable" by providing with higher quality, safer, evidence-based care. The HAC Program is intended to create incentives for hospitals to find ways to reduce hospital acquired conditions.

> Section 1886(p) of the Social Security Act established the statutory requirements for the HAC Reduction Program. Beginning with Fiscal Year (FY) 2015 discharges (i.e., effective October 1, 2014), the HAC Reduction Program requires the Secretary of Health and Human Services to adjust payments to hospitals that rank in the worst-performing 25 percent of all subsection (d) hospitals with respect to HAC quality measures. Hospitals

with a Total HAC Score greater than the 75th percentile of all Total HAC Scores (i.e., the worst-performing quartile) are subject to a 1 percent payment reduction.

Total HAC Score is based on data for the following quality measures:

CMS Recalibrated Patient Safety Indicator (PSI) 90 (CMS PSI 90). The PSI 90 is composed of the following ten injury rates:

- Pressure Ulcer Rate
- Iatrogenic Pneumothorax Rate
- In-Hospital Fall with Hip Fracture Rate
- Perioperative Hemorrhage or Hematoma Rate
- Postoperative Acute Kidney Injury Rate
- Postoperative Respiratory Failure Rate
- Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate
- Postoperative Sepsis Rate
- Postoperative Wound Dehiscence Rate
- Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate

Five Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) healthcare-associated infection (HAI) measures:

- Central Line-Associated Bloodstream Infection (CLABSI)
- Catheter-Associated Urinary Tract Infection (CAUTI)
- Surgical Site Infection (SSI) – colon and hysterectomy
- Methicillin-resistant Staphylococcus aureus (MRSA) bacteremia
- Clostridium difficile Infection (CDI)

Research to evaluate the effectiveness of the program – which will inevitably be a moving target as features of it change over time – is quite limited. But the program clearly aims at incentivizing safety, at least for the specified conditions.

Hospital Readmissions Reduction Program

The Hospital Readmissions Reduction Program (HRRP) penalizes hospitals that have excessive preventable readmissions for certain conditions. Section 3025 of the Patient Protection and Affordable Care Act requires the Secretary of the U.S. Department of Health and Human Services to establish HRRP and reduce payments to Inpatient Prospective Payment System hospitals for excess readmissions. In addition, the 21st Century Cures Act directs CMS to assess a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full Medicaid benefits beginning in FY 2019.

The HRRP was launched in FY 2013 with a 1% maximum penalty, which increased each year until reaching its current 3% maximum penalty. The penalty is applied to all of a hospital's Medicare charges, not only those of patients who had the procedures being scrutinized. Over time, more conditions were added to the list of those that are monitored and trigger penalties.

CMS currently includes the following six condition or procedure-specific 30-day risk-standardized unplanned readmission measures in the program:

- Acute myocardial infarction (AMI)
- Chronic obstructive pulmonary disease (COPD)
- Heart failure (HF)
- Pneumonia
- Coronary artery bypass graft (CABG) surgery
- Elective primary total hip arthroplasty and/or total knee arthroplasty (THA/TKA)

Whether this program can be thought of as being concerned with iatrogenic harm is debatable, but we mention it as a hybrid of quality improvement and safety improvement. We can, at least, note that, with about one in five patients who are admitted to hospitals being readmitted within 30 days with the same condition, those conditions are problems needing solutions.

Enterprise Liability and Enterprise Insurance

A different way to restructure incentives in an effort to stimulate increases in patient safety is to move the financial responsibility for iatrogenic injuries and legal responsibility away from individuals (notably doctors) and onto corporate entities (hospitals and other healthcare organizations).

A move of this sort has been under discussion for decades. It has never been imposed by law, though it has tended to arise organically in those healthcare organizations where doctors are salaried employees. Some reformers have long suggested that a shift of responsibility along these lines, mandated by state law, would generate several major benefits. Two principal versions of this shift have been conceived.

One, termed enterprise insurance, would require hospitals and other concentrations of patient care to provide liability insurance coverage for all patient care activities taking place within their institution's walls. Tom Baker, *Medical Malpractice Insurance Reform: "Enterprise Insurance" and Some Alternatives*, in William M. Sage and Rogan Kersh (eds.), MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM (2006). The insurance provided would cover harms caused by any and every caregiver. Importantly, providers who are not employees of the organization would remain personally legally liable for negligent harm they might cause; lawsuits would be filed against the individual, not against the organization that paid for their liability insurance. But note that the payer of the insurance premiums has acquired an interest in the performance of its non-employee insureds.

The other version of the shift-to-the-enterprise concept is dubbed enterprise liability, signifying that the enterprise not only pays the insurance premiums but also is responsible for all liability. Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARVARD LAW REVIEW 381 (1994). Lawsuits against individual providers would not be permitted. All claims would have to be filed against the enterprise. Under enterprise liability, the law would require all individual healthcare providers to be associated with a healthcare organization – a hospital, a nursing home, a healthcare plan, a private group practice, something. Any of those could be the enterprise that would assume legal responsibility for the torts of the individuals associated with it.

One expected benefit of such policies is that a larger organization can manage insurance costs better than can individuals. It can purchase liability insurance for the group at a lower price than the sum of the individual policies that would have been purchased by the individuals being insured. More important, the organization can better weather the insurance underwriting cycle than individuals can. The organization is in a better position to plan for, manage, and smooth out the budgeting for those costs – better able to benefit from soft markets and endure hard markets.

Most important from the viewpoint of encouraging investments in patient safety, enterprise solutions focus the liability and the costs on an organizational unit that is in a better position than any individual to do something to prevent it. By aiming lawsuits at the organizational level, enterprise solutions put pressure on the people who control those systems. By making the enterprise the financially responsible party, the enterprise acquires an incentive to look for ways to be sued less, for less, and then to pay lower premiums. A good way to do that would be to find ways to reduce the frequency or seriousness of preventable harms, that is, to increase patient safety.

Pigovian Taxation

Pigovian taxation is probably most familiar in environmental law. Economists came to realize that firms that poured their waste into rivers or the atmosphere were avoiding having the full cost of their good or services reflected in the price they charged customers. Instead, they were externalizing those costs onto the larger public. Pigovian taxation internalizes those costs, so those firms must either raise their prices or find more efficient and effective ways to dispose of their waste. The hoped-for solution would be to reduce their taxes by reducing their pollution.

The same could be done in the world of iatrogenic injuries and deaths. At present, tens or hundreds of billions of dollars are externalized by unsafe healthcare practices in the form of harm to patients, the costs of which are not reflected in the price of the services provided, but are subsidized by unlucky patients, first-party health insurers, disability insurers, and taxpayers. As a result, American society under-estimates the true cost of its healthcare. Pigovian taxation might go a long way toward making up for the market failures and tort system deficiencies that have been described. Pigovian taxation would help supply the business case for investment in safety that does not now exist.

Healthcare organizations could be taxed in proportion to the value of the harms they generate. This might be called an “iatrogenic injury tax.” Note the phrase “in proportion.” The full amount of the externalities need not be taxed in order for the system to work, but the taxes should correlate with the healthcare organizations’ relative externalities. Thus, the least safe would be taxed the most. Once the costs of harm started being internalized, healthcare organizations would be motivated to find ways to deliver healthcare more safely. As each organization began to develop safer systems and procedures, its iatrogenic injury tax would begin to fall. Innovative healthcare organizations would no longer find themselves having to say that the health care system pays them to hurt patients and punishes them when they don't. Accomplishments in patient safety would be rewarded with low or no iatrogenic injury taxes.

Error Reporting

In its seminal 1999 report on medical error, the Institute of Medicine (IOM) recommended that the cure for the epidemic of healthcare harm was reporting, both of serious harms (to a public database) and of near-miss events (to a confidential site). This recommended solution to iatrogenic harm was both brave and naïve – brave because it challenged more than a century of medical resistance to reporting and naive because it believed such a system could command the profession's support.

The IOM hoped to utilize something akin to the Federal Aviation Administration's (FAA) Aviation Safety Reporting System (ASRS) to generate a flow of information that could identify procedures likely to lead to injury. The ASRS seeks to have all those involved in aviation confidentially report on possible errors. Potential reporters only face disciplinary consequences if they do not report dangerous situations. The focus is on "near misses." Reports are required to be filed within five days and are routinely responded to in a fairly rapid fashion, often with recommended safety checklists. The system is credited with making aviation, especially commercial aviation, far safer.

The ASRS is generally viewed as an excellent approach to safety. It is, however, a poor fit for medicine. The FAA controls aviation in America. There is no single entity with similar authority over medicine. Contributors to the aviation reporting system have a keen interest in safety – it often implicates their own wellbeing. There is no similar interest in medicine – errors harm patients not treaters. The volume of reports to ASRS, about 30,000 a year, is dwarfed by what would be generated by an effective near miss system in healthcare. The safety recommendations generated by ASRS are often operationalized as checklist items to be incorporated in regular flight operations. Medicine is notorious for resisting checklists of any type as "cookbook" medicine. Those involved in flight operations share a common language and a circumscribed set of challenges. The range of problems faced in medicine is several orders of magnitude larger with very much less common ground. All of this suggests that reporting systems would be difficult to establish to address medical safety problems.

These impediments might be overcome but medicine's deeply entrenched attitudes against reporting present an even more serious barrier. Treaters, since the 19th century, if not before, have resisted public reporting. Doctors who criticize other physicians are, generally, the targets of extreme hostility. Physicians and hospitals fear for their reputations and see accusations of error as an existential threat though, in reality, they are nothing of the sort. Even where medicine fosters review and discussion of some errors, as in the Morbidity and Mortality (M & M) conference, Charles Bosk, who studied such conferences in his celebrated book FORGIVE AND REMEMBER: MANAGING MEDICAL FAILURE (2d ed. 2003), found that no records were kept, no reports were filed and no follow-up investigations were launched. Hospitals, since the 1970s, have relied on "risk managers" to control the flow of information about error and their primary mission has virtually always been to insure public silence about medical mistakes.

In this environment it should come as no surprise that the major medical error reporting systems have all been failures. This has been the case with respect to the National Practitioner Data Base

(NPDB) that is supposed to record physician malpractice, license revocation and other disciplinary action. It has been routinely evaded and knowledgeable observers have called for its abandonment. William M. Sage, *Bridging the Relational-Regulatory Gap: A Pragmatic Information Policy for Patient Safety and Medical Malpractice*, 59 Vanderbilt L. Rev. 1263 (2006). The same is true of the Joint Commission's "sentinel event" system which was supposed to get reports of a range of "never" events. It received 3,000 such reports between 1995 and 2004, approximately 1% of the events likely to have qualified for reporting.

If safety is to be enhanced, it is unlikely to be by reporting.

Engaged Surveillance

One means of improving medical safety might be through official mandates and surveillance. Government, however, has not been very good at using mandates and surveillance to improve safety, often opting for technique mandates or equipment requirements which are inflexible and often of limited efficacy. What is needed is not command-and-control directives enforced through inspections but the establishment of performance outcome goals that place improvement responsibility squarely on the shoulders of those responsible for the regulated activity.

In medicine the challenge of fixing such goals and enforcing them through surveillance is substantial. One program that has demonstrated the potential for genuine safety improvement through surveillance has been the New York State program to evaluate and improve the safety of coronary artery bypass graft (CABG) surgery programs. Edward L. Hannan et al., *The New York State Cardiac Registries*, 49 J. AM. COLL. CARDIOL. 2309 (2012).

In 1987, the New York Department of Health, under the leadership of Dr. David Axelrod, established a "registry" for the submission of data on all CABG surgeries performed in the state. What it found was a more than 500% variation in mortality rates. This shocking variation led the department to seek to use surveillance and performance comparisons to push dangerous programs into reforms that would improve safety.

To achieve its safety-promoting purpose, the department could not simply use raw mortality data. An elevated death rate might simply reflect a sicker patient population rather than dangerous medical practice. Edward L. Hannan et al., *Adult Open Heart Surgery in New York State. An Analysis of Risk Factors and Hospital Mortality Rates*, 264 JAMA 2768 (1990). Pressing programs with a sicker patient population might have the undesired consequence of encouraging them to refuse treatment to particularly risky patients. To address this issue, with the substantial assistance of a blue-ribbon group, the Cardiac Advisory Commission, the department established a battery of questions to identify patients with significant health problems that created additional risk.

Once these risk factor standards were established the department set about assembling comparative mortality data. These examined the performance of each of the approximately 30 CABG centers in the state and identified "outliers." These institutions were required to improve

their practice or face revocation of their Certificate of Need--government permission to perform CABG surgery.

The institutional data, and doctor-specific data as well, became a point of dispute between the press and the department. Under freedom of information laws, the press sought full disclosure of both hospital and doctor performance statistics. To the caregivers' dismay, all these data were, eventually, made public.

The impact of release of this information was dramatic. "Outliers" scrambled to improve their mortality record and, thereby, avoid shutdown and substantial reputational harm. Those doctors whose records showed elevated patient mortality risk faced a variety of pressures both from their institutions and their peers. In significant numbers, these physicians left CABG practice in New York – some moving elsewhere, others changing the nature of their practice.

The results of this program were impressive. New York became the safest state for CABG surgery in the country. The state is credited with inspiring nationwide improvement in CABG practice.

Mandates and engaged or vigorous surveillance are not a panacea. Such processes are expensive. They are only warranted with serious medical interventions where mortality is a genuine risk. The sorts of improvements such programs may demand can be costly. They will only be warranted where the procedure being scrutinized is one of financial significance to a provider. This was the case with CABG operations which have been described as a key to the financial survival of a number of hospitals.

Such initiatives are likely to provoke a powerful medical profession backlash. Most New York cardiac physicians disliked the program and let people know that. Researchers who shared these sympathies argued that the sickest patients were being turned away by doctors afraid of elevated mortality risk. This claim was not effectively supported by research but the Health Department did make changes to recognize an expand number of risk factors.

What might be done with the engaged surveillance model? We have suggested that a promising follow-on candidate is the "Volume Pledge" program instituted by Dartmouth, Johns Hopkins and the University of Michigan. These hospital systems have agreed not to allow inexperienced doctors to perform what have been identified as risky surgeries. The surveillance aspect of this approach is to identify "risky" procedures. For the "Volume Pledge" consortium this has included certain cardiovascular procedures and cancer resectionings. Analysts have argued that extending the pledge to elective surgeries like knee and hip replacements might save a large number of lives. Low volume hospitals lose 70% more knee replacement patients, 50% more hip replacement patients and 20% more congestive heart failure patients. John D. Berkmeyer et al., *Hospital Volume and Surgical Mortality in the United States*, 346 N. Engl. J. Med. 1128 (2002); Andrea K. McDaniels, *Complications More Likely When Doctors Don't Do Enough Surgeries, Study Says*, Baltimore Sun (May 29, 2015), http://www.baltimoresun.com/health/maryland-health/bs-hs-low-volume-surgery-20150520-story.html.

Conclusion

We have described the problem of iatrogenic harm in the U.S. healthcare system, discussed the inadequacy of the traditional legal response (malpractice liability), and argued that innovative legal processes need to be adopted if massive patient harm is not to remain a feature of American healthcare. We discussed several innovations – actual ones and possible ones – under the headings of new incentives, error reporting, and engaged surveillance. All of these are in the nature of administrative, rather than litigative, innovations. More suggested innovations are discussed in Saks & Landsman, CLOSING DEATH'S DOOR: LEGAL INNOVATIONS TO END THE EPIDEMIC OF HEALTHCARE HARM (Oxford, 2021). And still more can be imagined by others, including you. We hope you will in one way or another join the search for legal innovations to help end the epidemic of healthcare harm.