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In From the Cold? Law's Evolving Role in Patient Safety

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IN FROM THE COLD? LAW'S EVOLVING ROLE IN PATIENT SAFETY

David M. Studdert and Michelle M. Mello***

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INTRODUCTION

The Institute of Medicine's (IOM's) 1999 report, *To Err is Human*, launched the modern patient-safety movement.¹ Rereading it nearly twenty years later, one is struck by two pervasive tones: alarm and optimism.

There was plenty to be alarmed about. Summarizing available evidence on the incidence of medical injury, the report estimated that preventable adverse events in U.S. hospitals caused between 44,000 and 98,000 deaths annually at a cost of \$17–\$29 billion.² Because the scale of the public health problem was not widely known, these statistics had shock value.³ Medical error had suddenly surpassed motor vehicle accidents to become the most prevalent type of serious injury and now ranked near diabetes mellitus and Alzheimer's disease as a leading cause of death.

In spite of the daunting magnitude of the problem, the report is infused with a sense that major gains were within reach. The critical move was for health care delivery systems to emulate strategies developed and implemented successfully by other high-risk industries—manufacturing, nuclear energy, and aviation. That theme underpins most of the IOM report's major recommendations: improved reporting and surveillance of risks and events; culture change within health care organizations, including a “no-blame” climate to promote reporting of adverse events; enhanced oversight by payors as well as licensing and accreditation bodies; prioritization of safety at the highest levels of institutional leadership; adoption of error-reduction technologies and interventions with proven efficacy; and investment in research.

What role did the IOM report envision for law and lawyers? To the limited extent that they are mentioned at all, the message is clear: Get out of the way. Safety was “hindered through the liability system and

1. See generally INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 1999) [hereinafter IOM REPORT].

2. *Id.* at 1–2.

3. The IOM report's upper bound on the empirical estimates was derived from a study of adverse events in New York hospitals published nearly a decade earlier. See Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 *NEW ENG. J. MED.* 370 (1991) [hereinafter Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients*]; Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II*, 324 *NEW ENG. J. MED.* 377 (1991). The estimate's lower bound came from a similar study conducted in Colorado and Utah that was completed and under peer review at the time the IOM report was being written. See Eric J. Thomas et al., *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 *MED. CARE* 261 (2000) [hereinafter Thomas et al., *Incidence and Types of Adverse Events*].

the threat of malpractice, which discourages the disclosure of errors.”⁴ Discoverability and admissibility of information in legal proceedings “encourages silence about errors committed or observed.”⁵ Risk management within hospitals was an enterprise focused on “loss control,” not safety or quality improvement.⁶ Further, the report’s recommendations for enhanced oversight looked mainly to professional bodies, rather than government regulators or courts.⁷ In sum, law was not the solution or even part of the solution; it was part of the problem.

Did the IOM report put law in its proper place? In this Article, we argue that it did not, and that the patient-safety movement’s posture from the outset—indifference at best, and occasionally open disdain—has had enduring consequences. Although there are real tensions between the core objectives and approaches of quality improvement and the legal system, leaders of the movement have been so transfixed by these tensions that they have failed to recognize the necessity and potential usefulness of legal institutions to the enterprise.

Part I briefly reviews the movement’s progress. Part II questions some of the received wisdom about the corrosive impact of legal forces. Part III describes the divide that opened up between the patient-safety movement and certain legal institutions (chiefly, the tort system and practitioner boards) that are devoted to the pursuit of individual accountability. Parts III and IV discuss several contributions to making care safer these institutions have nevertheless made and others they could make.

I. PROGRESS IN THE WAR ON MEDICAL ERROR

Fresh consideration of roles for legal institutions is important because of the need to reinvigorate medical error reduction efforts. Although the past two decades have seen some notable achievements, progress overall has not met expectations. With easy wins now mostly exhausted, the pace and magnitude of further improvements are likely to diminish.

4. IOM REPORT, *supra* note 1, at 43.

5. One of the only positive statements the Report makes is that, “Liability is part of the system of accountability and serves a legitimate role in holding people responsible for their actions.” *Id.* at 110.

6. *Id.* at 270.

7. *Id.* at 132–54.

A. *Advances*

A period of frenetic activity followed release of the IOM report. Congressional inquiries were convened and legislation was passed.⁸ Federal agencies and influential expert bodies set ambitious patient-safety goals, as accreditors moved quickly to adopt patient-safety standards.⁹ The Agency for Healthcare Research and Quality pivoted toward more research on medical error, pushing patient safety from a peripheral area of health services research to the field's core. Adverse event reporting systems were established in states and hospitals across the country.¹⁰ Health care delivery organizations hired patient-safety officers and launched countless initiatives aimed at improving safety.

Did this wave of activity make a difference? Examples of progress are readily identifiable.¹¹ The Centers for Medicare and Medicaid Services (CMS) and most states now require adverse events involving harm to be reported to regulators, adding to voluntary reporting initiatives that have made health care quality and safety data more available to the public.¹² Accreditation standards now routinely include

8. See, e.g., Medical Error Reduction Act of 2000, S. 2038, 106th Cong. (2000); Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000, S. 2378, 106th Cong. (2000); Medication Error Prevention Act of 2000, H.R. 3672, 106th Cong. (2000); Patient Safety and Errors Reduction Act, S. 2738, 106th Cong. (2000); Voluntary Error Reduction and Improvement in Patient Safety Act, S. 2743, 106th Cong. (2000).

9. See Michelle M. Mello et al., *The Leapfrog Standards: Ready to Jump from Marketplace to Courtroom?*, 22 HEALTH AFF. 46, 46–47 (2003) (discussing a range of goals and initiatives that emerged in several years after the IOM report); see also INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY, at ix–x (2001) [hereinafter IOM, CROSSING THE QUALITY CHASM] (following up on the initial IOM Report, *supra* note 1, and recommending additional steps to improve quality of care and patient safety); *Special Edition: JCAHO Patient Safety Goals 2003*, TOPICS IN PATIENT SAFETY (VA Nat'l Ctr. for Patient Safety), Dec. 2002; Milt Freudenheim, *Big Companies Lead Effort to Reduce Medical Errors*, N.Y. TIMES (Nov. 16, 2000), <https://www.nytimes.com/2000/11/16/business/big-companies-lead-effort-to-reduce-medical-errors.html>; *Safe Practices for Better Healthcare*, NAT'L QUALITY F., http://www.qualityforum.org/news_and_resources/press_kits/safe_practices_for_better_health_care.aspx (last visited Jan. 24, 2019).

10. CARRIE HANLON ET AL., NAT'L ACAD. FOR STATE HEALTH POLICY, 2014 GUIDE TO STATE ADVERSE EVENT REPORTING SYSTEMS 2 (2015), https://nashp.org/wp-content/uploads/2015/02/2014_Guide_to_State_Adverse_Event_Reporting_Systems.pdf.

11. Useful summaries are available in Allen Kachalia et al., *Legal and Policy Interventions to Improve Patient Safety*, 133 CIRCULATION 661 (2016) [hereinafter Kachalia et al., *Legal and Policy Interventions to Improve Patient Safety*]; Robert M. Wachter, *Patient Safety at Ten: Unmistakable Progress, Troubling Gaps*, 29 HEALTH AFF. 165 (2010); and *National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data from National Efforts to Make Health Care Safer*, AGENCY FOR HEALTHCARE RES. & QUALITY (Dec. 2016), <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html>.

12. Kachalia et al., *Legal and Policy Interventions to Improve Patient Safety*, *supra* note 11, at 661–64.

patient-safety indicators.¹³ Further, there have been several salutary moves from payors. Medicare, for example, has deemed a select group of complications of in-hospital care unacceptable and will no longer pay for associated care.¹⁴ More broadly, CMS and other payors have broadened use of performance-based payment incentives that are linked to measures of quality and safety,¹⁵ though it is unclear whether this trend will continue in light of mounting evidence that payment incentives (at least as currently structured) do not stimulate large improvements in quality.¹⁶

There are promising signs of culture change, including a clearer understanding among providers that unanticipated outcomes of care should be disclosed to patients and their families, reported to hospitals and regulatory bodies, and investigated.¹⁷ In conducting those investigations and acting on findings, there is also keener commitment to considering upstream links in the causal chain, not merely the hapless provider at its end. Evidence that improvements in safety culture translate into reduced error rates exists, though it is quite weak.¹⁸

Most importantly, a handful of highly promising interventions to improve safety have been identified and widely adopted.¹⁹ The two most celebrated are an aviation-style checklist and team training intervention designed to prevent bloodstream infections in intensive care

13. See, e.g., “Patient Safety Systems” (PS) Chapter, JOINT COMMISSION (Dec. 18, 2017), https://www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_program/.

14. Arnold Milstein, *Ending Extra Payment for “Never Events”—Stronger Incentives for Patients’ Safety*, 360 NEW ENG. J. MED. 2388, 2388 (2009).

15. Sylvia M. Burwell, *Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care*, 372 NEW ENG. J. MED. 897, 897 (2015); Kachalia et al., *Legal and Policy Interventions to Improve Patient Safety*, *supra* note 11, at 664.

16. See Michelle M. Mello et al., *The Role of Transparency in Patient Safety Improvement*, in *TRANSPARENCY IN HEALTH AND HEALTH CARE* (Holly F. Lynch et al. eds., forthcoming 2019) (citing Aaron Mendelson et al., *The Effects of Pay-for-Performance Programs on Health, Health Care Use, and Processes of Care: A Systematic Review*, 166 ANNALS INTERNAL MED. 341, 348–50 (2017)).

17. Thomas H. Gallagher et al., *Disclosing Harmful Medical Errors to Patients*, 356 NEW ENG. J. MED. 2713, 2713 (2007) [hereinafter Gallagher et al., *Disclosing Harmful Medical Errors to Patients*].

18. See generally Sallie J. Weaver et al., *Promoting a Culture of Safety as a Patient Safety Strategy: A Systematic Review*, 158 ANNALS INTERNAL MED. 369 (2013).

19. See, e.g., Alex B. Haynes et al., *A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population*, 360 NEW ENG. J. MED. 491 (2009); Julia Neily et al., *Association Between Implementation of a Medical Team Training Program and Surgical Mortality*, 304 JAMA 1693 (2010); Teryl K. Nuckols et al., *The Effectiveness of Computerized Order Entry at Reducing Preventable Adverse Drug Events and Medication Errors in Hospital Settings: A Systematic Review and Meta-Analysis*, 3 SYSTEMATIC REVIEWS. 56 (2014); Peter Pronovost et al., *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 NEW ENG. J. MED. 2725 (2006).

units,²⁰ and the World Health Organization's surgical safety checklist.²¹ In addition, most types of hospital-acquired infections, a sustained target of quality improvement efforts, have declined markedly over the last decade.²²

Nonetheless, there is a broad consensus that overall progress has been frustratingly slow. The absence of any comprehensive longitudinal studies of adverse event rates makes it difficult to say how slow, but the available evidence suggests that overall rates of medical injury have either not declined or, at best, receded slightly and unevenly.²³ The report's goal of a 50% reduction in error by 2005 almost certainly remains unmet in 2018. Indeed, it is questionable whether a typical patient receiving care from a typical health professional in a typical U.S. hospital or clinic today is at appreciably lower risk of experiencing a preventable medical injury than she was twenty years ago.

B. *Stumbling Blocks*

Why have improvement efforts fallen short? A number of expert commentaries have addressed this question and draw some consistent conclusions.²⁴ First, inevitably, the initial surge of enthusiasm waned, and patient safety eventually took its place in the host of pressing problems that compete for attention in health care delivery systems. Second, the goalposts shifted into the distance. More recent studies

20. Pronovost et al., *supra* note 19.

21. Haynes et al., *supra* note 19.

22. CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL AND STATE HEALTHCARE ASSOCIATION INFECTIONS: PROGRESS REPORT 5–6 (2016), <https://www.cdc.gov/HAI/pdfs/progress-report/hai-progress-report.pdf>.

23. DANIEL R. LEVINSON, OFFICE OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., OEI-06-09-00090, ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES, at i (2010) (estimating that 1 in 7 Medicare beneficiaries discharged from hospitals in October 2008 experienced an adverse event during their stay); Rebecca J. Baines et al., *Changes in Adverse Event Rates in Hospitals over Time: A Longitudinal Retrospective Patient Record Review Study*, 22 *BMJ QUALITY & SAFETY* 290, 292–93 (2013) (showing adverse event rates among hospitalized patients in the Netherlands increased from 4.1% in 2004 to 6.2% in 2008 and rates of preventable adverse did not change); Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 *NEW ENG. J. MED.* 2124, 2127–30 (2010) (showing no significant reductions in rates in adverse events or preventable adverse events in 10 hospitals that were actively pursuing improvements in patient safety); Yun Wang et al., *National Trends in Patient Safety for Four Common Conditions, 2005–2011*, 379 *NEW ENG. J. MED.* 341, 344 (2014) (finding declines in adverse event rates from 2005 to 2011 among patients hospitalized for myocardial infarction and congestive heart failure, but not among those hospitalized with pneumonia and conditions requiring surgery).

24. See, e.g., Kaveh G. Shojania & Eric J. Thomas, *Trends in Adverse Events over Time: Why Are We Not Improving?*, 22 *BMJ QUALITY & SAFETY* 273 (2013); Wachter, *supra* note 11; see also Mark R. Chassin, *Improving the Quality of Health Care: What's Taking So Long?*, 32 *HEALTH AFF.* 1761 (2013).

suggest that the true rate of medical injury exceeds the report's original estimates,²⁵ increasing the size of what was already an enormous challenge.

Third, and most importantly, after the patient-safety movement's early efforts successfully harvested some low-hanging fruit,²⁶ it became apparent that the etiology of medical error was much more complex than anticipated.²⁷ Health care delivery systems are more heterogeneous, fragmented, and multifaceted than other industries (e.g., airline, manufacturing) whose safety improvement strategies the report urged emulation. Consequently, the type of cross-cutting interventions that proved so successful in those industries did not translate neatly to health care. Rather, safety-improvement work in health care involves many specialty-, treatment-, and outcome-specific initiatives. It is, in large part, a thousand skirmishes, not the broad frontal assault that some movement leaders had envisioned.

Fourth, it became apparent almost immediately that the science of patient safety was overmatched.²⁸ The influx of adverse event reporting systems produced an explosion of information, but little of it was used to generate useful knowledge or guide action. Reporting was selective, crucial information on causal factors and patient outcomes was missing, and standardized definitions and frameworks for categorization and analysis were slow to emerge. Despite some noteworthy

25. MATT AUSTIN & JORDAN DERK, *LIVES LOST, LIVES SAVED: A COMPARATIVE ANALYSIS OF AVOIDABLE DEATHS AT HOSPITALS GRADED BY THE LEAPFROG GROUP* (2016); David 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); John T. James, A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care, 9 *J. PATIENT SAFETY* 122 (2013); Landrigan et al., *supra* note 23; Martin A. Makary & Michael Daniel, *Medical Error—The Third Leading Cause of Death in the US*, 353 *BMJ* i2139 (2016). *But see* Kaveh Shojania & Mary Dixon-Woods, *Estimating Deaths Due to Medical Error: The Ongoing Controversy and Why It Matters*, 26 *BMJ QUALITY & SAFETY* 423 (2017) (arguing that recent studies estimating higher rates of mortality due to medical error have substantial methodological flaws).

26. Examples of early wins include simple steps to reduce central-line-associated bloodstream infections, insert chest tubes more safely, avoid chemotherapy overdoses, and avoid accidental injection of highly concentrated solutions of potassium chloride. *See* Lucian L. Leape et al., *Promoting Patient Safety by Preventing Medical Error*, 280 *JAMA* 1444, 1444 (1998); *10 Patient Safety Tips for Hospitals*, AGENCY FOR HEALTHCARE RES. & QUALITY (Dec. 2009), <https://www.ahrq.gov/patients-consumers/diagnosis-treatment/hospitals-clinics/10-tips/index.html> (last updated June 2018).

27. NAT'L ACADS. OF SCI., ENG'G, & MED., *IMPROVING DIAGNOSIS IN HEALTH CARE 1* (Erin P. Balogh et al. eds., 2015).

28. Troyen A. Brennan et al., *Accidental Deaths, Saved Lives, and Improved Quality*, 353 *NEW ENG. J. MED.* 1405 (2005); Paul G. Shekelle et al., *Advancing the Science of Patient Safety*, 154 *ANNALS INTERNAL MED.* 693 (2011).

strides,²⁹ fundamental measurement challenges remain. As Kaveh Shojania and Eric Thomas have noted, one troubling consequence of this is that even if substantial improvement had occurred, it is still not clear we would know it.³⁰

Fifth, the bleak reality is that all of the effort and investment to date has produced disappointingly few interventions with proven efficacy in reducing errors. A number of the most widely adopted interventions—including computerized physician order entry and decision support, rapid response teams, medication reconciliation, time limits on trainee shifts, and efforts to improve safety culture—have demonstrated some success, but there are reasons to be cautious. Very few of the evaluations are rigorous enough to demonstrate causal associations, and successes in one place have often proved difficult to replicate in others.³¹

Indeed, it is increasingly clear that the effectiveness of prevention measures is highly context-dependent. This is the sixth factor underlying our slow progress on patient safety. Even technological interventions, like computerized order entry, and rigorously evaluated ones, like the surgical checklist, appear to be highly sensitive to the manner in which they are implemented and the environment into which they are placed.³² This context dependency raises fundamental questions about how useful conventional evaluation markers like average effects are in understanding the utility of interventions.

Seventh, as the patient-safety movement matured, disagreements emerged among its leaders about directions and priorities. One point of divergence related to what constituted sufficient proof of an inter-

29. See, e.g., World Health Organization, *More Than Words: Conceptual Framework for the International Classification for Patient Safety*, WHO/IER/PSP/2010.2 (2010), <http://www.who.int/patientsafety/implementation/taxonomy/ICPS-report/en/>.

30. Shojania & Thomas, *supra* note 24, at 274–75.

31. See, e.g., *id.*; Elzerie de Jager et al., *Postoperative Adverse Events Inconsistently Improved by the World Health Organization Surgical Safety Checklist: A Systematic Literature Review of 25 Studies*, 40 *WORLD J. SURGERY* 1842, 1843 (2016); Asad Latif et al., *Evaluating Safety Initiatives in Healthcare*, 4 *CURRENT ANESTHESIOLOGY REP.* 100, 100–01 (2014); Nuckols et al., *supra* note 19.

32. Checklists have emerged as a study in the importance of attending to institutional context and mode of implementation. See, e.g., PETER PRONOVOST & ERIC VOHR, *SAFE PATIENTS, SMART HOSPITALS: HOW ONE DOCTOR'S CHECKLIST CAN HELP US CHANGE HEALTH CARE FROM THE INSIDE OUT* (2010); Charles L. Bosk et al., *Reality Check for Checklists*, 374 *LANCET* 444, 445 (2009); Daniel E. Ho et al., *Do Checklists Make a Difference? A Natural Experiment from Food Safety Enforcement*, 15 *J. EMP. LEGAL STUD.* 242, 245–48 (2018) (reviewing evidence of the efficacy of checklists in health care and noting that their implementation is typically accompanied by a host of other institutional changes that may confound the “treatment effect” of the checklist itself); David R. Urbach et al., *Introduction of Surgical Safety Checklists in Ontario, Canada*, 370 *NEW ENG. J. MED.* 1029, 1030 (2014).

vention's efficacy to justify rollout. While some urged action even when limited evidence was available to support it, others urged caution until the efficacy of proposed interventions could be properly assessed.³³ Another divide pitted "lumpers" against "splitters." Whereas lumpers sought to focus effort and resources on high-level interventions, like team training or cultural improvements, with potential to drive reductions in many different forms of error, splitters saw tailored solutions to specific clinical problems as the most promising path forward. There is not an intrinsic conflict between these contrasting approaches; they can operate as effective complements.³⁴ But in setting priorities, these have sometimes manifested as competing worldviews.

Finally, we believe the patient-safety movement's extreme emphasis on systemic causes of error and shunning of individual accountability has contributed to its slow pace of achievement. This move, established as a core philosophy of the IOM report and espoused by patient-safety leaders ever since, was well intentioned. A shift away from the historical, near-exclusive focus on individuals' errors was also necessary and appropriate. And indubitably, the fresh, hard look at systems has led to good things, such as an improved climate for transparency about error. With the benefit of hindsight, however, we believe the pendulum swung too far away from individual accountability and toward systems-think. This impeded progress in some respects, not least by marginalizing an important group of potentially valuable partners: legal institutions.

II. THE PRODUCTION OF MEDICAL ERROR

A. *The Primacy of System Factors*

The IOM report, and the patient-safety movement that followed in its wake, roundly rejected the notion that legal accountability has a constructive role to play in addressing patient-safety objectives. The rejection was premised on two main claims. One claim is utilitarian, or pragmatic, in nature: Tackling individual failings is counterproductive

33. Andrew D. Auerbach et al., *The Tension Between Needing to Improve Care and Knowing How to Do It*, 357 *NEW ENG. J. MED.* 608, 608 (2007); Lucian L. Leape et al., *What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety*, 288 *JAMA* 501, 501 (2002); Kaveh G. Shojania et al., *Safe but Sound: Patient Safety Meets Evidence-Based Medicine*, 288 *JAMA* 508, 508 (2002); Robert W. Wachter & Peter J. Pronovost, *The 100,000 Lives Campaign: A Scientific and Policy Review*, 32 *JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY* 621 (2006).

34. Shojania & Thomas, *supra* note 24, at 274, make the interesting point that the "central line bundle," one of the most successful patient-safety intervention to date, included elements of both schools.

because it causes too much collateral damage to safety-improvement efforts overall. The other is scientific: To interpret error as the product of individual failings is to misunderstand its etiology. We review and evaluate both claims.

1. Pragmatism

The thrust of the pragmatic claim is that a focus on individual failings undermines efforts to improve patient safety because it has corrosive effects on transparency about error.³⁵ Blaming individuals stifles adverse event reporting and frustrates investigations into what went wrong and why. Blame also thwarts prevention by submerging information needed to design effective error-reduction measures and fouling the provider trust and buy-in on which successful implementation of such measures depends. The stock-in-trade of tort litigation and disciplinary systems is ferreting out and punishing individual failings. The IOM committee concluded that, although those mechanisms might redress individual instances of harm, they set the long game of safety improvement back.

The only legal intervention the report firmly recommended was to implement stronger rules to protect clinicians' statements regarding adverse events from use in legal proceedings. This was the reverse of an accountability move; it was a way for the legal system to curb its own destructive reach. Another way to mitigate the law's deleterious effects would be to abandon individually focused, fault-based liability altogether, replacing it with enterprise liability, no-fault compensation systems, or both. The report stopped short of recommending those models, but urged further consideration of them, noting that they "might produce a legal environment more conducive to reporting and analysis."³⁶

In 2001, the IOM published a second report, *Crossing the Quality Chasm*, which provided a more detailed roadmap for surmounting barriers to quality and safety improvement.³⁷ It took up the cudgel: Law, again, was placed among the barriers to be surmounted, not among the surmounting strategies. After echoing the first report's concerns about the noxious effect of the specter of liability on trans-

35. IOM REPORT, *supra* note 1, at 3 ("Providers also perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors."); *id.* at 22 ("Liability concerns discourage the surfacing of errors and communication about how to correct them."); *id.* at 43 (claiming that the threat of malpractice litigation "discourages the disclosure of errors" and that "[t]he discoverability of data under legal proceedings encourages silence about errors committed or observed[]").

36. *Id.* at 111.

37. See generally IOM, *CROSSING THE QUALITY CHASM*, *supra* note 9.

parency, the second report discussed chilling effects on innovation, technology adoption, and evidence-based care.³⁸ In addition, there was another nod to enterprise liability and no-fault compensation as alternatives that promised to be more hospitable to the work of quality improvement.³⁹

2. *The Science of Medical Error*

The claim that aggressive pursuit of individual accountability for errors in health care settings subverts safety-improvement activities has intuitive appeal and a considerable body of anecdotal evidence supporting it, although rigorous empirical evidence for the proposition is surprisingly hard to come by. But if it could be shown that holding clinicians individually accountable for some types of medical error did not lead them to suppress information or dampen their enthusiasm for patient-safety initiatives, would it be appropriate to do so?

The answer to this question in both IOM reports is a resounding “no.” The reports’ authors justified that position through several scientific claims regarding the etiology of medical error. These claims warrant close analysis because they remain influential today; they have become a leitmotif of the patient-safety movement, and have been instrumental in setting the tone of the movement’s relationship with legal institutions.

Drawing on accident research in other industries,⁴⁰ *To Err Is Human* explained that targeting individual behavior in efforts to address medical error is misguided because it rests on a misunderstanding of the role of human agency in the production of medical error:

One of the greatest contributors to accidents in any industry including health care, is human error. However, saying that an accident is due to human error is not the same as assigning blame because most human errors are induced by system failures. Humans commit errors for a variety of known and complicated reasons.⁴¹

In this account, errors arise from interactions between layers of causal factors, some of which relate to the decisions and actions of individuals and some of which transcend individuals. System factors encom-

38. See, e.g., *id.* at 79, 218–19 (discussing various negative effects of the legal system).

39. *Id.* at 20. *Crossing the Quality Chasm* went further than *To Err is Human* had here. It recommended that the federal government “fund research to evaluate how the current regulatory and legal systems (1) facilitate or inhibit the changes needed . . . and (2) can be modified to support health care professionals and organizations that seek to accomplish [the aims set forth in the report].” *Id.* at 20.

40. See, generally, two excellent accounts of evolving understanding of and approaches to error in other sectors: CHARLES PERROW, *NORMAL ACCIDENTS: LIVING WITH HIGH-RISK TECHNOLOGIES* (1984) and JAMES REASON, *HUMAN ERROR* (1990).

41. IOM REPORT, *supra* note 1, at 65.

pass an array of influences—organizational, technological, bureaucratic, and so on—that shape the environment in which care is delivered. When a medication overdose kills a patient, for example, the physician’s prescription error and the failure of the physician and pharmacist to catch it are types of individual factors. The hospital’s continuing use of handwritten prescriptions (instead of computerized order entry systems), confusing labels (instead of barcodes), and unsupervised trainee pharmacist shifts are all system factors.⁴²

When the individual and systems factors interact, as they often do in the production of medical error, the former are cast as the junior partners in this mix. Although they frequently appear as necessary elements in the causal chain and may be the most proximate causes, individual factors are always induced, enabled, amplified, and unstopped by upstream, systemic determinants.

This etiological account undergirds the conclusion that prevention measures must target system factors. As well as being the principal culprits in the causal chain, they are the most amenable to correction. System redesign has the potential to stop whole classes of error in their tracks. Emphasizing behavioral change at the individual level, by contrast, is a fool’s errand because, well, to err is human.

B. *An Inconvenient Truth*

Two decades of patient safety research confirms the reports’ characterization of medical error as complex and multifactorial in nature.⁴³ It is also true that the tort system’s frame for understanding how errors occur is too narrow to capture the full range of causal factors, and sits in some tension with wider efforts to improve safety.⁴⁴ (This is one reason we have been critical of the medical liability system and vocal advocates for the kind of liability reforms discussed in both IOM reports.⁴⁵) However, in so thoroughly de-emphasizing the importance of

42. For the sake of argument, we describe individual factors and system factors as distinct here. This is an oversimplification, both because the distinction between them is blurry for some errors and because they routinely interact as causal factors. Thus, the individual/system distinction is perhaps better understood as a spectrum, with each type of factor playing a more or less important role at different points along the spectrum. Our concept of “individual-dominant errors,” see *infra* Section B.1, accommodates this more nuanced reality.

43. See generally ROBERT WACHTER & KIRAN GUPTA, UNDERSTANDING PATIENT SAFETY (3d ed. 2017).

44. Michelle M. Mello & David M. Studdert, *Deconstructing Negligence: The Role of Individual and System Factors in Causing Medical Injuries*, 96 GEO. L.J. 599, 601 (2008).

45. *Id.* at 600; Michelle M. Mello et al., “Health Courts” and Accountability for Patient Safety, 84 MILBANK Q. 459, 464–66 (2006); David M. Studdert & Troyen A. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, 286 JAMA 217, 217 (2001).

individual factors in the production of medical error, *To Err Is Human* overplayed its hand.

The major flaw in that etiological account is that it assumes a degree of homogeneity across different types of medical error with respect to the relative importance of individual and system factors. As we shall argue, there is a good deal of heterogeneity among errors on this dimension. Thus, while rightly stressing the complexity of error causation, the report overlooked important variation in how different types of causal factors mix.

1. *Individual Dominant Errors*

Most medical errors are caused by a combination of individual and system factors; strands of both are evident in the causal chain, and the error is unlikely to have occurred without the independent and intertwined contributions of both.⁴⁶ For other errors, system factors are highly salient and can be considered dominant causes; indeed, there may be no contribution by a clinician at all, or only an incidental one. There is a third group of errors—certainly less common than errors in the first group, and probably less common than those in the second group—in which the actions (or inactions) of individual clinicians dominate as causes. System factors may also be in play, but to suggest that the individual's role is somehow subordinate to system factors stretches credulity. Moreover, an attempt to configure the individual factors as a form of systemic failure summons so spectacularly broad a conception of what constitutes “systemic” as to render the term quite meaningless.

Table 1 provides several illustrative examples. Vignette 1 describes a “system dominant error.” Vignette 2 describes an error in which it would be difficult to conclude whether system or individual factors played a dominant causal role. These are textbook examples of adverse events, and the literature is replete with similar examples. Our focus is to contrast these errors with others whose causality is dominated by failures of individuals. Vignettes 3 and 4 describe such “individual dominant errors” (IDEs).

It is useful to divide IDEs into those that are not appreciably more likely to recur at the hands of the same clinician than at the hands of a colleague (“type I” IDEs, Vignette 3) and those that stem from some underlying trait of the clinician that has played a causal role in past errors, portends an elevated risk of future errors, or both (“type II” IDEs, Vignette 4). The trait may be incompetence or inexperience,

46. See Mello & Studdert, *supra* note 44, at 600, 610.

such as the clinician's inability to perform a particular procedure safely. It may be a personality flaw, such as arrogance, lack of insight, inability to work effectively as part of a team, or unwillingness to learn from experience. Or the trait may be an impairment, such as fatigue, mental illness, or addiction, which interferes with the clinician's ability to deliver to safe care.

2. *System Factors Are Not Always Trumps*

We have floated our notion of IDEs in patient-safety circles, and it gets a cool reception. In discussions with fellow researchers and experts over the years, several lines of resistance have become familiar.

One line rejects the basic premise that individual factors can stand alone as causes of error, or eclipse system factors in importance. According to this argument, every individual causal factor is better understood as a system factor. Characterizing the errors described in the third and fourth vignettes in Table 1 as individual dominant, for example, reflects a unidimensional understanding of the etiology of these errors. In Vignette 3, a nurse or resident might have corrected Dr. Y's error, especially if the hospital's culture had empowered them to speak up. In Vignette 4, the error is likely traceable to the hospital leadership's willingness to allow Dr. Y to continue to operate.

Taking this approach, one can easily expose the "superficiality" and "falsehood" of attributing errors primarily to individual factors. Indeed, the legions of patient-safety consultants who appeared in the wake of the report would teach the paramouncy of system factors with case studies designed to re-educate in precisely this way.

Consider another example: A neurosurgeon chooses to conduct a complex, non-emergent, high-risk procedure with which he has minimal experience in a rural hospital that does not have the staff and facilities needed to safely support the operation.⁴⁷ Errors occur during and after the operation, and the patient experiences a catastrophic outcome. Any number of system-level interventions may have prevented the harm: "speak up" protocols and training for ancillary providers; hospital rules prohibiting performance of certain high-risk procedures; rules regarding when procedures should be referred out to other institutions; stricter re-credentialing requirements for the medical staff; and so on.

But the argument that this error, any more than those described in Vignettes 3 and 4, should be understood primarily as a product of sys-

47. This vignette is an adaptation of the fact pattern in *Johnson v. Kokemoor*, 525 N.W.2d 71, 74 (Wis. Ct. App. 1994).

TABLE 1. SYSTEM DOMINANT ERRORS AND INDIVIDUAL DOMINANT ERRORS.

| Type of Error | Illustrative Vignette |
|---|--|
| <i>System dominant</i> | 1. A physician writes a prescription for a new medication for which there is a drug-drug interaction. The interaction is severe, but rare and not well-known among providers. The hospital has a computerized order entry system and the physician uses it appropriately in making the prescription, but the drug-drug interaction database to which the system refers to has not been updated to include this particular interaction. The patient takes the new medication, the interaction occurs, and the patient dies. |
| <i>Neither system nor individual dominant</i> | 2. In an effort to save money and standardize care, a hospital stops allowing orthopedic surgeons to use whichever prosthetic discs they prefer in lumbar disc replacement surgery. An exclusive purchasing arrangement is made with Zebra, a highly regarded device company. Dr. Y is an orthopedic surgeon at the hospital who has limited experience with Zebra disc prostheses and the accompanying tools. In one of her first operations using a Zebra disc, she inserts it using a technique that is appropriate for the prosthesis she is accustomed to using but inappropriate for Zebra's prosthesis. The disc later becomes loose and painful, requiring a complicated second operation. |
| <i>Individual dominant – type I</i> | 3. Same facts and patient outcome as Vignette 2, except: The exclusive switch to Zebra's disc prosthesis was inconsequential for Dr. Y because she had been using them for years with very good results. It was a momentary and inexplicable lapse in her attention during the disc replacement surgery that led to the operative error that resulted in the patient's poor outcome. |
| <i>Individual dominant – type II</i> | 4. Same facts and patient outcome as Vignette 2, with additional facts: The hospital's Department of Orthopedic Surgery led the consolidated purchasing initiative and underwent a rigorous consultative process with staff in deciding which device company to choose. It then organized a series of training sessions for surgeons who lacked experience with Zebra prostheses. Dr. Y did not participate in the consultation process; she had stopped going to department meetings and participating in hospital activities years ago. She also rejected repeated personalized invitations to enroll in the training sessions, stating in response to one that she was "just too busy these days for extra homework." |

tem failures is unpersuasive for a couple of reasons. First, it muddles an *ex ante* claim about the etiology of error with an *ex post* claim about a preferred approach to prevention. To say that a system-level change may have prevented an IDE is not equivalent to saying a system failure caused it. The neurosurgeon's misjudgment and overconfidence in the example above is crucial to understanding what happened, as is the orthopedic surgeon's apathy, arrogance, and isolation in Vignette 4. Moves to de-emphasize such individual causal factors downplay and likely perpetuate a patient-safety risk.

To be clear, we do not dispute that the optimal interventions for addressing some (perhaps many) IDEs lie at the system level, not the individual level. Our point is that the background possibility that a system-level intervention could have prevented the error cannot remake the etiology of an IDE that has already occurred. If this distinction sounds semantic, it is not; to victims of medical injury who seek provider accountability, it is sharp and consequential.

A second weakness in the systems-as-trumps argument is that it rests on undue optimism about the availability and efficacy of preventive measures. It uses a lens that reflects the sanguinity of the IOM report, not the sobering real-world experience that followed. To return to the neurosurgery example, could a system-level intervention *really* have prevented that adverse outcome? Which intervention, or combination of interventions, exactly? Has the intervention's efficacy in averting the type of harm at issue been demonstrated? Is it feasible to implement? In ameliorating the targeted safety risk, does it inadvertently give rise to others? And can we be confident that it would have averted the harm *in this case*? Given the scarcity of patient-safety interventions with proven efficacy, the standard answers to these questions are don't know, maybe, or no. Appeals to the optimality of system-level interventions to prevent error ring hollow if those interventions cannot actually be identified or evidence of their efficacy is lacking.

An alternative line of resistance to IDEs is to accept the construct, but point to a version of the pragmatic claim articulated in the report. Namely, even if characterizing these errors as fundamentally individual in nature is accurate, and even if remedial measures focusing on individual accountability are indicated, that strategy exacts too high a toll on the larger safety-improvement enterprise.

This objection has force. However, we are suspicious of it as an absolute claim on two grounds. First, IDEs are more important pieces in the overall picture of medical error than has been generally assumed, and as a result, the pragmatic calculus may underestimate the poten-

tial benefits of strategies aimed at addressing them. Research suggests that IDEs may account for a small proportion of all adverse events, and even a minority of the quarter of adverse events that are due to negligence.⁴⁸ But there is emerging epidemiological evidence, which we review in Part V below, that IDEs are nevertheless quite common. Studies show that malpractice claims and patient complaints are unevenly distributed across physicians, with a relatively small group of “frequent flier” physicians accounting for a substantial proportion of them. These findings also show that type II IDEs, in particular, may be a substantial problem in this subpopulation.⁴⁹ Of course, malpractice claims and patient complaints are the iceberg’s tip. Frequent fliers treat hundreds of thousands of patients each year, generating many more poor outcomes that never surface as claims or complaints.

Second, the collateral-damage argument is unsubtle. Simply declaring that pursuing individual accountability for error is objectionable to rank-and-file practitioners falls back into the old trap of ignoring heterogeneity in types of errors and persons who commit them. What if a subset of practitioners who pose special risks to patients—recurrent committers of type II IDEs—could be reliably identified and dealt with in ways that substantially reduced risks to patients? It seems plausible that other providers would welcome that. It would not escape their notice that these are the same practitioners who are often refractory to quality-improvement initiatives; who, in team-based care settings, expose their colleagues to heightened medico-legal risk; and who threaten the credibility of a blame-free, systems orientation.

Thus, finding effective ways to isolate and manage the relatively small subgroup of providers who are at high risk for future involvement in certain kinds of errors may well help, not hinder, the wider patient-safety enterprise. It happens to be a task that legal institutions, particularly medical boards and liability insurers, are best positioned to undertake.

48. See Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients*, *supra* note 3, at 371–72, and Thomas et al., *Incidence and Types of Adverse Events*, *supra* note 3, at 261, both finding that approximately one-quarter of adverse events among hospitalized patients were due to negligent care. See also Eric J. Thomas et al., *Costs of Medical Injuries in Utah and Colorado*, 36 *INQUIRY* 255, 259 (1999) (finding that 58% of adverse events among hospitalized patients in Utah and Colorado in 1992 were preventable).

49. See *infra* notes 89–92.

C. Consequences for Safety Improvement

The patient-safety movement's over-systematized account of the etiology of medical error has adversely impacted progress on quality improvement in at least two ways.

The first relates to disclosure of adverse events to patients and families. Following publication of the report, physicians, hospitals, regulators, and accreditation agencies coalesced around the idea that disclosure was a professional imperative.⁵⁰ Broad agreement emerged that patients had a right to know what happened, how it happened, and what was being done to ensure it would not happen to other patients. But at the same time that the IOM report propelled disclosure into routine practice, it undermined its moral force. By emphasizing errors as systems problems, it undercut physicians' inclination to communicate a meaningful, authentic acceptance of responsibility for them.

One manifestation of this problem has been the controversy over whether disclosures should include an apology, and if so, what sort of apology. In the view of some patient-safety experts, an apology of responsibility ("I am sorry I/we harmed you") was a step too far. It overemphasized human agency and contravened the etiologic paradigm of a system breakdown. Apologies of sympathy ("I am sorry this happened") became prevalent in organizations that adopted this way of thinking.⁵¹ Or, if an apology of responsibility was offered, it was often done grudgingly and strategically, out of awareness that apology can be effective in reducing patients' dissatisfaction and propensity to sue.⁵²

Patients and family members hear this inauthenticity loud and clear, and they resent it.⁵³ They want to know that someone is genuinely

50. Gallagher et al., *Disclosing Harmful Medical Errors to Patients*, *supra* note 17, at 2713.

51. Thomas H. Gallagher et al., *Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients*, 166 ARCHIVES INTERNAL MED. 1585, 1589 (2006).

52. See Richard C. Boothman et al., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, 2 J. HEALTH & LIFE SCI. L. 125, 143, 159 (2009) [hereinafter Boothman et al., *A Better Approach to Medical Malpractice Claims?*] (explaining the mechanisms of effect in such programs); Allen Kachalia et al., *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*, 153 ANNALS INTERNAL MED. 213, 213 (2010) [hereinafter Kachalia et al., *Liability Claims and Costs*] (finding an association between the adoption of a communication-and-resolution program and reductions in both malpractice claims volume and malpractice costs at an academic medical center).

53. Jennifer Moore et al., *Patients' Experiences with Communication-and-Resolution Programs After Medical Injury*, 177 JAMA INTERNAL MED. 1595, 1599 (2017); Jennifer Moore & Michelle M. Mello, *Improving Reconciliation Following Medical Injury: A Qualitative Study of Responses to Patient Safety Incidents in New Zealand*, 26 BMJ QUALITY & SAFETY 788, 792 (2017).

accepting responsibility for what occurred.⁵⁴ They place trust in their clinician, and when things go badly, they look to the clinician for answers.⁵⁵ They have very limited tolerance for descriptions of causal webs and upstream determinants—convolutions that deflect attention from the role of people. There is no escaping the reality that families' reactions to the experience of a harmful medical error, especially an IDE, include expectations of individual accountability. But the centrality of systems thinking within health care has inhibited the providers' capacity to discern and meet this expectation.

A second, more insidious consequence of the report's conceptualization of medical error and roadmap for addressing it was—certainly within the quality-improvement enterprise and probably beyond—an erosion of the legitimacy of legal institutions focused on individual accountability. The two main legal institutions charged with protecting patients against substandard care are state medical licensing boards and the tort system, which we collectively call medico-legal agencies (MLAs). For MLAs, the movement's manifesto and directions were marginalizing. They were viewed as non-partners in safety improvement and called upon to try to do as little as possible of what they had always done.

This was a missed opportunity. To be sure, MLAs' historical role in quality improvement has been underwhelming, and in some respects counterproductive. And there is certainly tension between the vision and methods of the MLAs and those of the patient-safety movement. But here was a moment to begin a process of recalibrating the mission of MLAs and finding new opportunities for them to contribute to safety improvement. With a few notable exceptions, that did not happen.

III. CROSSING THE OTHER QUALITY CHASM

The collection of tensions that exist between the respective agendas of the patient-safety movement and MLAs have been described and analyzed at length elsewhere.⁵⁶ For current purposes, it is sufficient to provide a brief summary of the major ones: differences in perspective, unit of interest, detection capacity, and transparency. These differ-

54. Thomas H. Gallagher et al., *Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors*, 289 JAMA 1001, 1003 (2003).

55. Moore et al., *supra* note 53, at 1598 tbl.3, 1601; Moore & Mello, *supra* note 53, at 793.

56. See, e.g., David A. Hyman & Charles C. Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893 (2005); Mello et al., *supra* note 45; Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL., POL'Y & L. 375 (2005); Studdert & Brennan, *supra* note 45.

ences collectively comprise a chasm that is broad, deep, and consequential—the other quality chasm.

A. *The Other Chasm*

The most glaring tension between the patient-safety movement and MLAs relates to perspective. The central goal of safety-improvement work is to prevent future errors and harms. Aspects of this work are backward-looking—for example, root-cause analyses and epidemiological studies of error—but that perspective is instrumental: its overriding purpose is to derive lessons for improving care prospectively. MLAs, by contrast, are intrinsically backward-looking and reactive. Malpractice actions address specific provider behaviors and patient injuries that have already occurred. Disciplinary actions do the same, although their purview may extend to addressing certain risky behaviors that have not (yet) caused actual patient harm.

MLAs' perspective is also highly circumscribed. Whereas risky patterns of care are the gold nuggets that patient-safety analysts seek to discover and redress, rules of evidence generally dictate that only acts and omissions directly responsible for the harm at issue may be considered in litigation. Thus, courts will usually be required to disregard a defendant's checkered history of similar errors as extraneous and potentially prejudicial to the case at hand.⁵⁷ With more relaxed evidentiary rules, disciplinary inquiries and hearings have more latitude, but not a lot more.

Another key point of divergence between the patient-safety movement and MLAs relates to the type of threat to which each responds. In patient-safety work, all unexpected events, from “near misses” to catastrophic injuries, matter—regardless of cause or severity. All are considered useful signals of quality-of-care problems and potentially valuable inputs for designing prevention strategies. MLAs, in contrast, have a considerably narrower focus. Malpractice litigation targets negligent care that causes harm, and disciplinary actions target unprofessional conduct. By patient-safety standards, this approach is misguided because only a minority of adverse events involve negligence or unprofessional conduct,⁵⁸ leaving the lion's share of medical injury outside MLAs' field of vision.

57. Aaron S. Kesselheim et al., *Will Physician-Level Measures of Clinical Performance Be Used in Medical Malpractice Litigation?*, 295 JAMA 1831, 1832 (2006).

58. See Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients*, *supra* note 3, at 371 (estimating that approximately 30% of inpatient adverse events in New York hospitals in 1984 involved negligence); Thomas et al., *Incidence and Types of Adverse Events*, *supra* note 3, at 261 (estimating that approximately 30% of adverse events in Utah and Colorado

While true as a general description of the epidemiology of medical error, this critique elides the fact that *preventable* adverse events are the principal target of safety-improvement work. Negligent care is implicated in nearly half those events and in an even higher proportion of the most serious ones.⁵⁹ Moreover, the incidence of negligent adverse events is likely to be correlated with the incidence of non-negligent adverse events at both individual and institutional levels. So, if deterrence worked, targeting the former could have positive spillover effects on the latter. Thus, if all else were equal, a focus on errors associated with negligence and misconduct should be a useful complement to tackling a wider array of adverse events by other means. In our view, the quarrels patient-safety experts and advocates have with MLAs' relatively narrow focus are better understood as a proxy for other concerns about them, such as MLAs' emphasis on individual accountability and their anemic performance in deterring error.

In fact, the most troubling dimension of MLAs' coarseness is not the unit of analysis they favor but their poor performance in detecting it. The gist of this problem is that MLAs net a lot of kelp and let many sharks swim by.⁶⁰ Early research into the epidemiology of malpractice litigation suggested that the kelp—unfounded malpractice claims, or “false positives”—were a major problem; more recent evidence suggests otherwise.⁶¹ Malpractice claims rarely occur in the absence of patient injury, and they target negligent care more often than not.⁶² “False negatives,” on the other hand, are a much bigger problem: The vast majority of injuries caused by negligent care are never litigated.⁶³

hospitals in 1992 involved negligence); Michelle M. Mello et al., *Outcomes in Two Massachusetts Hospital Systems Give Reason for Optimism About Communication-and-Resolution Programs*, 36 HEALTH AFF. 1795, 1798, 1801 (2017) (finding that substandard care was implicated in about a quarter of adverse events reported to risk managers in Massachusetts hospitals).

59. David M. Studdert et al., *Can the United States Afford a “No-Fault” System of Compensation for Medical Injury?*, L. & CONTEMP. PROBS., Spring 1997, at 2; Studdert & Brennan, *supra* note 45, at 220.

60. See PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION 75 (1993) (invoking a similar metaphor, that of a traffic cop who lets many offenders proceed while stopping many law-abiding drivers).

61. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2025 (2006).

62. *Id.*; A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III*, 325 NEW ENG. J. MED. 245, 245 (1991); Troyen A. Brennan et al., *Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation*, 335 NEW ENG. J. MED. 1963, 1966–67 (1996).

63. Helen R. Burstin, *Do the Poor Sue More? A Case-Control Study of Malpractice Claims and Socioeconomic Status*, 270 JAMA 1697, 1697–98 (1993); David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE 250, 255 (2000) [hereinafter Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*].

The false-negative problem almost certainly plagues medical licensing boards, too. The incidence of such sanctions is very low, approaching zero annually in some states.⁶⁴ With limited resources and investigative and prosecutorial capacity, boards prioritize forms of conduct that are relatively easy to detect and prove. Sexual relationships with patients, substance abuse, impairment, and inappropriate advertising and billing are examples of such conduct. Garden-variety forms of substandard care and incompetence, on the other hand, are harder to identify and prove. Consequently, boards tend to pursue only the most egregious of such cases, and often only after malpractice litigation has unearthed them and assembled an evidentiary record.⁶⁵

Finally, MLAs and patient safety part ways on transparency. We have discussed the premium the movement places on informational openness, and the threat the liability system is perceived to pose to that objective. Within MLAs themselves, openness remains a foreign concept. During the adjudication process, the information is held close for fear of prejudicing case outcomes. After case closure, detailed information on what happened is not pooled and subjected to the type of causal analysis that patient-safety researchers value. It remains spread across liability insurance companies, attorneys' offices, the offices of professional boards, and courts. And thanks to confidentiality agreements among litigants, it is routinely cloaked in a veil of permanent secrecy.⁶⁶ For patient-safety experts and advocates, this data loss represents a woeful missed opportunity for learning.

B. Crossing Points

Although the chasm between the patient-safety movement and MLA approaches remains wide, some bridges have appeared or extended their arc over the last twenty years. We identify four of these bridges in this Section and elaborate on a fifth in the next Section.

First, health-services researchers have intensified their efforts to mine the data trove submerged within the malpractice litigation system. As hospital- and state-based adverse event reporting systems grew in prevalence, awareness dawned that the medical malpractice

64. Sidney M. Wolfe et al., *Public Citizen's Health Research Group Ranking of the Rate of State Medical Boards' Serious Disciplinary Actions, 2009-2011*, PUB. CITIZEN (May 17, 2012), <https://www.citizen.org/sites/default/files/2034.pdf>.

65. Haavi Morreim, *Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank*, 27 OHIO ST. J. ON DISP. RESOL. 109, 163 (2012). See also generally TROYEN A. BRENNAN & DONALD M. BERWICK, *NEW RULES: REGULATION, MARKETS, AND THE QUALITY OF AMERICAN HEALTH CARE* (1996).

66. See generally Michelle M. Mello & Jeffrey N. Catalano, *Should Malpractice Settlements Be Secret?*, 175 JAMA INTERNAL MED. 1135 (2015).

system naturally generated much of the information those reporting systems sought to collect. Litigation was, in a sense, an adverse event reporting system of its own. It was a biased reporting system, to be sure, skewed toward adverse events that involved severe injuries and suspected negligence. It eventually became clear, however, that every reporting system suffered from one form of selective reporting or another, sometimes dramatically so. Thus, the bias evident in malpractice claims data could hardly be considered a fatal flaw.

In figuring out how to harness the value of claims data, an unlikely group lit the way: anesthesiologists. As early as 1984, a research team based at the University of Washington with ties to the American College of Anesthesiology nurtured relationships with several dozen liability insurers and developed tools and methods for periodically harvesting those insurers' claims data. The researchers then used the data to study a range of problems in anesthesia and develop safety-enhancing interventions, with impressive results.⁶⁷

Their success inspired other efforts, including several studies led by Harvard-based teams.⁶⁸ The broadest of these efforts was the Malpractice Insurers Medical Error Prevention Study (MIMEPS) in the early 2000s, which sought to apply the anesthesiologists' approach to a wider range of clinical areas.⁶⁹ Drawing on the claim review methodology developed in the MIMEPS project, the Controlled Risk Insurance Company (CRICO), the professional liability insurer for the

67. Frederick W. Cheney, *The American Society of Anesthesiologists Closed Claims Project: What Have We Learned, How Has It Affected Practice, and How Will It Affect Practice in the Future?*, 91 ANESTHESIOLOGY 552 (1999).

68. For a description of three studies that were designed to address quality problems (in emergency, critical, and surgical care, respectively) and were motivated in part by problems identified in the Harvard hospitals' malpractice claims experience, see Helen R. Burstin et al., *Benchmarking and Quality Improvement: The Harvard Emergency Department Quality Study*, 107 AM. J. MED. 437 (1999); Jeffrey P. Burns et al., *Results of a Clinical Trial on Care Improvement for the Critically Ill*, 31 CRITICAL CARE MED. 2107 (2003); and Atul A. Gawande et al., *Risk Factors for Retained Instruments and Sponges After Surgery*, 348 NEW ENG. J. MED. 229 (2003). See also *infra* note 69.

69. See generally Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, *supra* note 61. For other products of the MIMEPS project, see Tejal K. Gandhi et al., *Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims*, 145 ANNALS INTERNAL MED. 488 (2006); Caprice C. Greenberg et al., *Patterns of Communication Breakdowns Resulting in Injury to Surgical Patients*, 204 J. AM. C. SURGEONS 533 (2007); Allen Kachalia et al., *Missed and Delayed Diagnoses in the Emergency Department: A Study of Closed Malpractice Claims from 4 Liability Insurers*, 49 ANNALS EMERGENCY MED. 196 (2007); Scott E. Regenbogen et al., *Patterns of Technical Error Among Surgical Malpractice Claims: An Analysis of Strategies to Prevent Injury to Surgical Patients*, 246 ANNALS SURGERY 705 (2007); Selwyn O. Rogers et al., *Analysis of Surgical Errors in Closed Malpractice Claims at 4 Liability Insurers*, 140 SURGERY 25 (2006); Hardeep Singh et al., *Medical Errors Involving Trainees: A Study of Closed Malpractice Claims from 5 Insurers*, 167 ARCHIVES INTERNAL MED. 2030 (2007).

Harvard-affiliated hospitals, established a business subsidiary to offer a service that harvested information from claim files. Dozens of insurers and providers now share their data and approximately thirty percent of all closed malpractice claims in the United States are subjected to this systematic review.⁷⁰ The data are analyzed to identify causal factors, and the organizations that provided them receive benchmarking and other feedback.

Second, many liability insurers have become advocates for transparency and disclosure following adverse events. To be sure, many still crouch in the traditional “deny and defend” position, but they are increasingly regarded in the professional liability community as dinosaurs. Progressive organizations communicate expectations to their insureds that adverse events will be disclosed to patients, and they offer guidelines and supports to help ensure these conversations go well. For example, guidelines issued by CRICO highlight important needs that injured patients have and urge providers to obtain just-in-time disclosure coaching before initiating communications.⁷¹

Third, a growing number of liability insurers have implemented alternative approaches to patient compensation that are more compatible with patient-safety objectives.⁷² Known as “communication-and-resolution programs” (CRPs) these approaches combine disclosure with rapid investigation and proactive offers of compensation in cases where an error caused serious harm.⁷³ Such programs have attracted interest from hospital systems and liability insurers primarily because early adopters achieved radical reductions in claims costs,⁷⁴ but they are also appealing because they promote transparency about adverse

70. CRICO, *How Does Your Organization Compare?*, HARVARD, <https://www.rm.f.harvard.edu/Products-and-Services/CRICO-Strategies-Products-and-Services/CBS> (last visited Jan. 24, 2019).

71. Debbie LaValley, *Guidelines for Disclosure*, HARVARD (Sept. 12, 2016), <https://www.rm.f.harvard.edu/Clinician-Resources/Guidelines-Algorithms/2009/Guidelines-for-Disclosure>.

72. Some insurers even market these programs as a customer benefit that differentiates them from competitors, under the mantle of “de-escalation services.” See, e.g., *Claims*, COVERYS, <https://www.coverys.com/Services/Claims> (last visited Jan. 24, 2019) (“In some instances, litigation can be avoided by responding effectively when a dispute first emerges. To help you leverage this important window, we offer a proprietary service known as REACT—free to eligible policyholders . . .”).

73. For a general overview of the approach, see Boothman et al., *supra* note 52; Mello et al., *supra* note 58; *About CARE*, MACRMI, <http://www.macrmi.info/about-macrmi/about-dao/#sthash.SF4ztdbq.dpbs> (last visited Jan. 24, 2019); *Communication & Resolution Programs*, COLLABORATIVE FOR ACCOUNTABILITY & IMPROVEMENT, <http://communicationandresolution.org/communication-and-resolution-programs/> (last visited Jan. 24, 2019).

74. See Kachalia et al., *Liability Claims and Costs*, *supra* note 52, at 213; Bruce L. Lambert et al., *The “Seven Pillars” Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes*, 51 HEALTH SERVS. RES. 2491, 2491–92 (2016).

events, as well as learning from errors.⁷⁵ Indeed, leading proponents of the CRP model, such as Richard Boothman at the University of Michigan Health System, characterize the model as a patient-safety program first and a risk-management program second.⁷⁶

Fourth, although state medical boards look, in many respects, much as they did a half-century ago,⁷⁷ advances in a few areas reflect the ideals of the patient-safety movement. One remarkable shift has occurred in Washington, where the Medical Quality Assurance Commission (MQAC) had long maintained a reputation as one of the most punitive boards in the country. MQAC agreed to partner with a group of researchers at the University of Washington⁷⁸ and the Washington State Foundation for Health Care Quality to pilot a new regulatory approach known as “CRP Certification.”⁷⁹ Certification involves a panel of CRP experts and patient advocates reviewing CRP cases that have been voluntarily submitted by the involved facility, insurer, or clinician to determine whether the response to the event on the part of the hospital, the insurer, or both faithfully included all of the key elements of the CRP process: timely reporting and disclosure of the adverse event, event analysis and prevention planning, resolution communications with the patient, and disseminated learning.⁸⁰ If so, the case is deemed “CRP Certified,” and the presumption is that MQAC will close such cases as satisfactorily resolved without impos-

75. Boothman et al., *A Better Approach to Medical Malpractice Claims?* *supra* note 52, at 139, 145–46 (discussing the patient-safety benefits of the University of Michigan Health System’s program); Mello et al., *supra* note 58, at 1795–96 (finding that Massachusetts communication-and-resolution programs frequently identified safety-improvement interventions based on their investigations).

76. Richard C. Boothman et al., *Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk Through Disclosure: Lessons Learned and Future Directions*, 28 *FRONTIERS HEALTH SERVS. MGMT.* 13, 17 (2012) (“To understand the Michigan Model, it is critical to understand that the claims management process is only the public face of an organic culture shift that seeks to elevate patient safety to the foreground and relegate claims considerations to the background.”).

77. See generally BRENNAN & BERWICK, *supra* note 65; MALCOLM K. SPARROW, *THE REGULATORY CRAFT: CONTROLLING RISKS, SOLVING PROBLEMS, AND MANAGING COMPLIANCE* (2000).

78. One of us (M.M.) has been involved in this initiative, which is being led by Tom Gallagher at the University of Washington.

79. Thomas H. Gallagher et al., *Collaboration with Regulators to Support Quality and Accountability Following Medical Errors: The Communication and Resolution Program Certification Pilot*, 51 *HEALTH SERVS. RES.* 2569, 2572 (2016) [Gallagher et al., *Collaboration with Regulators to Support Quality and Accountability Following Medical Errors*].

80. Thomas H. Gallagher, *CRP Certification: Promoting Accountability and Learning After Adverse Events*, GRANTOME, <http://grantome.com/grant/NIH/R18-HS024504-01> (last visited Jan. 24, 2019).

ing discipline.⁸¹ The CRP Certification program enshrines several pillars of the patient-safety movement: the notion that disciplinary process may unfairly blame individual providers for systems failures; a preference for nonpunitive processes of adverse-event investigation and resolution; and involvement of patients and patient advocates in event resolution and learning.⁸² The program has faced a number of challenges in launching,⁸³ but represents an important step toward a different kind of role for medical boards.

Although the Washington experiment is *sui generis*, at least for now, a broader initiative among state medical boards has been to strengthen the showings that practitioners must make concerning their continuing competence in order to renew their licenses. In 2010, the Federation of State Medical Boards, which represents and supports seventy medical and osteopathic boards in the United States and its territories,⁸⁴ adopted a framework for “Maintenance of Licensure.” The framework recommended that member boards require practitioners to regularly participate in three types of activities: (1) “reflective self-assessment” of their areas of strength and weakness; (2) objective assessments of skills and knowledge, which could include examinations administered by medical specialty boards;⁸⁵ and (3) evaluations of their performance in actual clinical practice.⁸⁶ Although individual state boards have discretion over implementing the framework and many are still in the process of doing so, adoption of the framework is a sign that boards as a group are taking seriously their obligation to

81. “Cases involving providers who pose a significant risk of harm to patients through gross incompetence, recklessness, boundary violations, provider impairment, or intentional misconduct are ineligible for CRP certification.” Gallagher et al., *Collaboration with Regulators to Support Quality and Accountability Following Medical Errors*, *supra* note 79, at 2574. One reason for this carveout is to keep frequent fliers squarely on MQAC’s radar screen.

82. *Id.* at 2569–71.

83. *Id.* at 2577–79.

84. *About FSMB*, FED’N ST. MED. BOARDS, <https://www.fsmb.org/about-fsmb/> (last visited Jan. 24, 2019).

85. In a parallel “maintenance of certification” movement, medical specialty boards, which certify physicians as competent in particular clinical specialties, have increasingly adopted maintenance of certification requirements that require practitioners to submit to periodic examinations to demonstrate their continuing competence and to participate in various quality-improvement initiatives. These requirements have confronted heated opposition from physicians and remain controversial. Kachalia et al., *Legal and Policy Interventions to Improve Patient Safety*, *supra* note 11, at 665. The FSMB’s maintenance of licensure framework envisions that participation in maintenance of certification activities would satisfy the maintenance of licensure requirements. Humayun J. Chaudhry et al., *Maintenance of Licensure: Supporting a Physician’s Commitment to Lifelong Learning*, 157 *ANNALS INTERNAL MED.* 287, 288 (2012).

86. Chaudhry et al., *supra* note 85, at 287–88; DAVID A. JOHNSON & HUMAYUN J. CHAUDHRY, *MEDICAL LICENSING AND DISCIPLINE IN AMERICA: A HISTORY OF THE FEDERATION OF STATE MEDICAL BOARDS* 263 (2012).

actively monitor provider competence, as opposed to merely reacting to reports of serious competence problems that arrive on their doorstep.

In summary, there are several ways MLAs have begun bridging the chasm that separates them from the patient-safety movement. These moves are tentative and by no means widespread, but nonetheless indicate that these actors are capable of re-envisioning their role in combating medical errors. As we discuss in the following Section, there is much more they could do. In particular, they could, and should, improve their capacity to identify and address the safety risks posed by problem physicians.

IV. A PROMISING TOEHOLD: FREQUENT FLIERS

Dr. X, a cardiologist, has been sued three times in the last three years—a significantly higher rate than the regional average for cardiologists. Two of the suits ended in settlement payments. Dr. X was also censured by the state medical board for a fourth incident following the board's investigation of a patient complaint. Dr. X's liability insurer, The RiskShrink Group, assisted Dr. X in all four disputes and retains detailed information on them.

RiskShrink routinely uses a predictive algorithm to determine risks of future medico-legal events for each of its insured practitioners. The algorithm combines information on practitioners' demographic characteristics, specialty, clinical load, practice location and setting, and past events to produce an individualized risk score. Dr. X's score is high, indicating a substantial risk of additional claims and/or disciplinary actions within the next two years.

RiskShrink responds by conducting an internal review of Dr. X's cases.

Summaries of the cases suggest they are unrelated, but closer analysis shows otherwise. All three plaintiffs had coronary artery disease and heart failure. Dr. X placed stents in each patient and all of them suffered myocardial infarctions within six months. Reports from several of the plaintiffs' experts criticized the post-procedure medication regimen: They opined that Dr. X prescribed three or four drugs to each patient, not the five-drug regimen (clopidogrel, ace inhibitor, beta blocker, aspirin, and statin) that is considered best practice.

In addition, the analysis shows that two of the claims and the complaint involved secondary allegations regarding the informed consent process that preceded the stent procedure. The patients claim that Dr. X rushed them into agreeing, did not adequately explain risks, and was dismissive of their questions about possible complications.

RiskShrink asks two senior cardiologists from other hospitals to interview Dr. X. Both confirm that his medication knowledge is out-of-date and that, after repeatedly citing his decades of clinical experience, he was resistant to accepting that the five-drug regimen consti-

tutes best practice. The cardiologists' report also notes that, in discussing the malpractice cases, Dr. X was very critical of the liability system and appeared to lack empathy for the patients who had died under his care.

RiskShrink advises Dr. X that continuing liability coverage at the standard, specialty-wide rate is contingent on his undertaking two week-long training courses within three months: one in managing patients with coronary heart disease and another in general communication skills. It identifies the programs, enrolls Dr. X, requests certificates of completion, and advises the medical board of its actions. It renews Dr. X's coverage, but places him on a list of insureds for whom any additional complaint or legal action triggers immediate notification to RiskShrink's Chief Medical Officer.

This scenario is science fiction. Liability insurers today do not systematically estimate individual physicians' risks of future claims and complaints, and if they respond at all to situations like Dr. X's, it is to simply terminate his coverage. This is unfortunate. MLAs are well-positioned to do much more; they could make an important contribution to identifying and intervening with risky practitioners, particularly those whose track records evince type II IDEs. Although such an approach focuses on individuals, it is thoroughly consistent with core tenets of patient safety, including event surveillance, pattern analysis, and prevention. Not pursuing it may be MLAs' biggest missed opportunity to come off the patient-safety movement's sidelines and join the game.

Two emerging findings from empirical research underscore the potential value of initiatives to mitigate the risks posed by frequent fliers like Dr. X. One finding is the significance of claim- and complaint-prone physicians to the overall burden of these events. The other is mounting optimism that it is technically feasible to reliably identify such practitioners early in their event trajectories. In this section, we review the research and briefly consider what it would take for MLAs to make a meaningful contribution on this front.

*A. Frequent Fliers*⁸⁷

It has long been recognized that some physicians experience substantially more claims and complaints than their peers.⁸⁸ Several studies in the 1980s and 1990s, most analyzing claims from single insurers, showed a marked clustering of the claims among some physicians that could not be explained by observable demographic and specialty characteristics.⁸⁹ More recent studies using larger datasets, multiple data sources, and longer timelines have brought the maldistribution of medico-legal events into sharper focus and highlighted its significance at the population level.⁹⁰ Our recent study of paid malpractice claims in the United States between 2005 and 2014, for example, found that 1% of all physicians accounted for one third of all claims,⁹¹ which was almost identical to the concentration detected in a national study of patient complaints lodged against physicians in Australia.⁹²

87. Portions of the text in subsections A, B, and C appeared in the following post, written for the Agency for Healthcare Research and Quality's "Perspectives on Safety" series: David Studdert, *Doctors with Multiple Malpractice Claims, Disciplinary Actions, and Complaints: What Do We Know?*, AHRQ: PATIENT SAFETY NETWORK (July 2017), <https://psnet.ahrq.gov/perspectives/perspective/229/doctors-with-multiple-malpractice-claims-disciplinary-actions-and-complaints-what-do-we-know>.

88. Thomas H. Gallagher & Wendy Levinson, *Physicians with Multiple Patient Complaints: Ending Our Silence*, 22 *BMJ QUALITY & SAFETY* 521, 521 (2013); Kaveh G. Shojania & Mary Dixon-Woods, 'Bad Apples': *Time to Redefine as a Type of Systems Problem?*, 22 *BMJ QUALITY & SAFETY* 528, 528 (2013).

89. See, e.g., T. Elaine Adamson et al., *Characteristics of Surgeons with High and Low Malpractice Claims Rates*, 166 *W. J. MED.* 37 (1997); Randall R. Bovbjerg & Kenneth R. Petronis, *The Relationship Between Physicians' Malpractice Claims History and Later Claims: Does the Past Predict the Future?*, 272 *JAMA* 1421 (1994); Gerald Hickson et al., *Development of an Early Identification and Response Model of Malpractice Prevention*, 27 *L. & CONTEMP. PROBS.* 8 (1997); Frank A. Sloan et al., *Medical Malpractice Experience of Physicians: Predictable or Haphazard?*, 262 *JAMA* 3291 (1989); Mark I. Taragin et al., *Physician Demographics and the Risk of Medical Malpractice*, 93 *AM. J. MED.* 537 (1992).

90. Marie M. Bismark et al., *Identification of Doctors at Risk of Recurrent Complaints: A National Study of Healthcare Complaints in Australia*, 22 *BMJ QUALITY & SAFETY* 532 (2013); Gerald B. Hickson, et al., *Patient Complaints and Malpractice Risk*, 287 *JAMA* 2951 (2002); Kaushik Mukherjee et al., *All Trauma Surgeons Are Not Created Equal: Asymmetric Distribution of Malpractice Claims Risk*, 69 *J. TRAUMA* 549 (2010); Adam C. Schaffer et al., *Rates and Characteristics of Paid Malpractice Claims Among US Physicians by Specialty, 1992–2014*, 177 *JAMA INTERNAL MED.* 710 (2017); David M. Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, 374 *NEW ENG. J. MED.* 354 (2016) [hereinafter Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*].

91. Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, *supra* note 90, at 356.

92. Bismark et al., *supra* note 90, at 534–35. We note that distributional statistics of this kind must be interpreted with caution. They do not include information on the incidence of the events in the underlying population, which is influential. To illustrate, consider an extreme example: In a population of 100 physicians in which only 1 claim is filed against one of them in a specified period, 1% of the physicians would account for 100% of claims. Such basic distributional statis-

Not much is known about the personal characteristics and traits of frequent fliers. A dozen or so studies stretching back to the 1980s profiled physicians who experienced one or more claims and complaints, typically by comparing them to peers with unblemished records. Those studies identified some consistent risk factors, both on the physician side (e.g., poor communication skills⁹³ and male gender⁹⁴) and the patient side (e.g., occurrence of severe adverse outcomes⁹⁵). However, it is not appropriate to extrapolate characteristics of frequent fliers from these results. Frequent fliers constitute a fraction of the much larger group of physicians with one or two claims and complaints, and it is a subgroup that may well be distinctive.

Few studies have explicitly sought to identify characteristics of frequent fliers.⁹⁶ Compared to physicians who experience no or few events, they are more likely to be male, international medical graduates, and work in certain high-risk specialties (e.g., orthopedic surgery

tics have more meaning over longer periods of time and in large populations in which the average level of claims risk is not close to zero.

93. Wendy Levinson et al., *Physician-Patient Communication: The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons*, 277 JAMA 553 (1997); Gerald B. Hickson et al., *Factors That Prompted Families to File Malpractice Claims Following Perinatal Injuries*, 267 JAMA 1359 (1992).

94. Emily Unwin et al., *Sex Differences in Medico-Legal Action Against Doctors: A Systematic Review and Meta-Analysis*, 13 BMC MED. 172 (2015).

95. See, e.g., Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, *supra* note 63 (examining the relationship between adverse events and malpractice claiming). Some interpreted evidence of the poor correlation between the incidence of claims and both adverse events and negligent adverse events as indicating that such events did not predict claims. That is not correct. The medical injury studies in New York, Utah, and Colorado showed very clearly that both medical injury and negligent care were risk factors for claims and for claims that led to payments. See Michelle M. Mello & David Hemenway, *Medical Malpractice as an Epidemiological Problem*, 59 SOC. SCI. & MED. 39, 39–40 (2004).

96. See generally Bismark et al., *supra* note 90; Mukherjee et al., *supra* note 90; Sloan et al., *supra* note 89; Matthew J. Spittal et al., *The PRONE Score: An Algorithm for Predicting Doctors' Risks of Formal Patient Complaints Using Routinely Collected Administrative Data*, 24 BMJ QUALITY & SAFETY 360 (2015); Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, *supra* note 90; Taragin et al., *supra* note 89.

and obstetrics and gynecology).⁹⁷ Findings are mixed regarding whether physician age is a risk factor.⁹⁸

B. Past as Prelude?

Missing from the list of distinctive characteristics discussed above is the most obvious one: prior events. Given the clustering phenomenon, it may seem axiomatic that past claims are an important predictor of future ones. But this does not necessarily follow, and merely identifying clustering does not quantify the importance of prior events relative to other characteristics. The early studies comparing physicians with no claims to those with at least one shed no light here: because claims history defined the comparison groups, it could not be examined as a predictor.

The extent to which prior claims and complaints portend future ones has been the subject of some debate, dating back to the early 1990s, around the time when the National Practitioner Data Bank was launched.⁹⁹ A founding premise of the Data Bank was that arming health care institutions with information about the medico-legal histories of physicians who sought to affiliate with them was a useful step for improving quality and safety of care. If, however, those histories were an unreliable indicator of future medico-legal risk, the premise was questionable. Commentators from within the liability industry raised doubts; they stressed that meritless malpractice claims were often settled when the costs of defending them were likely to exceed their “pay-off” value; that blurred the connection between claims history and competence, and thus between claims history and risk of

97. See Bismark et al., *supra* note 90, at 536 (finding male gender, membership of certain specialties, and older age were risk factors for recurrent complaints); Sloan et al., *supra* note 90, at 3295 (finding that female and older physicians were at a lower risk of repeated claims, whereas physicians in certain specialties were at a higher risk); Spittal et al., *The PRONE Score*, *supra* note 96, at 364; Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, *supra* note 90, at 359 (finding membership of certain specialties and male gender, as well as training outside of the United States, were risk factors for recurrent malpractice claims that resulted in payments, however physician age was not a significant risk factor); Taragin et al., *supra* note 90, at 539 (finding that physicians with larger numbers of claims were more likely to be in certain specialties and male).

98. See sources cited *supra* note 97.

99. Bovbjerg & Petronis, *supra* note 89; John E. Rolph et al., *Malpractice Claims Data as a Quality Improvement Tool. II. Is Targeting Effective?*, 266 JAMA 2093 (1991) [hereinafter Rolph et al., *Malpractice Claims Data as a Quality Improvement Tool*]; Lawrence E. Smarr, *Malpractice Claims—Does the Past Predict the Future?*, 272 JAMA 1453 (1994); U.S. GEN. ACCOUNTING OFFICE, GAO/IMTEC-92-56, PRACTITIONER DATA BANK: INFORMATION ON SMALL MEDICAL MALPRACTICE PAYMENTS (1992).

claims recurrence.¹⁰⁰ Proponents of the Data Bank, on the other hand, were so sure of claims' predictive value that they advocated for expanding the repository's reach beyond closed claims to matters still proceeding through the litigation process.¹⁰¹

A close reading of the literature from this period suggests that the opposing sides talked past one another on several points. The concerns of leading skeptics centered on the predictive value of small malpractice payments, not claims in general. More importantly, the word "prediction" has multiple meanings and is often used loosely.¹⁰² In this instance, much of the disagreement over the "predictive" value of physicians' claims history appears to have arisen from confusion over two related but distinct questions: (1) do prior events explain risk, in the sense that they signal elevated risk of future claims?; and (2) is it feasible to use claims history to accurately predict claims at the physician level in large groups?

These are distinct questions because a characteristic can be strongly and independently associated with an outcome, and thus a significant "predictor" of that outcome, as that term is commonly used in regression analysis. Nonetheless it still may be statistically infeasible to use as a reliable basis for prospectively identifying individuals in a population who will experience the outcome. The relationship between depression and suicide helps to illustrate the point. People who die by suicide are much more likely to be depressed than people who do not. Yet it has not proven feasible to accurately predict suicide using detailed information about patients' histories of depression, in part because depression is prevalent in the general population and suicide is rare.¹⁰³

With respect to the first question posed above—do prior events signal elevated risk of future claims? The answer is indisputably yes. At any given moment in time, risks of claims and complaints are significantly higher among physicians with poor medico-legal track records than among physicians with clean records.¹⁰⁴ Indeed, of all physician characteristics that are routinely observed by MLAs, prior events are

100. Smarr, *supra* note 99, at 1453; U.S. GEN. ACCOUNTING OFFICE, *supra* note 99, at 9; OFFICE OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUMAN SERVS., OEI-OI-90-00521, NATIONAL PRACTITIONER DATA BANK: MALPRACTICE REPORTING REQUIREMENTS 1, 5 (1992).

101. See OFFICE OF INSPECTOR GEN., *supra* note 100, at 1–2.

102. See generally Galit Shmeuli, *To Explain or to Predict?*, 25 STAT. SCI. 289 (2010).

103. See generally Joseph C. Franklin et al., *Risk Factors for Suicidal Thoughts and Behaviors: A Meta-Analysis of 50 Years of Research*, 143 PSYCHOL. BULL. 187 (2017).

104. See generally Sloan et al., *supra* note 89; Bovjerg & Petronis, *supra* note 89; Hickson et al., *supra* note 90; Bismark et al., *supra* note 90; Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, *supra* note 90.

easily the strongest risk factor for future ones. Past isn't always prelude, but it's a very useful marker of future risk.

The answer to the second question—whether it is possible to use this and other information to reliably identify who, in a large group of physicians, will experience future events—is less clear.

C. Prediction

A series of studies in the 1980s and early 1990s explored whether physicians' claims history could be combined with other readily-observable characteristics, such as gender and specialty, to identify with reasonable accuracy physicians who would go on to experience malpractice claims.¹⁰⁵ These studies were motivated chiefly by a desire to assess the feasibility of "experience rating" the premiums physicians paid for liability insurance coverage (that is, calibrating the price a physician pays for insurance to the physician's claims history). Accordingly, the study designs involved statistical models that attempted to predict which physicians in an insurance pool would attract one or more claims. None of these studies focused specifically on frequent fliers. The broad conclusion of this body of research was that reliable prediction at the physician level was not possible.¹⁰⁶

Several recent studies of patient complaints and malpractice claims have revisited the prediction question.¹⁰⁷ Their focus has been somewhat different: to investigate whether it is feasible to accurately identify which physicians, among those *who have already attracted one or two claims or complaints*, will attract more in the near term. The results are more promising than those from the earlier studies.

For example, a 2015 study of formal patient complaints to state regulators in Australia by Matthew Spittal and colleagues showed that four variables—number of prior complaints, time passed since the last

105. Bruce Cooil, *Using Medical Malpractice Data to Predict the Frequency of Claims*, 85 J. AM. STAT. ASS'N 285 (1991); Patricia M. Danzon, *Liability for Medical Malpractice*, 5 J. ECON. PERSP. 51 (1991); Robert D. Gibbons et al., *A Random-Effects Probit Model for Predicting Medical Malpractice Claims*, 89 J. AM. STAT. ASS'N 760 (1994); Rolph et al., *Malpractice Claims Data as a Quality Improvement Tool*, *supra* note 99; John E. Rolph, *Some Statistical Evidence on Merit Rating in Medical Malpractice Insurance*, 48 J. RISK INS. 247 (1981); Emilio C. Venezian et al., *The Distribution of Claims for Professional Malpractice: Some Statistical and Public Policy Aspects*, 56 J. RISK INS. 686 (1989); Derek A. Weycker & Gail A. Jensen, *Medical Malpractice Physicians: Who Will Be Sued and Who Will Pay?*, 3 HEALTH CARE MGMT. SCI. 269 (2000).

106. Bismark et al., *supra* note 90, at 532.

107. Bismark et al., *supra* note 90; Spittal et al., *The PRONE Score*, *supra* note 96; Matthew J. Spittal et al., *The PRONE-HP Score: An Algorithm to Identify Practitioners at High Risk of Complaints to Health and Medical Regulators* (2019) [hereinafter Spittal et al., *The PRONE-HP Score*] (unpublished manuscript) (on file with authors); Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, *supra* note 90.

complaint, specialty, and gender—explained 70% of the variation in risk of additional complaints among a group of physicians who had already experienced at least one complaint.¹⁰⁸ The researchers also developed a simple risk algorithm, the “PRONE score,” based on these parameters and found it performed well in predicting physicians’ risks of future complaints. The researchers recently extended their method to medical board complaints, with similarly encouraging results.¹⁰⁹ Their 2015 report concluded:

A risk calculator, like the PRONE score, could be deployed retrospectively or prospectively. As part of a general case load review, such an algorithm could be applied to identify practitioners at highest risk of further events and in need of prompt intervention. Another approach would be to incorporate the tool into day-to-day handling of complaints or claims, giving regulators an ability to observe ascending levels of risk and tailor responses accordingly. The potential for prospective use is particularly novel and exciting because it holds the promise of ushering medicolegal agencies into the prevention business.¹¹⁰

D. Stepping Up

If prediction of claims and complaints is feasible for certain high-risk physicians, why aren’t MLAs doing it? What would it take for them to step up into the kind of role the fictional RiskShrink Group played in the Dr. X scenario?

1. Why Frequent-Flier Programs Are Rare

We have discussed the emerging evidence on the importance of frequent fliers with leaders of several major liability insurance companies. It is apparent that they are aware of the problem and have concerns. But, given the eye-popping statistics on the extent of clustering, what is most striking in these conversations is how low a priority addressing the problem seems to be.

There is an obvious explanation: Liability insurers already have a way of addressing the problem, one that is simpler and cheaper than the approach we have described above. The standard strategy for dealing with physicians who incur multiple “strikes,” at least among major commercial and captive liability insurers, is to show them the door. This eliminates the problem for the insurer going forward.¹¹¹

108. Spittal et al., *The PRONE Score*, *supra* note 96, at 362.

109. Spittal et al., *The PRONE-HP Score*, *supra* note 107.

110. Spittal et al., *The PRONE Score*, *supra* note 96, at 366–67.

111. The insurer may still have responsibility for claims that are yet to be reported but relate to incidents that occurred during the covered period. Some insurance policies (known as “occur-

However, it does not eliminate the safety threat these physicians pose; it merely makes it someone else's problem. Indeed, it may well enlarge the threat because when Dr. X heads to other pastures, his erstwhile insurer's detailed knowledge of his history heads into record storage. Future employers, insurers, and colleagues are unlikely to have any more information on the risks posed by Dr. X than the skeletal information available from the National Practitioner Data Bank.

Fragmentation of responsibility for physicians across dozens of liability insurers and state medical boards thus creates a collective-action problem in dealing with frequent fliers. It should be fixed. Ideally, this would be done voluntarily by key leadership organizations, such as the Physician Insurers Association of America and the Federation of State Medical Boards. But if they cannot or will not do it, then government regulation may be required.

The fact that it is simpler to get rid of a physician than to improve his care is probably the most important reason why MLAs have not moved to initiate programs to address the risks and costs posed by frequent-fliers. But there are technical barriers too. The kind of predictive modeling we have outlined above requires advanced skills in quantitative analysis, which few MLAs have in house. Liability insurers are accustomed to commissioning and studying risk models, typically from actuaries and reinsurers. However, that group-level financial modeling is a different species of prediction from the approach outlined above. Identifying Dr. X and remediating the risks he poses necessitate development of robust, individual-level risk models that are informed by expertise in legal process, clinical medicine, patient safety, and statistics. Most MLAs will need technical help from external partners, which may include academic researchers or commercial analytics firms, in order to design and implement large-scale predictive modeling tools.

2. *Encouraging the Growth of Frequent-Flier Programs*

A clearer understanding of frequent fliers and IDEs would help build momentum to address them. As is evident from our earlier review of relevant research, knowledge of these practitioners remains rudimentary.

rence" policies) provide this type of coverage. In contrast, "claims-made" policies only cover claims filed during the coverage period. Insurers may offer optional "tail coverage" policies that allow physicians to extend coverage beyond the termination date of their claims-made policy. See Scott Dutton, *What Is Malpractice Tail Coverage?*, STUDENT DR. NETWORK (Nov. 28, 2012), <https://www.studentdoctor.net/2012/11/28/what-is-malpractice-tail-coverage/>.

One set of questions relates to frequent fliers' professional trajectory. What proportion of frequent fliers continue to work after accumulating multiple claims or complaints, and where? Are they driven into solo practice, as hospitals and fellow practitioners cut ties? Which organizations credential them? Who provides them with liability insurance? Does their patient load dwindle or their patient mix shift to less complex cases as their problematic track record accumulates? Are the physicians who continue to refer to them unaware of their history? Are frequent fliers relatively itinerant, "starting fresh" in places where their reputation does not precede them or where physician shortages make it imperative for the community to accept all comers?¹¹²

Another set of questions relates to factors that drive IDEs and recurrence. To what extent does a physician's accumulation of events spring from innate personal limitations that cut across multiple dimensions of care (e.g., poor communication skills, lack of insight), as opposed to more circumscribed shortcomings (e.g., lack of competence to perform a particular procedure)? What does the periodicity of a typical event series look like? A succession of events accumulated in a short period of time may signal a different kind of quality problem (e.g., a decrement in job performance due to a life crisis event) than a series accumulated steadily over an extended period. A physician-level study of event typologies and timing among frequent fliers would be revealing.

Filling these knowledge gaps would help to define the contours of the problem and devise intervention strategies. It would also help catalyze public expectations for MLAs to act. However, risk identification alone, even if done superbly, cannot improve safety. To make a difference on the ground, it must operate as the front end of a risk-reduction strategy, guiding application of interventions that effectively mitigate risk. To encourage the growth of frequent-flier programs, the evidence regarding what works to mitigate the risks posed by problem physicians needs to be expanded.

Ideally, MLAs would have a suite of interventions at their disposal to tackle frequent fliers. For a given clinician, an intervention would be selected to match the level and nature of risk presented.¹¹³ Interventions would run the gamut of intensity, from simply notifying a practitioner of his elevated risk of a future event to suspension of the practitioner's medical license or insurance. In the middle of this spec-

112. In a forthcoming paper, we seek to address some of these questions. See David M. Studdert et al., *Changes in Practice Among Physicians with Malpractice Claims* (2019) (unpublished manuscript) (on file with authors).

113. See Spittal et al., *supra* note 96, at 366–67.

trum lie peer-intervention strategies, targeted education and training, as well as various rehabilitative options, including medical treatment for impaired practitioners.¹¹⁴

MLAs themselves may not be the best organizations to design or deliver these interventions, but they should partner with organizations that can. Globally, the best-known existing program aimed at risk identification and intervention with problem physicians is the Patient Advocacy Reporting System (PARS) developed at Vanderbilt University.¹¹⁵ Over 140 hospitals nationwide now participate.¹¹⁶

Do approaches like PARS work in reducing risks posed by problem physicians? A modest body of evidence indicates that some are effective.¹¹⁷ For example, recent evaluations of the PARS program's "peer feedback" intervention were positive: There was strong buy-in by clinical staff and the incidence of complaints declined among high-risk physicians who received the intervention.¹¹⁸ There is general evidence

114. *Id.*

115. Gerald B. Hickson et al., *A Complementary Approach to Promoting Professionalism: Identifying, Measuring, and Addressing Unprofessional Behaviors*, 82 *ACAD. MED.* 1040, 1046–47 (2007); Hickson et al., *Development of an Early Identification and Response Model of Malpractice Prevention*, *supra* note 89; Hickson et al., *Patient Complaints and Malpractice Risk*, *supra* note 90.

116. James W. Pichert et al., *Advances in Patient Safety and Medical Liability*, AGENCY FOR HEALTHCARE RES. & QUALITY (Aug. 2017), <https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/liability/advances-in-patient-safety-medical-liability/pichert.html>.

117. *See, e.g.*, Gerald B. Hickson & James W. Pichert, *Identifying and Addressing Physicians at High Risk for Medical Malpractice Claims*, in BARBARA J. YOUNGBERG, *PATIENT SAFETY HANDBOOK* 347 (2d ed. 2013); Karen E. Hauer et al., *Remediation of the Deficiencies of Physicians Across the Continuum from Medical School to Practice: A Thematic Review of the Literature*, 84 *ACAD. MED.* 1822 (2009); Hilary Sanfey, *Pursuing Professional Accountability: An Evidence-Based Approach to Addressing Residents with Behavioral Problems*, 147 *ARCHIVES SURGERY* 642 (2012).

118. The PARS program evaluated in these studies involved a formal process through which a health practitioner's colleagues could report unsafe or disrespectful behavior and a progressive series of responses that would be taken by hospital representatives following a report. After one report, a "peer messenger" has a "cup of coffee conversation" in which she relays the substance of the report, elicits the provider's reaction, and requests that the practitioner reflect and self-correct. After additional reports, the response is escalated to include other hospital representatives, a formal corrective action plan, and potentially, disciplinary measures. Lynn E. Webb et al., *Using Coworker Observations to Promote Accountability for Disrespectful and Unsafe Behaviors by Physicians and Advanced Practice Professionals*, 42 *JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY* 149, 149–50 (2016). *See also generally* James W. Pichert et al., *An Intervention Model That Promotes Accountability: Peer Messengers and Patient/Family Complaints*, 39 *JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY* 435 (2013).

for the efficacy of training programs,¹¹⁹ but relatively little for programs targeted at frequent fliers.¹²⁰

Although the evidence regarding what works to avoid recurrences for frequent fliers is limited, movement among MLAs toward grappling with IDEs, frequent fliers, and risk identification should not wait. Advances in these areas would up the ante, propelling investment, innovation, and experimentation with prevention strategies.

CONCLUSION

The patient-safety movement launched with lofty goals and optimism about prospects for making major inroads into the scourge of medical error. It has had a sobering two decades, as the enormity of the public health problem and the difficulty of progress have settled in.

The movement's relationship with law and legal institutions got off on the wrong foot. A posture of distaste and mistrust—outright antipathy in the case of the liability system—was established as an early precept, and has largely endured. We have argued that this posture was premised on a false account of the etiology of certain medical errors, and an over-minimization of individual accountability for those errors—positions that have not served the movement well. We recognize that these arguments are controversial, especially in patient-safety circles. But one need not accept all (or even most) of them to credit our core proposal: A relationship reset is in order.

MLAs, in particular, have considerable latent potential to contribute to error reduction efforts. To participate successfully in such efforts, MLAs will need to step beyond traditional blinkered notions of individual accountability, embrace greater transparency, and recognize that gains should not be measured solely in terms of reductions in malpractice costs and claim filing. Innovative MLAs are already there, and more could be brought into the fold if a path to participation was clearer, and if they were more fully embraced as partners in the enterprise. At a moment when the patient-safety movement needs allies more than ever, it's time to bring law in from the cold.

119. Dave Davis et al., *Impact of Formal Continuing Medical Education: Do Conferences, Workshops, Rounds, and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes?*, 282 JAMA 867 (1999).

120. Mark O'Brien et al., *The Clinical Communication Program: An Effective Intervention for Reducing Future Risk for High-Risk Physicians*, 9 ASIA PAC. J. HEALTH MGMT. 8 (2014).