

Deconstructing Negligence: The Role of Individual and System Factors in Causing Medical Injuries

MICHELLE M. MELLO* & DAVID M. STUDDERT**

TABLE OF CONTENTS

INTRODUCTION	600
I. STUDY METHODOLOGY	602
A. INSURERS, CLINICAL CATEGORIES, AND CLAIM FILES	602
B. CLAIM FILE REVIEW	602
C. CLASSIFICATION OF CONTRIBUTING FACTORS	604
II. FINDING 1: MEDICAL-INJURY CAUSATION IS MULTIFACTORIAL AND COMPLEX	605
A. EMPIRICAL RESULTS	605
B. IMPLICATIONS FOR TORT DOCTRINE	607
III. FINDING 2: CAUSAL PATTERNS FREQUENTLY MIX INDIVIDUAL AND SYSTEM FACTORS	610
A. EMPIRICAL RESULTS	610
B. IMPLICATIONS FOR TORT DOCTRINE	615
IV. FINDING 3: THE MOST PROMISING INTERVENTIONS TO AVOID INJURIES EXIST AT THE SYSTEM LEVEL	617
A. INTERVENTIONS SUGGESTED BY EMPIRICAL RESULTS	617
B. IMPLICATIONS FOR TORT DOCTRINE	618
V. THE NEED FOR DOCTRINAL REALIGNMENT	620

* Mello is the C. Boyden Gray Associate Professor of Health Policy and Law, Department of Health Policy and Management, Harvard School of Public Health, mmello@hsph.harvard.edu. © 2008, Michelle M. Mello.

** Studdert is Professor and Federation Fellow, Faculty of Law and Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, d.studdert@unimelb.edu.au. © 2008, David M. Studdert. The empirical study described in this Essay was funded by the Agency for Healthcare Research and Quality (Grant No. HS011886-03) and the Harvard Risk Management Foundation. The authors thank Lee Langston for able research assistance and Kathy Zeiler, Harold Luntz, and Paul Nisselle for helpful comments on an earlier draft.

INTRODUCTION

Medical malpractice litigation and its doctrinal substructure are heavily oriented toward holding individuals liable for medical injuries.¹ Doctrines that contemplate the role of organizations—most notably, vicarious and corporate liability—have gained some traction in health care settings over the last half-century, but the chief focus of most cases remains individual physicians and their slips, omissions, errors of judgment, or incompetence.² Like most branches of tort law, medical malpractice is largely premised on the notions that injuries arise from individual carelessness or lack of expertise, that culpable actors can be readily identified, and that their negligence can be deterred by setting damages sufficiently high to induce medical professionals to take due care.³

The emerging science of patient safety takes a very different view of the occurrence and prevention of medical injury.⁴ This field, which draws heavily from the traditions of industrial organization and complex-systems engineering, emphasizes the role of “system failures” in causing injuries, rejecting simple characterizations of error as individual physicians’ carelessness or incompetence.⁵ A “system” in this context is “a set of interdependent elements,” both human and non-human, “interacting to achieve a common aim.”⁶ In other words, the concept refers to the interrelationships among health care providers, the tools they use, and the environment in which they carry out their work. The system view of accident causation asserts that it is misguided to prioritize, and dead wrong to focus exclusively on, lapses by individual health care providers because most medical outcomes, including those that flow from errors, are essentially the product of organizational structures and processes.⁷ It is a view that resonates with providers at the front lines of care. But although the preeminence of systemic causes of injury and error has quickly become something of a mantra in health policy circles, the relationship between individual and systems factors in the production of medical injury has been little studied until quite recently.

In this Essay, we examine new evidence about the nature of that relationship

1. Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 399 (1994).

2. *Id.* at 387–93.

3. See Jennifer Arlen & W. Bentley MacLeod, *Torts, Expertise, and Authority: Liability of Physicians and Managed Care Organizations*, 36 RAND J. ECON. 494, 507–08 (2005). See generally STEVEN SHAVELL, *ECONOMIC ANALYSIS OF ACCIDENT LAW* (1987) (distinguishing competing liability rules in medical malpractice cases).

4. See, e.g., Jeffrey B. Cooper et al., *Preventable Anesthesia Mishaps: A Study of Human Factors*, 49 ANESTHESIOLOGY 399 (1978) (discussing the interrelationship between human error and faulty equipment design, inadequate experience, and insufficient familiarity with equipment and surgical procedures); Lucian L. Leape, *Error in Medicine*, 272 JAMA 1851, 1852 (1994) (“All humans err frequently. Systems that rely on error-free performance are doomed to fail It seems clear . . . that if physicians, nurses, pharmacists, and administrators are to succeed in reducing errors in hospital care, they will need to fundamentally change the way they think about errors.”).

5. See INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 49–68 (Linda T. Kohn et al. eds., 2000).

6. *Id.* at 52 (internal quotation marks omitted).

7. See, e.g., James Reason, *Human Error: Models and Management*, 320 BRIT. MED. J. 768 (2000).

and consider its salience for tort doctrine's conventional view of injury causation. The evidence comes from the Malpractice Insurers Medical Error Prevention and Surveillance Study (hereinafter "MIMEPS"), a large empirical study of closed malpractice claims we conducted in 2001–2006. The major goals of the study were to examine the prevalence of medical error among claims, determine the failures and breakdowns in care that led to the injuries represented, and identify—based on the causal factors identified—promising prevention measures. Among 1452 reviewed files, 889 were judged to involve injury to a patient due to one or more medical errors.⁸ The methodology for identifying and characterizing errors borrowed from a systems-engineering framework.⁹ This framework gives attention to the types of individual failures that tend to be the principal focus of the negligence inquiry in tort litigation, but embeds them within a broader consideration of causal factors that are distal or not directly related to individual actions.¹⁰

After outlining the study methodology, we discuss three key findings that have implications for tort doctrine. Each is at odds with conceptions of medical error and safety promotion in tort law. First, the causality of medical injuries is multifactorial and weblike. This challenges the traditional tort-law notion of the causal chain. Second, in analyzing the complex causality typically associated with medical injury, it is difficult to cleanly separate individuals and their failures from the larger environments or systems in which they work. This raises questions about medical malpractice doctrine's heavy focus on individual liability. Finally, the pattern of etiologic factors identified suggests that the most promising opportunities for injury prevention lie at the organizational level. Yet tort incentives currently run to individuals, not organizations.

We conclude with some suggestions for realigning tort doctrine to better reflect the realities of medical-injury causation. In particular, a reorientation to expand corporate or enterprise liability is needed. Although doctrines of vicarious liability and corporate liability present possibilities for holding health care institutions accountable in some situations, those circumstances are fairly narrow in theory and, according to our findings, play a secondary role in malpractice litigation.¹¹ When physicians have played a role in causing the injury,

8. See David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 *NEW ENG. J. MED.* 2024, 2027–28 (2006).

9. Among the leading articulations of this framework are CHARLES PERROW, *NORMAL ACCIDENTS: LIVING WITH HIGH-RISK TECHNOLOGIES* (Princeton Univ. Press 1999) (1984); JAMES REASON, *HUMAN ERROR* (1990); JAMES REASON, *MANAGING THE RISKS OF ORGANIZATIONAL ACCIDENTS* (1997) [hereinafter REASON, *MANAGING THE RISKS*]; and Reason, *supra* note 7.

10. See, e.g., Reason, *supra* note 7, at 768 ("The basic premise in the system approach is that humans are fallible and errors are to be expected. . . . Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in 'upstream' systemic factors.").

11. See Abraham & Weiler, *supra* note 1, at 387–93 (reviewing relevant case law and concluding that plaintiffs generally cannot hold hospitals liable for malpractice unless (1) the involved physicians were hospital employees (which often they are not) or parties to a contract to provide services such as

proceeding against them will usually be the best course for maximizing chances of recovering damages, notwithstanding the naïve account of causation on which such a case is likely to depend. Without doctrinal evolution to accommodate advances in knowledge of how medical injuries occur, our ability to successfully target the tort deterrent signal to those who are in the best position to prevent medical injuries is seriously compromised.

I. STUDY METHODOLOGY

The approach used to gather and analyze data in the MIMEPS study has been described in previous publications.¹² Here, we summarize the methodology and focus on aspects of it that are particularly relevant to the current analysis.

A. INSURERS, CLINICAL CATEGORIES, AND CLAIM FILES

Five malpractice insurance companies based in four regions of the U.S. participated in the study. In 2004, these companies covered a combined total of approximately 33,000 physicians, 61 acute care hospitals, and 428 outpatient facilities. Teaching hospitals were overrepresented in the sample, and community hospitals underrepresented, relative to their prevalence in the population.

We extracted data from random samples of closed-claim files at each insurer, all of which included medical records pertaining to the episode of care at issue. A “claim” was defined as a written demand for compensation for medical injury.¹³ We focused on four clinical categories: (1) obstetrical injuries, (2) surgical injuries, (3) injuries arising from a missed or delayed diagnosis, and (4) medication-related injuries. Collectively, these categories account for approximately eighty percent of malpractice claims filed in the U.S.¹⁴ The number of claims sampled from each insurer ranged from 84 to 662 (median=294), varying according to the insurer’s annual claims volume.

B. CLAIM FILE REVIEW

The claim file reviews were conducted on the premises of the insurer or at

anesthesiology, pathology, radiology, or emergency care, or (2) the hospital was negligent in its credentialing process, or (3) non-physician hospital employees such as nurses were negligent).

12. 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); Selwyn O. Rogers, Jr. et al., *Analysis of Surgical Errors in Closed Malpractice Claims at 4 Liability Insurers*, 140 SURGERY 25 (2006); Studdert et al., *supra* note 8. The methods description herein draws heavily on these previous works, particularly Studdert et al.

13. This definition has been used in previous closed-claims studies. See, e.g., PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION 65–67 (1993); David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE 250, 252 (2000).

14. See Amitabh Chandra et al., *The Growth of Physician Medical Malpractice Payments: Evidence from the National Practitioner Data Bank*, W5 HEALTH AFF. 240, 246 (2005) (showing that diagnostic, surgical, obstetric, and medication-related claims collectively accounted for approximately 80% of payments between 2001 and 2003).

facilities they insured. The reviews were performed by physicians who were board-certified attending physicians, fellows, or final-year residents in surgery (surgical claims), obstetrics (obstetric claims), or internal medicine (diagnosis and medication claims). Physician investigators from the relevant specialties trained the reviewers in one-day sessions and the reviewers were assisted by a detailed manual. Reviews took 1.6 hours per file, on average, and were conducted by one reviewer.

Reviews followed four data-extraction instruments which were designed to be completed in sequence. First, insurance staff recorded administrative details of each claim. Second, the physician reviewers recorded details of the adverse outcome the patient experienced, if any, and scored it on a nine-point severity scale ranging from emotional injury to death.¹⁵ Third, reviewers considered the potential role of seventeen “human factors,” or contributing factors, in leading to the patient’s adverse outcome.¹⁶ This set of candidate contributing factors was identified through a review of the patient-safety literature.¹⁷ Reviewers then judged, in light of all available information and their decisions about contributing factors, whether or not the adverse outcome was due to a medical error.¹⁸ Finally, for the subset of claims judged to involve errors, reviewers completed a form tailored to the specific clinical category in which the claim fell. This form collected additional, detailed information about process-of-care breakdowns. Agreement between reviewers with respect to the injury determination was

15. This scale was developed by the National Association of Insurance Commissioners, *see* NAT’L. ASS’N OF INS. COMM’RS, MALPRACTICE CLAIMS: FINAL COMPILATION: MEDICAL MALPRACTICE CLOSED CLAIMS 1975–1978, at 304 (M. Patricia Sowka ed., 1980), and has been used in previous research, *see, e.g.*, Eric J. Thomas et al., *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 *MED. CARE* 261, 265–66 & tbl.2 (2000).

16. Findings presented in this Essay focus on fourteen factors rather than seventeen. One factor, “another failure of communication,” which was intended to be a catch-all category for communication breakdowns, was rarely identified. When it was, physician-investigators judged that the issues described were subsumed by other more specific factors. A second factor, “failure to follow (or break) a prominent, well established protocol,” was excluded because it became evident during the course of the study that there was substantial confusion and variability among reviewers about its meaning (particularly the word “protocol,” which was not defined). Finally, two types of patient-related factors—those involving clinical factors (for example, obesity) and those involving non-clinical/behavioral factors (for example, failure to keep an appointment)—were collapsed for most study analyses, and we do the same here.

17. The term “human factors” refers to the investigation of “the interrelationships between humans, the tools they use, and the environment in which they live and work.” *INST. OF MED.*, *supra* note 5, at 63 (footnote omitted). It comes from the fields of industrial engineering and psychology, and has entered the patient-safety lexicon relatively recently. We avoid use of the term here, preferring the more generic “contributing factors” so as to avoid confusion with what we call “individual factors” later in the Essay.

18. We used the Institute of Medicine’s broad definition of error: “the failure of a planned action to be completed as intended (e.g., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning).” *INST. OF MED.*, *supra* note 5, at 54. In most cases, the reviewers’ examination of the claim file made them aware of the litigation outcome. Blinding them to the outcome would have been preferable but, given the sample size and the sprawling nature of claim files, it was logistically impossible to excise this information. Reviewers were instructed to ignore this outcome and exercise independent clinical judgment in rendering injury and error determinations. For a similar discussion of this issue, *see* Studdert et al., *supra* note 8.

substantial; agreement with respect to the error determination was moderate.¹⁹

C. CLASSIFICATION OF CONTRIBUTING FACTORS

The study instruments arrayed the contributing factors under five general headings: (1) environmental factors (interruptions, ergonomic failure, workload/inadequate staffing, technology failure, fatigue); (2) team/group behavior (hand-offs, lack of clear lines of responsibility, conflict, lack of supervision); (3) circumstantial factors (failure of vigilance/memory, error in judgment); (4) individual factors (lack of technical competence/knowledge, some other failing of an individual clinician); and (5) patient-related factors. For the present analysis, we collapsed the factors under headings (3) and (4) into a single group, which we call "individual factors." The remaining factors are lumped into a second group termed "system factors."²⁰

The crux of the distinction is that individual factors pertain directly to the behavior of individual clinicians; they are the classic kinds of failings envisioned by traditional tort-law understandings of negligence. The other group consists of a miscellaneous set of factors that are less directly, or not at all, the product of acts by lone providers. Rather, they deal with causes arising primarily at the organizational (hospital or physician practice) level. Most of these factors concern the interaction of individuals with one another or with the environment in which they work.

We would readily concede that the distinction we have drawn between individual and system factors is imperfect. Some factors that we have classified as systemic may have alternative bases. For example, when a physician makes an error out of fatigue because she is in the midst of her second twelve-hour shift, the spotlight falls on the system, but if her fatigue is instead the result of attending an all-night party, the individual provider's behavior is squarely at issue. Conversely, lack of technical competence, ostensibly an individual factor, may signal systemic problems if it arises because medical residents work in a poorly supervised training program.²¹

The potential for both types of misclassification certainly exists. Data source

19. Agreement among reviewers was measured by subjecting a random subsample of 10% ($n=148$) of the files to re-review by a second reviewer who was blinded to the first review. The pairs of reviews enabled calculation of kappa statistics for both the injury ($K=0.78$) and error determinations ($K=0.63$). The kappa statistic is a measure of inter-rater reliability that corrects for the probability of agreement due to chance; the statistic takes a value of 0 if agreement is no better than chance and 1 if agreement is perfect. For a discussion of the kappa statistic, see J. Richard Landis & Gary G. Koch, *The Measurement of Observer Agreement for Categorical Data*, 33 *BIOMETRICS* 159 (1977).

20. Patient-related factors do not fit neatly into this group. Because the aim of this analysis is to examine physicians' individual contributions to error in contradistinction to all other causal factors, we have elected to group patient factors with the system factors group. What they share in common with the other factors in this group is the lack of a primary connection to the behavior of individual physicians.

21. Indeed, some in the patient-safety community would argue that the very concept of an individual error is false and that every error has system roots, beginning with the apparent absence or inadequacy of failsafe mechanisms designed to stop the individual action from causing harm. But if our critique

limitations compound this risk: the information available in claims files may lead to under-recognition of some contributing factors, particularly system factors that are tangential to the episode of care in dispute. Nonetheless, we believe the individual/system distinction stands as a meaningful one and, for most errors, represents a reasonable characterization of the primary nature of the breakdown.²²

With that as background, we now proceed to a discussion of three study findings with important implications for tort law.

II. FINDING 1: MEDICAL-INJURY CAUSATION IS MULTIFACTORIAL AND COMPLEX

A. EMPIRICAL RESULTS

Our study showed that among claims judged to involve individual and/or system failures, a diverse range of contributing factors typically led to the injury. Individual factors were highly prevalent, contributing to injuries in 96% of the 889 cases involving error (Table 1). Judgment errors were the most common type of individual factor, present in 70% of cases. Also widespread, however, were system factors, which were implicated in 56% of injuries (70% if patient-related factors are included among the system factors). Teamwork problems and other communication breakdowns were particularly prevalent types of system factors (40% of cases). Closer analysis showed that the presence of system factors was not unique to particular classes of injuries or clinical contexts; the proportion hovered in the 50–60% range for virtually every stratification of the data we examined.

In addition to diversity, contributing factors tended to operate in clusters and have cascading effects. The injuries due to error that were identified in our study averaged 3.14 different contributing factors, and more than a third of them had four or more contributing factors (Table 2). The breakdowns that led to injuries often occurred across or within multiple stages of care. Diagnostic errors, for example, might stem from an important omission in taking the patient's history, followed by a wrongly routed test result, misinterpretation of the test result when it finally reached the ordering physician, and then an inappropriate follow-up with the patient. Given such temporal and spatial breadth in the occurrence of errors and the team structure through which many health care services are delivered, it is not surprising that the majority of injuries involved more than one health care provider: 60% involved two or more clinicians, and a quarter involved three or more.

In sum, basic prevalence data on contributing factors, clinicians, and stages of care involved in injuries attributable to medical error are sufficient to

challenges tort doctrine for overvaluing the individual's contribution to injury, this view of causation surely undervalues it.

22. The importance of the second type of misclassification (the contamination of individual factors with underlying system factors) is diminished by the fact that our analytical focus ends up being the contrast between errors due to individual factors and those due to both individual and system factors.

Table 1. Individual, System, and Patient-Related Factors Contributing to Harmful Errors ($n=889$)

Contributing Factors	<i>n</i>	Proportion of All Error-Related Injuries
Individual factors:	854	96%
Error in judgment	625	70%
Failure of vigilance/memory	511	57%
Lack of technical competence/ knowledge	426	48%
System factors:	497	56%*
Teamwork and communication factors:	353	40%
Lack of supervision	176	20%
Handoffs	129	15%
Other communication problem	116	13%
Lack of clear lines of responsibility	87	10%
Conflict among personnel	17	2%
Other system factors:	175	20%
Workload/inadequate staffing	77	9%
Interruptions/distractions	58	7%
Technology failure	67	8%
Fatigue	18	2%
Ergonomic failure (lighting, setup, etc.)	10	1%
Patient-related factors (clinical and behavioral)	345	39%

* If patient-related factors are included, the proportion of injuries with system factors is 70%.

highlight the causal complexity of these injuries. Injuries that lead to malpractice claims tend to arise from a confluence of multiple causes, some of which will be quite distant from the “sharp end” of the sequence of events that leads to harm (Figure 1). As in other areas in which accidents in complex systems have been studied, the data indicate that “when large systems fail, it is due to multiple faults that occur together in an unanticipated interaction, creating a chain of events in which the faults grow and evolve.”²³

23. INST. OF MED., *supra* note 5, at 52 (footnotes omitted).

Table 2. Contributing Factors, Involved Clinicians, and Stages of Care in Which Errors Occurred

	All Clinical Categories (n=889)	Missed/Delayed Diagnosis (n=259)	Medication (n=163)	Obstetric (n=209)	Surgical (n=258)
Contributing factors: Mean (median)	3.14 (3)	3.15 (3)	3.03 (3)	3.18 (3)	3.16 (3)
≥2	742 83%	225 87%	124 76%	172 66%	221 85%
≥3	527 9%	160 62%	86 53%	125 48%	156 60%
≥4	313 5%	86 33%	55 34%	79 31%	93 36%
≥5	171 9%	49 19%	31 19%	45 17%	46 18%
Involved clinicians: Mean (median)	1.96 (2)	1.81 (2)	1.92 (2)	2.15 (2)	1.98 (2)
≥2	533 60%	130 50%	95 58%	151 72%	157 61%
≥3	221 25%	50 19%	35 21%	70 33%	66 26%
≥4	66 7%	19 7%	14 9%	15 7%	18 7%
Stages of care in which errors occurred:					
≥2	— —*	209 81%	65 40%	31 15%	79 31%
≥3	— —	127 49%	15 9%	2 1%	10 4%

* Overall frequency and proportion not calculated because the number of possible stages varied across clinical categories: Missed/delayed diagnoses were characterized according to nine stages—(1) care seeking, (2) history/physical, (3) test ordering, (4) test performance, (5) test interpretation, (6) transmission of test results, (7) follow-up plan, (8) referral, and (9) compliance with diagnostic plan. Medication errors were characterized according to five stages—(1) ordering, (2) transcribing, (3) dispensing, (4) administering, and (5) monitoring. Obstetric errors were calculated according to three stages—(1) prenatal, (2) intrapartum, (3) postpartum. Surgical errors were calculated according to three stages—(1) pre-operative, (2) intra-operative, and (3) post-operative.

B. IMPLICATIONS FOR TORT DOCTRINE

Tort law's standard account of causation, as applied to the medical malpractice context, conceives of negligence as a physician's failure to take due care resulting in an act (or omission) that directly causes injury, or sets in motion a chain of events that end in injury. Linearity and physical determinism are hallmarks of this Newtonian model of causation.²⁴ Newtonian reasoning emphasizes physical contacts between two objects in which one produces a change in the other—a series of "collisions that follow the physical laws defined by mathematics."²⁵ This gives rise to the metaphor of the "causal chain,"²⁶ in which events occur in a sequenced, linear fashion, can be

24. See, e.g., Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV. 469, 478–83 (1988).

25. *Id.* at 478.

26. H.L.A. HART & TONY HONORÉ, *CAUSATION IN THE LAW* 72 (2d ed. 1985); Brennan, *supra* note 24, at 480, 486.

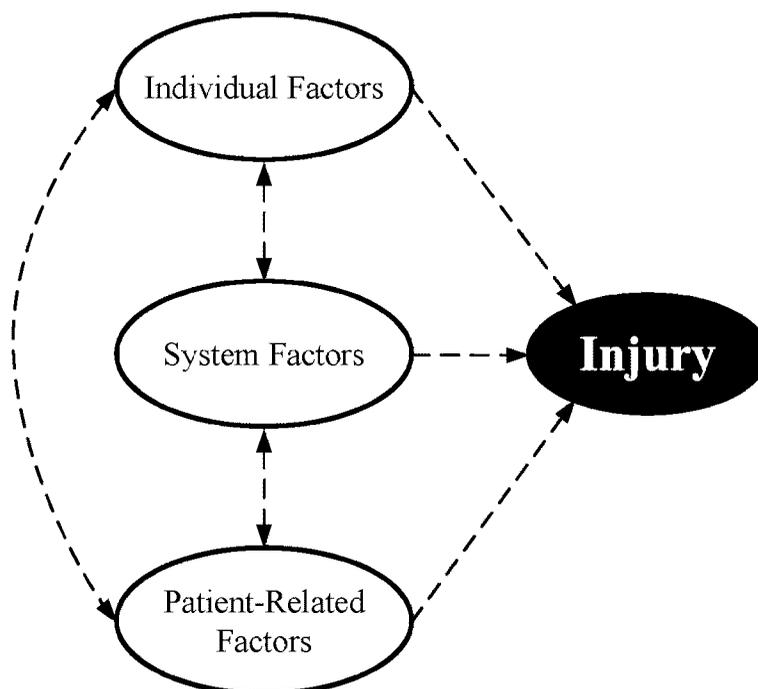


Figure 1. Mosaic of Contributing Factors to Medical Injuries

traced back step by step, and would not have occurred but for the antecedent events. Similarly, the legal notion of proximate cause, a prerequisite (along with causation in fact) of a finding of negligence, presumes that each event has “an identifiable, individual antecedent cause.”²⁷

This model is a poor fit with the data we observed. To the extent that antecedent events are sequenced, the behavior of physician defendants often appears to be located in the middle or at the end of the chain, rather than near its beginning. Their behavior may merely continue, or fail to interrupt, a harmful event already unfolding. An alternative, and in some ways more sophisticated, conception of injury causation is the “Swiss cheese” model described by James Reason in his seminal work on human error in complex systems.²⁸ Reason’s model, which has quickly become conventional wisdom among researchers and advocates in the patient-safety community, attempts to correct for precisely the deficiency described above in the causal-chain thesis. It contemplates a system with many dangerous attributes and actors working within it, but posits that most failures will be neutralized, deliberately or by luck, as they evolve.²⁹

27. Brennan, *supra* note 24, at 484 (citing John Borgo, *Causal Paradigms in Tort Law*, 8 J. LEGAL STUD. 419, 421–22 (1979)).

28. REASON, *MANAGING THE RISKS*, *supra* note 9, at 9.

29. *See id.*

When the dangerous features of the system's multiple layers (the "holes" in the cheese) align, however, harmful accidents result.

Reason's model presents an interesting blend of Newtonian logic and complex systems analysis. It takes seriously the phenomenon of multifactorial causation, but the "alignment" concept retains the Newtonian attachment to linear causality which our data resist. A broad view of medical-injury causation exposes the events that lead to harms in health care settings as less of a chain than a web. Strands of the web may resemble the Newtonian model, but they are interlinked with other strands in ways unaccounted for by that model.

The concept of a causal web fits better with the patterns of causation we observed. Framing causation in this way borrows from recent scholarship in epidemiology. This work has described a range of "multicausal" models which conceptualize diseases and other health states as "the consequence of a network, matrix, constellation, or web made up of determinants, component or contributory causes."³⁰ Individual components are not usually sufficient causes, and the evidence that is offered to prove the causal model is less conclusive than that which would be used to prove linear chains of necessary causes.³¹ Because evidence about factors that contribute to medical injuries is also often fragmentary and indefinite, and because it is often the case that injury occurs only when a number of causal elements coincide, this "mosaic approach"³² aptly describes what we saw. Multiple individual and system factors independently contribute to injuries and also interact with one another (Figure 1).³³ For example, system factors may underlie many physician errors in the sense that they create conditions in which human error is likely to occur and to go unnoticed until injury results.

If, as we have suggested, this conception of causation provides a more accurate account of how medical injuries actually occur, tort doctrine is in trouble. Negligence law's standard tests of causation-in-fact—the "but for" and "substantial factor" tests³⁴—are much too crude. Any one of the contributing factors may satisfy these tests. Nor is proximate causation much help because a number of contributing factors may be proximate to the injury. Alternative notions of causality also force us to revisit whether it is just to assign culpability to the most proximate and visible human agent. This actor may be like the child

30. Bruce G. Charlton, *Attribution of Causation in Epidemiology: Chain or Mosaic?*, 49 J. CLINICAL EPIDEMIOLOGY 105, 105 (1996).

31. *Id.* at 106.

32. *Id.*

33. Unfortunately, our approach to data collection in this study necessitated a unidimensional view of the various contributing factors; we could not prioritize, sequence, or interlink them in ways that would begin to give form to a causal web. It is highly doubtful whether the science of patient safety has yet advanced to a point that would make it possible to do this in a rigorous way. See Troyen A. Brennan et al., *Accidental Deaths, Saved Lives, and Improved Quality*, 353 NEW ENG. J. MED. 1405, 1408–09 (2005).

34. KENNETH S. ABRAHAM, *THE FORMS AND FUNCTIONS OF TORT LAW: AN ANALYTICAL PRIMER ON CASES AND CONCEPTS* 99–100 (1997).

in the birthday party game who is left holding the package when the music stops. Even if courts and juries could be educated on the empirics of medical-injury causation, they may find it cognitively difficult to sort through the web of contributing factors and apply traditional tort concepts of causation-in-fact and proximate causation.

III. FINDING 2: CAUSAL PATTERNS FREQUENTLY MIX INDIVIDUAL AND SYSTEM FACTORS

A. EMPIRICAL RESULTS

We found that individual failures play a causal role in the overwhelming proportion of medical injuries attributable to error, but in the majority of cases, they are precipitated, activated, or amplified by system failures. Only 30% of injuries were caused solely by individual factors, while 66% involved both individual and systemic factors (Figure 2).³⁵ Thus, in most cases, individual failures appear to be a necessary but not sufficient condition for injurious errors to occur.

A case example helps to illustrate the interrelationships observed between individual and system factors.³⁶ One claim involving a missed diagnosis began with a nine-year-old girl visiting a hospital emergency department four times in one week with a fever, sore throat, back pain, and abdominal pain. In the first visit, “a throat culture was taken and later tested positive for *Streptococcus* bacteria, but it was not specifically reported to anyone.”³⁷ The girl was sent home with a diagnosis of a viral syndrome. Her parents brought her back to the emergency department twice more in the same week, as her symptoms continued. During her second and third visits, the earlier culture results were not reviewed, and she was again diagnosed with a viral syndrome. She presented for her fourth emergency department visit later the same week and, after some delay in evaluation, was found to have an epidural abscess. By this late stage, her symptoms were quite acute. The delay in diagnosing the bacterial infection had resulted in a temporary paralysis of the girl’s legs and loss of bladder control.

What caused this injury? The laboratory’s failure to report the culture result? A lapse in memory or vigilance on the part of the first physician, who apparently did not follow up on the test result? A very busy emergency department that left the physician little time to focus on this patient’s case? The lack of a

35. Another, less direct measure of individual and system contributions is who had a role in causing the error. Physicians are the prototypical individual contributor, whereas nurses and ancillary staff can be considered part of the hospital system in which the physician works. In our sample, 22% of errors involved both physicians and non-physicians, 69% involved only physicians, and 9% involved only non-physicians.

36. This case is summarized in one of the study publications, 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, 200 ex.2 (2007).

37. *Id.*

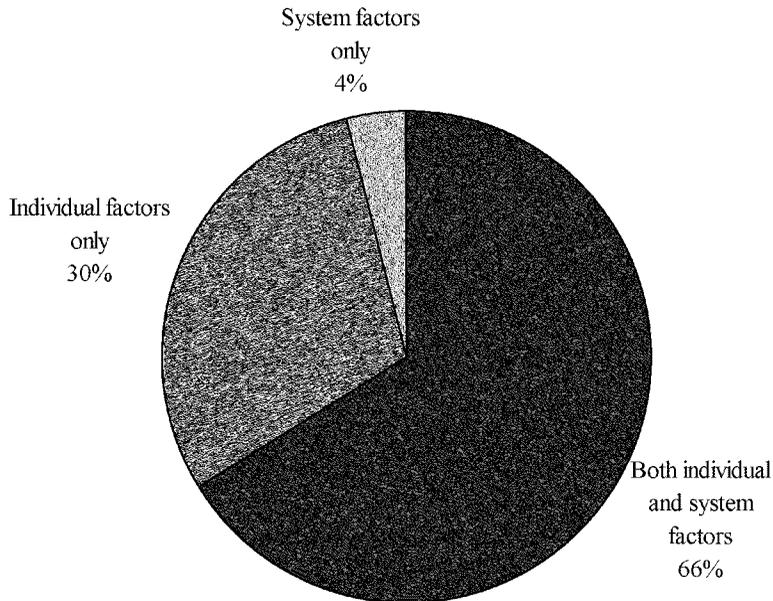


Figure 2. Claims Involving Harmful Error, by Type of Contributing Factor ($n=889$)

computerized reminder system to jog the physician's memory, or a computerized test-result reporting system? The failure of the patient's parents to inquire about the test result or mention to physicians on duty during their second and third visit that a culture was done? The failure of the attending physicians at those visits to determine that a test was previously ordered, or to think to order a new one? The final delay in evaluation on the fourth visit, again owing to workload and staffing concerns? Take your pick. Whatever combination of these breakdowns is selected, the girl's injury links back to a liberal mix of individual and system factors.

Several interesting differences emerged from a comparison of the characteristics of injuries due to individual factors only and those due to individual and system factors in our sample (Table 3). Although the proportions of claims within the two groups that received a payment were similar (72% vs. 76%), awards among paid claims were significantly higher for claims with system-factor involvement (median of \$292,875 vs. \$142,500, $P=0.0001$). A key driver of this difference appears to be the discrepancy in average injury severity across these two groups. Cases involving system as well as individual factors had a mean severity score of 7.3 (out of 9), compared to 6.8 for individual-factors-only cases ($P=0.003$). Deaths, in particular, occurred more frequently when system factors were involved.

The difference in severity suggests the existence of amplification effects when individual failures are accompanied by system failures, recalling the adage, "To err is human, but to really screw up you need a computer." By

Table 3. Characteristics of Claims Involving Harmful Error, by Contributions of Individual and System Factors

	Errors Due Only to Individual Factors (<i>n</i> =267)		Errors Due to Individual and System factors (<i>n</i> =587)		<i>P</i> -value
	<i>n</i>	%	<i>n</i>	%	
Payments:					
Received a payment	191	72%	445	76%	0.18
Mean payment*	\$381,573		\$573,564		0.006 [‡]
Median payment*	\$142,500		\$292,875		0.0001 [‡]
Clinical category:					
Missed diagnosis	86	32%	168	29%	
Surgery	50	19%	98	32%	
Obstetrics	72	27%	133	23%	
Medication-related	59	22%	98	17%	0.001 ^{†‡}
Severity of injury:					
Mean severity score	6.8		7.3		0.003 [‡]
Emotional / minor	49	18%	73	12%	
Significant	115	43%	237	40%	
Major	43	16%	102	17%	
Death	60	22%	175	30%	0.03 ^{†‡}

* 2004 dollars. Calculated from among paid claims only. *P*-value for comparison of means derived from two-sample *t*-test. *P*-value for comparison of medians derived from two-sample Wilcoxon rank-sum (Mann-Whitney) test.

[†] *P*-value derived from chi-square analysis of all four categories.

[‡] Statistically significant.

“amplification effects,” we mean that the presence of system failures worsens a harm caused by an individual’s lack of judgment, vigilance, or expertise. For example, consider the case (based on one from our sample) of a surgeon who inadvertently leaves a large sponge in the patient’s abdomen during an operation. The nurse’s instrument count does not pick up the problem. It does not help that the hospital lacks a protocol requiring at least one other member of the operative team to verify the count. The nausea and infection the patient sustains within forty-eight hours should have been important clues, but both the nursing staff and on-call surgical resident miss these signs—in the nurses’ case because of poor communication about who is responsible for the patient, and in the resident’s case because she is called away for an emergency procedure and has no one available to cover for her. The retained sponge is eventually discovered, but not before the patient goes into septic shock and spends a week in the intensive care unit. The initial failures to rescue the effects of a potentially minor failure greatly worsened the patient’s outcome.

System failures can have precipitating, as well as amplifying, effects. That is, they can create conditions ripe for individual failures to occur. No area of clinical care illustrates this dynamic better than the working conditions of residents, fellows, and medical students. In our sample, trainees were judged to have played at least a moderately important role in 240 (27%) of the 889 harmful errors.³⁸ Three of the leading factors identified as contributors to these trainee-related injuries were lack of supervision (54%), handoff problems (19%), and excessive workload (19%). Supervision problems typically are related to management decisions by hospitals about how to structure coverage of the clinical service, as well as cultural norms within the hospital and clinical specialty about when it is acceptable to consult attending physicians, particularly when they are not in the hospital. Smooth handoffs require carefully constructed protocols and “overlap” periods in which outgoing staff orient incoming staff to pressing clinical issues. Clinicians’ workloads are largely determined by labor-force and scheduling decisions made upstream by senior management, and excessive workloads are known to be associated with higher risks of adverse events.³⁹ Thus, each of these three leading factors may shape an environment in which inexperienced trainees are set up to do damage.

How does the liability system cope with the complexities introduced by heterogeneous causality? Not well. Consistent with its focus and conception of causation, it tends to disproportionately focus on individual failures. In our study sample, plaintiffs named physicians as defendants in the vast majority of claims, while institutions were named in approximately two-thirds of claims. The selection of defendants by plaintiffs and their attorneys displayed little sensitivity to the injury’s underlying etiology (Table 4). Institutions were no more likely to be named in cases involving injuries due to a combination of individual and system factors than in cases involving individual factors only ($P=0.67$). The obvious retort is that much tends to be unknown about what occurred at the time of filing, which makes a broad sweep of potential defendants a standard opening gambit in medical malpractice litigation, as indeed it is. However, this explanation does not account for the mismatch observed: 41% of injuries due to both individual and system factors targeted one or more of the involved clinicians but failed to name a health care facility at all.⁴⁰

The claims resolution process provided no substantive realignment. Physician defendants were staple contributors to payments across the board (Table 4). Institutional defendants contributed in less than one quarter of paid claims overall and were

38. Hardeep Singh et al., *Medical Errors Involving Trainees: A Study of Closed Malpractice Claims from 5 Insurers*, 167 ARCHIVES INTERNAL MED. 2030, 2031 (2007).

39. See Joel S. Weissman et al., *Hospital Workload and Adverse Events*, 45 MED. CARE 448, 453 (2007) (concluding that “an increase in the occupancy rate of 10 percentage points increases the rate of an [adverse event] by 15%, while a 0.1 increase in the ratio of patients to nurse staff increases the rate of an [adverse event] by 28%”).

40. Restricting the analysis to paid claims only produced trivial changes to the percentages shown in the upper part of Table 4.

Table 4. Naming and Payment Behavior of Defendants in Claims Involving Harmful Error, by Nature of Injury*

Role of Physicians and Institution in Claim	Injuries Due to Individual Factors Only		Injuries Due to Individual and System Factors		P-value
Named defendants:					
≥1 physician named as defendant	136/156	87%	427/473	90%	0.27
≥1 institution named as defendant	95/156	61%	279/473	59%	0.67
Paying defendants: [†]					
≥1 clinician defendants contributed to payment [‡]	98/111	88%	334/356	94%	0.05
≥1 institutional defendants contributed to payment	31/111	28%	82/356	23%	0.29
Institution(s) named but did not contribute to payment	31/69	45%	82/214	38%	0.33

* Analysis excludes claims from two insurers, one of which (an integrated delivery system) routinely listed the hospital as a named defendant in its claims records, and the other which covered physicians only and did not record specific information about litigation outcomes pertaining to co-defendants it did not insure.

[†] The denominator for these proportions is the number of paid claims.

[‡] Data did not permit separation of payments made on behalf of physicians from payments made on behalf of other clinicians (e.g., nurses, physical therapists, other allied health professionals).

no more likely to pay in cases involving harmful system failures than in cases in which the injury was linked solely to individual factors ($P=0.29$).⁴¹ Thus, individual providers bore the brunt of liability even though system factors were frequently involved in causing the injuries for which they were held liable.

In summary, individual and system factors appear to be in play and intertwined in at least two-thirds of medical injuries attributable to error in our sample of claims. Patients are at relatively high risk of sustaining severe injury when breakdowns in care occur at both levels. And neither the selection of defendants nor the outcomes of litigation appears to be sensitive to the presence of system-level contributors to injuries.

41. At first glance, the figures in Table 4 may suggest that the reverse was true—namely, institutions actually paid more often in individual-factors cases (28%) than in individual-and-system-factors cases (23%). However, the difference is not statistically significant ($P=0.29$). None of the cross-column differences in the table are significant at the $P<0.05$ level.

B. IMPLICATIONS FOR TORT DOCTRINE

These findings expose a blinkered approach to individual fault in tort doctrine. The atomistic view of the individual provider's role in causing injury is rooted in an outdated understanding of medical care processes and pays insufficient attention to the complicated causal webs that lead to most medical injuries. As the Institute of Medicine described in its landmark report on error in medicine:

Complex systems are characterized by specialization and interdependency. Complex systems also tend to have multiple feedback loops, and to receive information indirectly, and because of specialization, there is little chance of substituting or reassigning personnel or other resources.

In contrast to complex systems, linear systems contain interactions that are expected in the usual and familiar production sequence. One component of the system interacts with the component immediately preceding it in the production process and the component following it. Linear systems tend to have segregated subsystems, few feedback loops, and easy substitutions (less specialization).⁴²

Health care fits the description of a complex, rather than a linear, system.⁴³ The etiology of health care accidents is a web of interactions among system components. Thus, although the traditional model of negligence as the failure of one or more independent actors to take due care may have salience for some types of torts, for the majority of medical malpractice cases its applicability is highly questionable.

Holding individuals liable for a disproportionate share of the damages associated with medical injuries is problematic because it disrupts the possibilities for efficient deterrence. Deterrence requires that a tortfeasor's liability be restricted to the injuries that he causes in fact or to his proportional contribution to injuries that are jointly caused by more than one tortfeasor. Liability above this level will lead the defendant to take excessive (socially inefficient) precautions, which may result in higher economic costs, as in "defensive medicine," or social costs arising from his being deterred from participating in a socially desirable activity.⁴⁴ In our view, the optimal rule in cases of joint causation would allocate liability in proportion to fault. An alternative rule that held each party fully liable for the losses would be less desirable from the defendant's standpoint, and arguably from a justice standpoint,⁴⁵ but still efficient. Under such a rule, each party should take optimal precautions because each knows that

42. INST. OF MED., *supra* note 5, at 58–59.

43. *Id.* at 60 (footnote omitted).

44. SHAVELL, *supra* note 3, at 108.

45. From a defendant's perspective, it may not appear just. On the other hand, to a plaintiff who is unable to recover compensation in full because of an impecunious defendant who is particularly liable, that result would not seem just.

he could be held fully liable if he does not take due care.⁴⁶

Although doctrines for dealing with situations of multiple causation have developed within tort doctrine,⁴⁷ they are not often helpful in the medical-malpractice context because the hospital, de jure or de facto, is frequently insulated from liability. Because medical malpractice doctrine does not embrace corporate liability for hospitals except in narrow circumstances, most of the system factors that contribute to medical injuries are unlikely even to be raised in malpractice litigation. Consider, for example, a delayed diagnosis of fetal distress during the second stage of labor which results in injury to the newborn. The proximate cause of the delay was that the attending obstetrician forgot to check on the mother's progress after becoming overwhelmed with other patients. The nurse did not page him because she was unsure whether the fetal heart tracing truly indicated worrying signs. In such a case, the lawsuit is likely to focus on the obstetrician's failure of vigilance, and possibly also the nurse's competence. However, a range of system factors may also be in play but bypassed altogether: inadequate physician staffing of the labor-and-delivery service; the obstetrics department's unwillingness to pay the extra salaries needed to attract experienced midwives; a hospital culture that discourages nurses from asking physicians for help; and so on. Because there is no real prospect of recovering damages from the hospital, and because spotlighting the system factors will only detract from the case against the obstetrician, the plaintiff's attorney is unlikely to steer the negligence inquiry in that direction. Instead, the allegations will tend to center on a subset of the causal factors linked to proximate individual failures.

This account assumes, of course, that the system factors are visible to plaintiffs, and that choices can be made about which defendants are named and how the alleged breakdown in care is characterized. The medical record is the pivotal documentary reference point in most claims, however, and many system factors will be captured poorly, or not at all, in it.⁴⁸ Hence, information

46. SHAVELL, *supra* note 3, at 165. This is not the current rule, however, because the hospital is very unlikely to be held liable for the physician's contribution to the injury. Joint-and-several liability reform is now widespread for medical malpractice cases, and even in states that retain joint-and-several liability, the previously mentioned barriers to imposing liability on the hospital for the physician's negligence, *see supra* note 11, remain.

47. Joint-and-several liability, joint care, alternative liability, and other relevant doctrines are summarized in SHAVELL, *supra* note 3, at 109. *See also* ROBERT COOTER & THOMAS ULEN, *LAW AND ECONOMICS* 362–64 (4th ed. 2004) (summarizing “joint-and-several liability with and without contribution”); ARIEL PORAT & ALEX STEIN, *TORT LIABILITY UNDER UNCERTAINTY* 58–69 (2001) (providing example cases demonstrating several kinds of liability).

48. Although this point is surely accurate, we make it somewhat self-consciously here, recognizing that the review of claim files that powers much of our critique relied quite heavily on the medical record (and opinions of experts whose interpretation of events was influenced by the medical record). We have repeatedly noted in reports from the MIMEPS study that our data source almost certainly leads to an underestimation of the prominence of system-level contributors to injury. Two factors, however, partially mitigate the problem of using MIMEPS findings to make this point. First, MIMEPS reviewers were privy to a range of information in the defense insurers' files, including results of internal

limitations also lead plaintiffs toward individual accountability. In sum, tort doctrine and litigation dynamics tend to push the inquiry in malpractice cases away from the mosaic of contributing factors at the individual and system levels.

IV. FINDING 3: THE MOST PROMISING INTERVENTIONS TO AVOID INJURIES EXIST AT THE SYSTEM LEVEL

A. INTERVENTIONS SUGGESTED BY EMPIRICAL RESULTS

A key component of the MIMEPS study was analyzing patterns in the contributing-factor data in order to identify areas where avoidable injuries were prevalent, and the etiologic information suggested that particular measures could have substantial prevention value. A selection of the areas targeted and interventions recommended based on the study results is presented in Table 5.

A striking feature of these interventions, and one that follows naturally from the various clinical findings in MIMEPS regarding injury causality, is that few if any of them are amenable to implementation by individual rank-and-file clinicians, however dedicated to quality improvement such individuals may be. Rather, virtually all require the commitment of organizational leadership, centralized planning, and the mobilization of resources at the organizational level.

For example, consider again the problem of foreign bodies (sponges and surgical instruments) left inside a patient after surgery. This error is among the prototypical examples of medical malpractice. It would appear to present a classic case of an individual failure of vigilance or memory. Yet, the interventions suggested for addressing it are all system-level changes: improved compliance by the entire surgical team with formal procedures for counting sponges; use of bar-coding technology on surgical instruments and sponges, which facilitates accurate counts by replacing human counting with scanning and electronic counting; and routine X-rays of patients who are at a high risk of having a retained foreign body (such as patients who underwent emergency surgery).⁴⁹

By comparison, a strategy built around exhortations or imperatives to the lead surgeon and operating room nurse to simply be more vigilant in their counting seems anemic. Its prospects for success would be slim. Over the course of thousands of operations, the strategy would be compromised, perhaps seriously, by certain inevitable lapses in human cognition. Further, it rests on a primitive view of the error's etiology.

investigations, to which plaintiffs and their attorneys would not have had access. Second, the training that MIMEPS reviewers received emphasized the potential role of system-related factors, and would be expected to sensitize them to these factors and inspire deliberation about them in the file review process. By contrast, plaintiffs, with their focus on negligence and securing compensation, would be unlikely to view the injury etiology in the same light or attach the same relevance to system factors.

49. Atul A. Gawande et al., *Risk Factors for Retained Instruments and Sponges After Surgery*, 348 *NEW ENG. J. MED.* 229, 234 (2003) (suggesting that routine X-rays of high-risk patients "could prove to be a useful measure for detecting foreign bodies that have been inadvertently left behind").

The merits of organizational-level interventions are persuasive for a couple of reasons. First, as we have noted, this approach recognizes the critical contribution of systemic causes to injury. Even the surgical instrument left inside the patient, at first glance a quintessential individual gaffe, turns out to be deeply embedded in communication problems, teamwork breakdowns, and deficient protocols and procedures.

Second, even when injuries are primarily due to individual failures, it does not follow that optimal prevention lies in measures that target those failures. The error may be more efficiently avoided (or its consequences mitigated) through organizational-level interventions. Even if we felt it reasonable to place responsibility for ensuring an accurate sponge count exclusively on the lead surgeon, counting sponges is a process inherently prone to human error. The vast majority of retained foreign bodies in the MIMEPS study occurred not because no count was performed, but because the team erroneously believed they had counted accurately.⁵⁰ Most surgeons would view a miscount as possible even when due care is taken. In a complex surgery involving dozens of sponges and hundreds of pieces of equipment, such errors are not difficult to fathom. In emergency surgery, where time is of the essence, it often is not possible to perform a pre-operative count at all.⁵¹ Both problems could be addressed through bar coding or similar technological fixes. Similarly, in the case of the young girl with abdominal pain, much of the fault lies with the initial attending physician for not following up on the test result. But given the physician's workload and fragmented attention, a computerized laboratory-test reporting system that delivers test results to his email inbox and the patient's medical record is far more likely to ensure timely follow-up than a redoubling of the physician's commitment to remembering to follow up.

The foregoing suggests that steps to avoid or mitigate the consequences of many types of medical error can most effectively be implemented at the level of the hospital or physician practice. This has important implications for the deterrent function of malpractice liability.

B. IMPLICATIONS FOR TORT DOCTRINE

Our findings build the case that tort deterrence is best targeted at the institutional, not individual, level in medical malpractice law. This is not a novel suggestion: even before the science of patient safety emerged, medicolegal scholars suspected that the nature of medical error was such that "[t]he best vehicle for identifying and dealing with such incidents is the organization in which the doctor practices," and that hospitals would be more responsive than individual physicians to incentives sent by the tort system.⁵² Data from our

50. *Id.*

51. *See id.* at 232, 234.

52. 2 AM. LAW INST., REPORTERS' STUDY: ENTERPRISE LIABILITY FOR PERSONAL INJURY, 123 (1991). The advancement of error science has reinforced this view. *See, e.g.*, William M. Sage et al., *Enterprise*

study and others have confirmed these intuitions.

This poses two challenges for tort law. Most obviously, the lack of a robust corporate-liability doctrine in medical negligence law means that tort litigation rarely will send the deterrent signal to the party in the best position to prevent medical injuries.⁵³ The signal will be focused on individual physicians, who are largely powerless to effect the kinds of systemic changes that our study suggests are needed. Although liability may lead physicians to heighten their personal commitment to a high degree of vigilance, expertise, and sound judgment, these efforts may not be effective in preventing many breakdowns in care.

Second, the empirical findings suggest that in a range of cases, there will be a conflict between serving the deterrence and corrective-justice functions of tort law. The notion of corrective justice requires that the party who caused the injury also be the party who pays for the plaintiff's damages.⁵⁴ Tort law primarily directs liability to individual physicians, who certainly are among the parties who cause medical injuries—to restate our earlier results, individual failures contribute to more than nine out of every ten injuries due to error. It tends to underemphasize the role of the hospital, a point we will return to shortly. But to the extent that it does correctly identify individual physicians as contributing to injuries, it metes out a kind of corrective justice.

The difficulty is that although physicians may be causes-in-fact of medical injuries, they are not the parties in the position to prevent injuries at least cost. Thus, focusing liability on individuals may be appealing on fairness and corrective-justice grounds, but not on efficiency grounds. Efficient deterrence requires both accuracy in targeting the signal to the cause-in-fact of the injury and targeting it to the least-cost avoider. Our findings suggest that it will rarely be

Liability for Medical Malpractice and Health Care Quality Improvement, 20 AM. J.L. & MED. 1, 7 (1994) (“[T]he organizational unit that is ultimately responsible for efficient health care delivery should also bear direct financial liability for malpractice so that it will ‘internalize’ the cost of patient harm into its cost-benefit calculus.” (footnote omitted)).

53. Economists might argue that enterprise liability is unnecessary to force hospitals to internalize the costs of medical injuries because physicians will shift the costs that the tort system imposes on them to hospitals. In theory, physicians will demand wage or price increases to cover increased overhead costs when their insurance costs rise. See Arlen & MacLeod, *supra* note 3, at 512. See generally Kathryn Zeiler, *Medical Malpractice and Contract Disclosure: A Study of the Effects of Legal Rules on Behavior in Health Care Markets* (May 20, 2003) (unpublished Ph.D. thesis, California Institute of Technology) (available at <http://etd.caltech.edu/etd/available/etd-05222003-132311/unrestricted/finalthesis.pdf>). Two realities of health care organization interfere with this theoretical prediction, however. First, most physicians do not receive wages from hospitals. Rather, they are employed by physician practices that receive revenue from health insurers. Second, in today's environment, physicians' ability to obtain price or wage increases (from any payer) to make up for increased insurance costs is limited. See Mark Pauly et al., *Who Pays? The Incidence of High Malpractice Premiums*, 9 F. HEALTH ECON. & POL'Y 1, 7–8 (2006) (finding that “a sizeable and probably growing proportion” of insurance cost shifting by physicians is accomplished by providing more services using physician extenders, rather than by raising prices).

54. ABRAHAM, *supra* note 34, at 15. Of course, the near-universal prevalence of medical liability insurance which is only lightly experience-rated (if at all) poses a major challenge to the corrective-justice function of malpractice law.

possible to do both in medical malpractice cases. Guido Calabresi, in originally proposing the concept of the least-cost avoider,⁵⁵ recognized that a liability rule that placed liability on the party that could reduce harm at the lowest cost could serve the goal of efficient accident prevention at the expense of other social goals, including our “sense of justice.”⁵⁶ Medical malpractice presents this tradeoff.

V. THE NEED FOR DOCTRINAL REALIGNMENT

Our interpretation of the study findings can be summarized as follows. Health care systems, hospitals and other large entities through which care is delivered are directly implicated in the majority of harmful medical errors. Measures designed and implemented at the institutional level represent our best shot at reducing the frequency of those errors. Such measures are probably also our best shot at curbing the residual burden of harmful errors—those to which institutions are peripheral or non-contributors. However, neither plaintiffs nor the tort system see this easily. Information problems, tort doctrine, and litigation dynamics make them quite insensitive to the nuances of the injury causality. The result is a mistargeting of the deterrent signal⁵⁷ and a lost opportunity to use the legal system to improve patient safety. The problem also undermines the legitimacy of the medical liability system in the eyes of health care providers, further enervating their incentives to act on problems it signals.

As we have already suggested, the crux of the doctrinal problem is that the tort system, in the medical-malpractice context, is largely oriented to holding individuals accountable. Doctrinal realignment to reflect the realities of medical-injury causation and prevention requires the development of a more robust role for enterprise liability.

Some conceptions of enterprise liability envision that the health care organization will be the sole locus of liability,⁵⁸ while others see possibilities either for exclusive corporate liability or individual and corporate joint liability.⁵⁹ The joint-liability notion generally contemplates that the hospital and its affiliated

55. See GUIDO CALABRESI, *THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS* 136 (1970). Steven Shavell applied the now-widely-used term “least-cost avoider” to Calabresi’s concept of the “cheapest cost avoider.” SHAVELL, *supra* note 3, at 17.

56. CALABRESI, *supra* note 55, at 175; *see id.* at 25–26.

57. Other forces also undermine the deterrent effect of tort law for medical negligence prevention and would continue to do so even if liability was perfectly allocated among tortfeasors. The very low claiming rate among patients injured by negligence means that tortfeasors will not bear the full social costs of the injuries they cause (much less the risks of injury they impose). See Michelle M. Mello et al., *Who Pays For Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives For Patient Safety Improvement*, 4 J. EMPIRICAL LEG. STUD. 835 (2007); Paul C. Weiler, *The Case for No-Fault Medical Liability*, 52 MD. L. REV. 908, 913 (1993); cf. Jennifer Arlen, *Compensation Systems and Efficient Deterrence*, 52 MD. L. REV. 1093, 1097–98, 1130 (1993) (defining efficient deterrence). Additionally, there is the aforementioned problem of non-experience-rated liability insurance.

58. Abraham & Weiler, *supra* note 1, at 384, 393.

59. William M. Sage, *Enterprise Liability and the Emerging Managed Health Care System*, 60 LAW & CONTEMP. PROBS. 159, 159 (1997).

physicians would have “channeled” liability insurance. In such an arrangement, the hospital would not formally accept liability for its physician affiliates, but the hospital and physicians would be insured under the same policy. The hospital would purchase the insurance and charge the physicians for their individual portion of the premium through a surcharge or lower salary.⁶⁰ Because our data suggest that failures of both individuals and systems cause injuries, we favor the joint over the exclusive model.⁶¹ The exclusive model also runs the risk of being applied to enterprises in which the physician and institution do not have the same liability insurance, which leads to fragmentation of incentives and inefficiencies in the defense of litigation.⁶²

Enterprise liability for medical malpractice faces some practical difficulties. Although the days of truly solo practice are waning, and physicians are increasingly linked into hospital and insurance networks, not all will have an enterprise that naturally envelops their clinical practice.⁶³ The more imposing barrier to enterprise liability is political; previous efforts to establish it, with managed-care organizations as the enterprise, failed during the Clinton health reform initiative due to organized opposition from medical professional organizations and liability insurers.⁶⁴ Targeting hospitals rather than managed-care organizations may be more viable, particularly in today’s climate, in which physicians better recognize institutional roles in patient safety improvement, seek greater insulation from liability exposure, and are learning that it is often less expensive and more secure to be rolled into a hospital’s insurance policy.⁶⁵ Even if enterprise liability is not formally recognized as a viable doctrine, hospitals and physicians can take steps towards realizing its promise by adopting channeling arrangements in which physicians’ contributions towards the insurance premium do not vary with the claims made on the policy, so that it is the hospital that stands to gain or lose from preventing injuries and claims.

The case for enterprise liability depends critically on being able to scientifically establish that health care institutions are in the best position to prevent accidents, by proving both causation and the existence of effective interventions. The history of enterprise liability for workplace injury illustrates the role that such empirical evidence—marshaled by managers and others close to the

60. *Id.* at 175.

61. Other scholars of patient safety and liability share this view. See Randall R. Bovbjerg & Robert Berenson, *Enterprise Liability in the Twenty-First Century*, in *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 219, 239–40 (William M. Sage & Rogan Kersh eds., 2006).

62. We thank Richard Epstein for this observation.

63. David M. Studdert & Troyen A. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, 286 *JAMA* 217, 222 (2001) (“An enterprise liability/no-fault system will not fit easily with every physician’s practice. For example, for the solo practitioner who admits patients to several hospitals the choice of a suitable enterprise to provide coverage may not be straightforward.”).

64. Bovbjerg & Berenson, *supra* note 61, at 230; Sage, *supra* note 59, at 162–64, 170–71.

65. See Michelle M. Mello et al., *Hospitals’ Behavior in a Tort Crisis: Observations from Pennsylvania*, 22 *HEALTH AFF.* 225, 230–31 (2003) (describing a growing preference for channeling at hospitals weathering a severe malpractice insurance crisis).

industry who are committed to injury reduction—can play in swaying the judicial development of tort doctrine.⁶⁶ We hope that empirical findings like ours will do the same in the medical-liability realm.

Table 5. Recommended Clinical Interventions To Reduce Harmful Errors*

Error Type	Recommended Interventions
Missed/delayed diagnosis in the ambulatory setting ⁶⁷	Clinical decision support and “ticklers” incorporated into the electronic medical record Improvements in scheduling procedures Improvements in test-result tracking systems
Missed/delayed diagnosis in the emergency department ⁶⁸	Improvements in clinical decision support Improvements in communication procedures pertaining to critical test results (e.g., direct lines of communication between ordering providers and radiology/laboratories) Standardized handoff procedures Enhanced staffing during periods of excessive workload Reform of resident-supervision procedures
General errors in surgery ⁶⁹	Targeting quality improvement activities at low-experience teams Targeting quality improvement activities at procedures on patients with high preoperative-risk profiles (obesity, previous surgery, complex medical history) Teamwork training

Continued

66. See generally John Fabian Witt, *Speedy Fred Taylor and the Ironies of Enterprise Liability*, 103 COLUM. L. REV. 1, 3–4 (2003) (linking the development of enterprise liability doctrine to the scientific-management movement, and the emergence of workers compensation statutes to companies’ successful experiments with accident insurance benefits).

67. Gandhi et al., *supra* note 12, at 494 tbl.4, 495.

68. Kachalia et al., *supra* note 36, at 203.

69. Rogers et al., *supra* note 12, at 31.

Table 5. Continued

Error Type	Recommended Interventions
Communication failures in surgery ⁷⁰	Defined “trigger” events to prompt mandatory consultation between nurse/resident and attending physician Standardized use of readbacks Structured protocols for handoffs Structured protocols for transfers Teamwork training
Retention of foreign bodies after surgery ⁷¹	Compliance with, and monitoring of compliance with, sponge-counting protocols Bar coding of instruments and sponges Radiographic screening of high-risk patients before they leave the operating room
Wrong-site surgery ⁷²	Mandatory use of model site-verification protocols
Errors involving medical trainees ⁷³	Reforms to graduate medical education to improve residents’ core competencies, particularly monitoring tasks Tighter standards for what constitutes adequate supervision, particularly in procedural work Improvements in information transfer protocols Teamwork training
Fetal distress during labor ⁷⁴	Standardized method of interpretation of fetal heart tracings Implementation of clinical algorithm for responding to sustained non-reassuring fetal heart tracings

* Selected interventions from among recommendations generated by the MIMEPS study. Table footnotes indicate the study publication describing the intervention.

70. Caprice C. Greenberg et al., *Patterns of Communication Breakdowns Resulting in Injury to Surgical Patients*, 204 J. AM. COLL. SURGEONS 533, 538–39 (2007).

71. Gawande et al., *supra* note 49, at 234.

72. Mary R. Kwaan et al., *Incidence, Patterns, and Prevention of Wrong-Site Surgery*, 141 ARCHIVES SURGERY 353, 355–57 (2006).

73. Singh et al., *supra* note 38.

74. Tom McElrath & Michelle Mello, Presentation at the Malpractice Insurers’ Medical Error Surveillance and Prevention Study Colloquium: Obstetrical Errors and Patient Safety Interventions (Nov. 2004) (presentation slides on file with author).