DOES MALPRACTICE LIABILITY PROMOTE PATIENT SAFETY? A METHODOLOGICAL EXCURSION

Michael J. Saks and Stephan Landsman*

ABSTRACT: A persistent question concerns the safety-promoting effects of malpractice liability. The goal of the present Article is to contribute to improved future research on the effects of liability risk on safety. The main focus is on the methodological challenges of conducting research capable of finding such effects when they exist and not finding them when they do not exist. A recent review of the empirical literature suggests that most of that research finds little indication of patient safety effects. The examination of the methodological challenges presented by the research question illuminates a series of hurdles that make detection of a safety effect, if one exists, unusually difficult. The most daunting of those potential obstacles is the possibility that all levels of liability risk above some threshold elicit much the same response. Consequently, studies that look at varied risk levels, all of which are above the threshold, are methodologically destined to find "no effect." We recommend a number of improvements that could be adopted in future empirical studies to strengthen their validity and enhance their ability to find safety effects that might exist. Or, if safety effects do not exist, to reach null results that are more convincing.

CITATION: Michael J. Saks & Stephan Landsman, *Does Malpractice Liability Promote Patient Safety? A Methodological Excursion*, 62 JURIMETRICS J. 397–419 (2022).

I. INTRODUCTORY REMARKS

American law's principal response to harm resulting from medical mistakes and missteps has long been, and remains, a variant of tort (the common law of accidents).[1] A victim of medical injury, or a decedent's family, may seek reimbursement of losses from those responsible for the harm. Such complaints usually resolve without trial. In cases that do reach trial, plaintiffs will prevail only if they prove by a preponderance of the evidence that a provider-patient relationship had been established; that a duty of care existed; that the care did not meet the relevant professional standard (negligence); that the breach caused the harm suffered; and that damages resulted. Along with tort law generally, malpractice liability frequently is said to provide compensation, deterrence, or corrective justice.

*Michael J. Saks is a Regents Professor in the Sandra Day O'Connor College of Law and Department of Psychology at Arizona State University. Stephan Landsman is Emeritus Professor of Law; Organizer and Director, Clifford Symposium on Tort Law and Social Policy, DePaul College of Law.

1. *See* MICHAEL J. SAKS & STEPHAN LANDSMAN, CLOSING DEATH'S DOOR: LEGAL INNOVATIONS TO STEM THE EPIDEMIC OF HEALTHCARE HARM ch. 5 (2021).

In our view, the most socially useful goal of medical malpractice liability is the prevention of future harm (a phrase we think is more accurate than "deterrence").[2] The familiar theory is that the risk of liability promotes safety by inducing potential tortfeasors to take steps to reduce the chances that their activities will cause accidental harm. It gives them a "business case" for investing in safety.[3]

Indeed, we have argued elsewhere that improving safety is the principal, if not the only, justification for tort liability, in light of well-established facts about the behavior of the tort system.[4] The malpractice liability system provides little compensation overall, and what infrequent compensation it provides it does so inefficiently with high transaction costs and, at least in modern times, affords little if any corrective justice.[5] Consequently, if tort liability were found to have no relationship to safety, its social value would and should come into serious question.

On the other hand, whatever motivation for prevention the malpractice liability system engenders, it achieves at a fraction of the effort and cost that, say, a comprehensive system of compensation would require. That relatively few victims of negligent injury are served by the tort system can be viewed as a failure if the system's function is to compensate. But, if viewed as a system that evolved to promote safety, that low compensation rate becomes a cost-efficiency feature, especially if that small number of cases is sufficient to achieve ample safety promotion. And though the system has high transaction costs *for those cases it touches*, it touches only a fraction of all cases of negligent injury.[6] *Total* transaction costs, therefore, are far less than would be required if society were relying on a more comprehensive administrative compensation system to motivate a comparable investment in safety. Finally, there are the compensation awards themselves: only a fraction of the awards that could potentially be made are made, and on average each award made is smaller than the theoretically available legal remedy.[7]

The question, then, is whether the malpractice liability system accomplishes that prevention goal and to what degree. The same question has arisen

2. Because we find the term *deterrence* to be more suitable for intentional harmdoing from which one may volitionally refrain, which iatrogenic harm rarely is, this Article will generally refer to *harm prevention* or the *safety effects* of malpractice liability.

3. For an extended discussion of the business case for quality and safety, see David Hyman & Charles 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).

4. *See* SAKS & LANDSMAN, *supra* note 1, chs. 5–6 (reviewing those facts in detail).

5. *See id*. at 71–73, 77, & 272 n.9. Corrective justice is especially scarce in the domain of malpractice liability, where all insureds of the same specialty in the same county typically pay the same premiums.

6. SAKS & LANDSMAN, *supra* note 1, ch. 5.

7. *Id.*

in other domains, such as workplace accidents,[8] auto crashes,[9] defective products,[10] and other settings.[11] Some studies in certain domains have found that potential tortfeasors can be responsive to the risk of liability and act strategically to avoid the costs of liability, but other studies suggest not.[12] Such mixed findings suggest a puzzle that needs solving. We believe that a substantial part of

8. Worker death rates declined where worker's compensation laws replaced common law tort, perhaps suggesting that the crucial factor in prompting increased safety is not the particular liability regime, but whether costs for the consequences of unsafe conditions or actions are imposed more dependably. *See* MICHAEL J. MOORE & W. KIP VISCUSI, COMPENSATION MECHANISMS FOR JOB RISKS 133 (1990); James R. Chelius, *Liability for Industrial Accidents: A Comparison of Negligence and Strict Liability Systems*, J. LEGAL STUD. 293, 303–06 (1976).

9. Though findings are mixed, the weight of evidence suggests that traffic fatality rates are lower under negligence regimes than under no-fault. *See* Michelle J. White, *An Empirical Test of the Comparative and Contributory Negligence Rules in Accident Law*, 20 RAND J. ECON. 308 (1989; Frank A. Sloan et al., *Effects of Tort Liability and Insurance on Heavy Drinking and Drinking and Driving*, 38 J.L. & ECON. 49, 49 (1995); Alma Cohen & Rajeev Dehejia, *The Effect of Automobile Insurance and Accident Liability Laws on Traffic Fatalities*, 47 J.L. & ECON., 357, 382 (2004); J. David Cummins et al., *The Incentive Effects of No-Fault Automobile Insurance*, 44 J.L. & ECON. 427, 427 (2001); Richard A. Derrig et al., *The Effect of Population Safety Belt Usage Rates on Motor-Vehicle-Related Fatalities*, 34 ACCIDENT ANALYSIS & PREVENTION 101 (2002); Paul Zador & Adrian Lund, *Re-Analyses of the Effects of No-Fault Auto Insurance on Fatal Crashes*, 53 J. RISK & INS. 226, 235 (1986); Paul S. Kochanowski & Madelyn V. Young, *Deterrents Aspects of No-Fault Automobile Insurance: Some Empirical Findings*, 52 J. RISK & INS. 269 (1985); Elisabeth M. Landes, *Insurance Liability and Accidents: A Theoretical and Empirical Investigation of the Effect of No-Fault Accidents*, 25 J.L. & ECON. 49, 50 (1982); Frank A. Sloan et al., *Tort Liability Versus Other Approaches for Deterring Careless Driving*, 14 INT'L REV. L. & ECON. 53, 66–67 (1994).

10. Elissa P. Gentry & Benjamin J. McMichael, *Responses to Liability Immunization: Evidence from Medical Devices*, 17 J. EMPIRICAL LEGAL STUD. 789 (2020) (examining what happened when the U.S. Supreme Court immunized medical devices from product liability claims if those devices had received premarket approval from the Food and Drug Administration, Riegel v. Medtronic, 552 U.S. 312 (2008), and finding that device manufactures strategically sought rigorous and expensive premarket approval for the highest risk product categories but not for lower risk categories).

Gentry & McMichael also noted that when manufacturers acted to shield themselves from liability, thereby shifting liability risk from themselves to surgeons, surgeons responded by reducing their own liability risk, particularly in high-malpractice-risk areas, by reducing their use of both coronary and cranial stents. Gentry & McMichael, *supra*. Relatedly, research has found that both coronary and cranial stents were not as effective as previously thought, so that medical management might be the preferred treatment approach. *See* Gina Kolata, *Study Is Ended as a Stent Fails to Stop Strokes,* N.Y. TIMES (Sept. 7, 2011), https://www.nytimes.com/2011/09/08/health/research/08stent.html [https://perma.cc/CDP5-VSW7]; Gina Kolata, *Surgery for Blocked Arteries is Often Unwarranted, Researchers Find: Drug Therapy Alone May Save Lives as Effectively as Bypass or Stenting Procedures, A Large Federal Study Showed*, N.Y. TIMES (Nov. 16, 2019), https://www.nytimes.com/2019/11/16/health/heart-disease-stents-bypass.html [https://perma.cc/W9WP-VQMD].

11. Karen K. Nelson & A.C. Pritchard, *Carrot or Stick? The Shift from Voluntary to Mandatory Disclosure of Risk Factors*, 13 J. EMPIRICAL LEGAL STUD. 266, 266 (2016). Nelson and Pritchard found that in making disclosures to investors, "[f]irms subject to greater litigation risk disclose more risk factors, update the language more from year to year, and use more readable language than firms with lower litigation risk," and that for predictable subsets of firms, "[t]hese differences in the quality of disclosure are pronounced . . . ." *Id.*

12. SAKS & LANDSMAN, *supra* note 1, ch. 6.

the solution to that puzzle is methodological. This Article is addressed to those various methodological concerns.

A. A Review of Provider-Focused Studies of Malpractice Liability Risk

A recent review of research examined studies that focused on the relationship (if any) between malpractice liability risk and healthcare outcomes.[13] That review reports a wide search for "original empirical studies of the association between indicators of malpractice liability risk and indicators of health care quality and safety."[14] Examples of measures of litigation risk exposure are cost indices of malpractice premiums, claim frequency, and tort reforms (versus lack thereof). Examples of outcome measures are mortality, readmissions, patient satisfaction ratings, and birth weight (in obstetrical settings).[15]

Of the 37 studies that met the reviewers' criteria, 28 examined only hospital care while 16 focused on obstetrical care. Of the hospital studies that measured patient mortality (20 of them), 15 found no evidence of an association with liability risk while 5 found limited evidence. Of those that measured readmissions and avoidable initial hospitalizations (7 of them), none found evidence of an association between liability risk and those outcomes. Of those that looked at other measures (e.g., patient safety indicators) (12 of those), 7 found no association between liability risk and those outcomes while 5 identified significant associations in some analyses. Of the 16 studies that focused on obstetrical care, 9 found no significant association between liability risk and outcomes, while 7 found limited evidence for an association.

On their face, those results seem to suggest that malpractice liability has a harm-prevention effect under some conditions, but usually does not. As the review's authors put it, "The available findings suggested that greater tort liability . . . was not associated with improved quality of care."[16] Or, presumably, safety as well.[17] If more liability does not enhance safety, then one might infer that less

---

13. Michelle M. Mello et al., *Malpractice Liability and Health Care Quality: A Review*, 323 J. AM. MED. ASS'N 352 (2020).

14. *Id.* at 353.

15. To view the full range of variation in exposure measures and outcome measures, see *id.* at 355–58 tbl.1.

16. *Id.* at 365.

17. What is meant by quality of care is itself a much discussed, considered, and debated concept. That discussion takes place at varied levels of abstraction from the philosophical to the operational (which measures or indicators reflect or capture quality). *See, e.g.*, INST. OF MED., PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE (Philip Aspden et al. eds., 2004); Pamela H. Mitchell, *Defining Patient Safety and Quality Care*, *in* PATIENT SAFETY AND QUALITY: AN EVIDENCE-BASED HANDBOOK FOR NURSES 1-1 (Ronda G. Hughes ed., 2008); THE MEDICAL-LEGAL ASPECTS OF ACUTE CARE MEDICINE: A RESOURCE FOR CLINICIANS, ADMINISTRATORS, AND RISK MANAGERS (James E. Szalados ed., 2021) [hereinafter MEDICAL-LEGAL ASPECTS OF ACUTE CARE MEDICINE].

The relationship of quality to safety is a part of that complexity. For example, the Institute of Medicine treats quality and safety as inseparably intertwined. *See* INST. OF MED., *supra*. Whereas,

> The National Patient Safety Foundation (NPSF) notes that "patient safety is related to 'quality of care', but the two concepts are not synonymous. Safety is an important subset of quality." Patient

liability will not diminish safety[18]—and that perhaps no harm would result from progressively weakening tort liability until it disappears altogether.

B. The Purpose of This Article

The broad goal of the present Article is to contribute to improved future research on the effects of liability risk on safety. The main focus is on the methodological challenges of conducting research capable of finding effects when they exist and not finding them when they do not exist. We believe these challenges are unusually knotty in the area of medical liability, though perhaps they afflict tort liability more generally. Occasionally these methodological issues merge into substantive interpretations of the phenomena of interest.

As we noted, whenever the works in a body of research point in contradictory directions, they present a puzzle to be solved. When studies produce inconsistent findings, researchers often look for patterns that reveal the conditions under which an effect obtains versus when it does not. Meta-analysis is a useful tool for this, sometimes revealing that some types of studies (e.g., observational) find an effect while other types (e.g., experimental) find no effect or the opposite effect.[19] Or it might be found that an effect obtains in some domains, or using some dependent measures, but not in other domains or on other measures. Such findings can be useful for policymakers, who would then be better informed about which legal interventions work under what circumstances. However, because the studies reviewed by Mello and her coauthors varied so greatly in so many respects, the review team concluded that "[m]eta-analytic pooling was not possible . . . ."[20]

Perhaps one might learn something from each study standing on its own. If each of the studies in the review were sound, and each study's results can be relied upon, then each is telling us about different parts of a multifaceted phenomenon, where sometimes liability risk promotes safety and sometimes does not. But this situation does not allow us to tote up the effects and the non-effects

---

> safety generally relates to the prevention and mitigation of adverse outcomes that stem from the processes of healthcare. The NPSF addresses patient safety in the context of defining characteristics. Patient safety has to do primarily with the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare itself. Thus, the NPSF considers "errors and deviations," "dangerous situations," "near misses," and accidents as elements of patient safety.

James E. Szalados, *Medical Error, Quality Management, and the Evolving Culture of Safety*, *in* MEDICAL-LEGAL ASPECTS OF ACUTE CARE MEDICINE, *supra*, at 219, 226.

For our purposes, we think it useful to suggest that safety is a component of quality, and that not everything that contributes to quality also contributes to safety. If that is a sound proposition, it carries methodological implications, and those in turn could affect substantive conclusions. These implications come into play below.

18. Mello et al., *supra* note 13, at 353 ("[S]kepticism about the deterrent effect of malpractice litigation reinforces arguments that liability can be limited without risking the quality of care.").

19. For example, observational studies suggested that hormone replacement therapy provided health benefits, but randomized trials indicated that hormone replacement caused serious illness in large numbers of women. *See* JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 23–38 (2004).

20. Mello et al., *supra* note 13, at 354. As indicated above, the diversity of study measures can be seen in *id.* at 355–58 tbl.1.

and declare an overall conclusion. One is tempted to allude to the parable of the blind men and the elephant: getting one's hands on any given piece does not provide the whole picture.[21]

Assuming, however, that the broad general conclusion of Mello and her coauthors' review is correct—namely, that tort liability does not improve healthcare safety—then another puzzle presents itself. Why, if liability for harm has been able to promote safety in other areas of activity, is it not doing so in the provision of healthcare?

Another puzzle is found *within* the healthcare arena. If medical providers practice wasteful and worthless[22] defensive medicine with the frequency that they claim to,[23] how can it be that all those efforts do nothing to make their practices safer?[24] Would it not be odd to find that doctors are highly responsive to liability risk but only by taking precautionary steps that are useless to patients and no steps that confer any health benefits?

Future research will be needed to try to solve those puzzles and others. Methodological shortcomings (or simply differences) are perhaps the most common sources of conflicting findings in empirical research. We therefore undertake to reflect on methodological problems that might account for differences in findings. Where we think those considerations have substantive implications for understanding liability risk and safety, we discuss those implications. The purpose is not to critique any particular study or review of studies. Our aim is broader and deeper than that, with an eye not on past research but on future research.

---

21. The variety of contexts and measures employed by the various studies reviewed also meant there were too few of any given subset to allow a meta-analysis of it, preventing confident conclusions from being drawn about any particular subset. Many readers of the review will, nonetheless, conclude that a mixed bag of studies, about a mixed bag of contexts and measures, leads to an overall meaningful conclusion.

22. The most unambiguous definition of defensive medicine is the provision of services administered in an effort to benefit the physician by fending off malpractice liability though the procedures afford no expected benefit to the patient. Michael J. Saks & Stephan Landsman, *The Paradoxes of Defensive Medicine*, 30 HEALTH MATRIX 25 (2020). This creates costs for the patient and society, income for the provider, and needless risk of patient harm. More ambiguous variations include procedures that offer *some* benefit to the patient though performed primarily to serve the doctor's goal of avoiding a lawsuit. *See id*. at 61.These types of defensive practice are referred to as "assurance" behaviors. *Id*. at 50–51. Who can say how high the ratio of patient benefit to physician benefit must shift before one can say the actions are not "defensive"? But we should be clear that practices that benefit the provider *because they benefit* the patient are not defensive; they are good medical care. An economic analysis would say that any practice that affords patient benefits that exceed costs cannot be regarded as defensive. *See id*.

An altogether different kind of defensive tactic is referred to as "avoidance" behavior, namely, refusal to treat certain kinds of patients or conditions because they are thought to create a heightened risk of a malpractice action. *Id*. Patients who receive no care, for whatever reasons, are not going to be the subjects of research on whether liability risk increases safety.

For more extended analysis of defensive practices, their existence, their cost, and other implications, see generally *id*.

23. *Id.*

24. Mello et al., *supra* note 13, at 353 ("Evidence of defensive medicine is common, whereas evidence of deterrence is more elusive.").

II. WHY MIGHT STUDIES FAIL TO FIND A SAFETY EFFECT IF ONE EXISTS?

Some of the methodological issues the Article discusses are well known, and we invite readers to skip the discussion of any issues they are familiar with. We touch only briefly on the most familiar. Other methodological stumbling blocks addressed are, we think, fairly novel and worth closer attention. The overall package of considerations will, hopefully, be informative for those contemplating future research in this area, and perhaps other areas confronting similar challenges.

A. General Considerations

1. *Multivariate and Other Correlational Designs*

Nearly all the studies of the research question at hand are unavoidably correlational (observational), rather than experimental (randomized controlled trials). That presents a largely familiar set of concerns. To avoid being misled (in either direction) by confounded variables, selection biases, directionality error, and other challenges of working with such data, researchers try to compensate for lack of experimental control with statistical control.

The ability to provide unconfounded insight into the relationship between predictors and criteria depends on the availability of control variables and the data analyst's skill in using the controls.[25] Too few control variables and confounding might not be adequately controlled; too many control variables and the tested models will be unstable and undependable. That is why statisticians advise reliance on theory about the process under study and against guessing about control variables or relying on blindly empirical efforts to achieve statistical control.[26] A much better approach would be the use of experimental or quasi-experimental designs, though opportunities for doing so are scarce in many research domains, including this one. But they are not unheard of.[27]

---

25. *See also* David P. MacKinnon & Sophia J. Lamp, *A Unification of Mediator, Confounder, and Collider Effects*, 22 PREVENTION SCI. 1185 (2021).

26. Unfortunately, the area of research we are discussing is under-theorized. Moreover, a simple count of models—how many produced a significant relationship versus how many did not—can be misleading. One needs to take into account what a model among a set of models was created to do. If research is testing a theory, the theory might lead to hypotheses about non-relationships as well as relationships. Those tests of predictions would not be an undifferentiated search for relationships. Finding relationships where expected and not where they are not expected would do much to support the theory. (But see discussion of null results.) If a study is an undifferentiated search for relationships (also known as a fishing expedition), trying various combinations of variables to see what happens, then it is looking in many directions for an effect if one exists. (And those it finds would be regarded with skepticism until confirmed by subsequent non-fishing-expedition research.)

27. *E.g.*, Michael Frakes & Jonathan Gruber, *Defensive Medicine: Evidence from Military Immunity*, AM. ECON. J.: ECON. POL'Y, Aug. 2019, at 197, 197.

2. *Skewed Outcome Variables*

What the preceding subsection had to say is elementary. Patient safety research is unusual because the dependent measures are almost always highly skewed. Serious iatrogenic errors are voluminous in the aggregate, but they occur relatively rarely within any given group of patients, such as those in a hospital on any given day. An obvious example is mortality: most patients are not killed by their healthcare, though a fraction of them suffers a lethal mistake.[28] Failure to use an appropriate statistical analysis with such variables (such as a Poisson distribution or appropriate transformations) leaves researchers with an increased risk of failure to detect an effect that exists (Type II error).[29] Most fundamentally, sample sizes would need to be large to be able to capture enough cases with the relatively rare outcome.

3. *Null Results*

Which brings us to the problem of null findings. Of course, one cannot formally affirm a null hypothesis.[30] But, as a practical matter, where "no effect" is an important possible outcome of research, and enough well-designed studies persistently fail to reject the null hypothesis, researchers and policymakers come to the reasonable conclusion that there is no relationship between the variables of interest. But the key words in the preceding sentence are "well-designed studies." Researchers, not to mention editors, approach null results cautiously because such outcomes can so easily be the product of flawed research designs.[31]

---

28. When anesthesiologists were making frequent errors, they were killing only 1 patient in 5,000. SAKS & LANDSMAN, *supra* note 1, at 86; *see* Frederick W. Cheney, *ASA Closed Claims Project—Where Have We Been and Where Are We Going?,* 57 AM. SOC'Y ANESTHESIOLOGISTS NEWSL. 8 (1993); Ellison C. Pierce, Jr., *The Development of Anesthesia Guidelines and Standards*, 16 QUALITY REV. BULL. 61 (1990); *infra* text accompanying note 56.

29. Abdelmonem Afifi et al., *Methods for Improving Regression Analysis for Skewed Continuous or Counted Responses*, 28 ANN. REV. PUB. HEALTH 95 (2007).

30. Michael J. Saks & Samantha L. Neufeld, *Convergent Evolution in Law and Science: The Structure of Decision-Making Under Uncertainty*, 10 LAW, PROBABILITY & RISK 133 (2011). Also see the discussion of hypothesis testing in any basic statistics textbook. To be clear, a conclusion that one cannot reject the null hypothesis on a study's data under the statistical criteria adopted is never the same as concluding that an effect size is zero. The real question of concern is whether a statistical analysis comparing two or more conditions is likely to miss an effect of meaningful size. It is not unusual for researchers obtaining null results to perform a post-hoc sensitivity power analysis to assess the minimum effect size that could have been detected. The true concern is whether such an effect is meaningful in the context of the phenomenon under study. At the end of the day, the important question is whether, even if a significant effect were to be found, is the effect of a size that matters. Tiny effect sizes, even if statistically significant, would be of little value in the context of patient safety.

31. One of the authors has himself coauthored a set of studies reaching the conclusion that an effect widely believed to exist did not exist, and experienced the customary editorial skepticism. Before our favored journal would accept the paper for publication, we had to conduct a series of additional experiments reflecting successive improvements in design capable of ruling out potential weaknesses in the initial experiment. The editor and reviewers wanted to be persuaded that the null findings revealed something about the reality of the phenomenon under study and not something about the studies' methodological inadequacies. *See* N.J. Schweitzer et al., *Neuroimages as Evidence in a Mens Rea Defense: No Impact*, 17 PSYCHOL. PUB. POL'Y & L. 357 (2011).

To gain the acceptance of the scientific community, null results need to be the product of studies that are as free of methodological flaws as possible, so one may infer that a finding of no significant difference reflects a true absence of an effect, rather than any of the various methodological, statistical, and measurement reasons why studies can fail to reject false null hypotheses.

4. *Directionality*

The final general concern is that of inferring the direction of relationships that are found. As noted above, studies of the question under examination are almost invariably correlational. A study would look, for example, at variation in rates of malpractice filings between jurisdictions and correlate that with variation in mortality rates among surgical patients in those jurisdictions. When a relationship is found between those two variables, what inference should be drawn?[32]

A common assumption is that exposure to liability risk is the cause and patient outcomes the effect. In that view, a prevention effect ("deterrence") would be reflected in a negative relationship: where filing rates are higher, mortality would be lower. On the same cause-effect assumption, a positive relationship would indicate an "antideterrent effect" (more liability risk leads to more iatrogenic harm, rather than less). But the causal arrow could be pointing in the opposite direction.[33] More iatrogenic harm might produce more lawsuits. For example, where car crashes are more numerous, we should expect personal injury lawsuits to be more numerous, while fewer crashes would be associated with fewer suits. Not because lawsuits cause car crashes, but because where injury occurs tort litigation follows. To get a handle on causal direction, other information is needed, such as would come from time-series designs. One cannot simply assume that a negative relationship reflects deterrence and a positive relationship reflects antideterrence.

Let's think as well about the directionality problem in the context of findings of *no* correlation—that is, where neither a positive nor a negative relationship can be discerned. That very well might show "no evidence of deterrence"—or antideterrence, either. But it might indicate something quite different. Suppose the tort system is working something like this: Where negligent iatrogenic injuries occur at higher rates, more victims and families consult attorneys and more malpractice complaints are filed. In time, in response to the rise in litigation, efforts are made to increase safety or otherwise avoid causing injuries, and those efforts succeed. Adverse events subside, litigation declines. That decrease in litigation risk, in turn, leads to more relaxed practices, less safety. Negligent injuries begin to increase again. That would be a cycle of reciprocal causation. If this is happening, to detect it would require careful time series inquiries. Otherwise, in any given study of liability-risk effects, positive and negative relationships might be mixed together—especially if different times and places, at

32. *See* William M. Sage & Kristen Underhill, *Malpractice Liability and Quality of Care: Clear Answer, Remaining Questions*, 323 J. AM. MED. ASS'N 315 (2020).

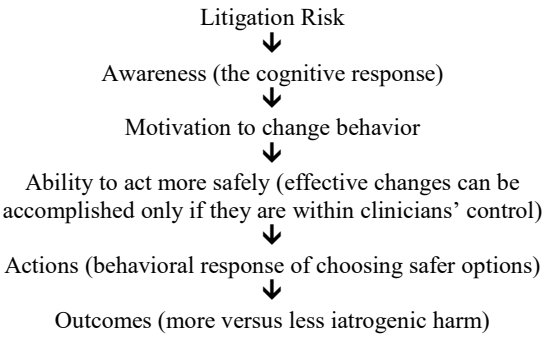
33. *Id.*

different stages of those cycles, are being analyzed together in one pool of data—producing an overall noisy pattern, and a correlation of zero. We do not insist that is what's happening. We merely suggest it as a plausible scenario, consistent with what tort litigation might be expected to do.

B. Liability-Specific Considerations

As we have noted repeatedly, studies of the question under consideration measure litigation risk and some outcome variable and look for a relationship between the two. Between that starting point and end point exist a sequence of intervening actions that must take place if the independent variable is to influence the dependent variable, but those intervening steps are rarely measured. By not knowing what is happening along the way from litigation risk to outcome, erroneous inferences might be drawn.

Let's consider the following (minimum) steps that would be needed to connect litigation risk to safer outcomes (if such an effect exists).



To find a relationship between different levels of litigation risk and safety outcomes, there must, first, be an actual, nontrivial difference in litigation risk. That difference must be more or less correctly perceived by healthcare providers. If providers are unaware of the level of risk, or are mistaken about it, then it can have no effect, or no rational systematic effect, on their behavior. Even if they are aware and motivated by that awareness to engage in safer conduct, if they have no ability to change care behavior in ways that increase safety (because the changes that need to be made are beyond their reach, outside of their power to control), then no improvement in safety can result. If the ability is within their control, then they must know what the safer practice is, how to perform it, and then do so.

If all of that can and does happen, then the possibility exists for improved outcomes. But if differences in litigation risk are nonexistent or trivial, or the risk is not accurately perceived, or any of the other intermediate steps are not possible or not performed, then there is no reason to expect safer outcomes to be observed. In other words, any break or failure in the causal chain will result in finding no effect, even if an effect would have been found if the chain were intact. Assuming the eventual correct and final conclusion is that malpractice

liability does not produce greater safety, the answer to "why doesn't it?" might be found somewhere in that chain of events.

1. *Litigation Risk*

A variety of measures of exposure to litigation risk are used in various studies. Some of them might not be faithful reflections of actual risk. A measure such as the *rate of malpractice claims* certainly suggests a higher or lower risk of litigation.[34] However, superficially different rates of filed claims, if controlled for the underlying incidence of negligent adverse events in the respective jurisdictions, might turn out to be no real differences in litigation risk at all or, indeed, be the reverse of the uncontrolled rate.

Consider a hypothetical illustration. Locale A has an annual malpractice filing rate of 1,000 claims per 1,000,000 hospital admissions. Locale B has a rate of 2,000 per 1,000,000 hospital admissions. Therefore, Locale B seems to have twice the litigation risk as Locale A. But suppose the underlying incidence of negligent adverse events in Locale A is 10,000 per year (so that 10% of negligent adverse events become filed claims), while Locale B has 40,000 negligent adverse events per year (of which 5% become filed claims). By controlling for the underlying incidence of negligent adverse events, it becomes apparent that the real litigation rate is the other way around: Locale A has twice the litigation risk of Locale B.

Measures such as *malpractice premiums* or *average size of paid claims* are even less clear. To be sure, premiums reflect the cost of defending claims and cost of paying successful claims. But they also reflect a firm's administrative costs, state insurance regulations, investment market conditions, the firm's practices concerning reserves and profits, the cost of living in an area, and other

34. In some studies, the measure of "liability risk" (defined as "the extent to which clinicians face the threat of being sued and having to pay damages," Mello et al., *supra* note 13, at 353) is the aggregate rate of suits per physician per year, while in others it is the individual physician's personal claims *history*. The former measure seems a fairly straightforward indication of the probability that, all else equal, a physician would face a lawsuit.

But what does the latter measure indicate about liability risk? Does it even meet the definition? One's experience of being sued certainty seems likely to make the concept vivid and salient. But how does it inform one's estimate of the probability of a future suit? If a version of the gambler's fallacy is at work, a physician might feel that, having been sued, the chances of a future suit have been *reduced*. A physician who thinks more like a probability theorist would regard each event as independent of the others in event space, and realize that the fact of having been sued does not provide any information about future liability risk. Or, a physician might interpret a past suit as a signal that she has an elevated error proneness, or lacks the bedside manner that leads the great majority of patients who suffer iatrogenic harm to lump their injuries, and therefore is more likely than equivalent colleagues to be sued. Or perhaps someone who had previously been sued becomes more of a target (the "blood in the water" hypothesis).

More important than how individuals respond to their particular unique experience of being sued previously (that is, specific deterrence) is the question of how potential tortfeasors respond to the population-wide (or relevant sub-population) risk of liability (that is, general deterrence).

The short of it is that these two measures of liability risk are quite different, and the meaning of one (personal claims history) is especially poorly understood. Indeed, the experience of being sued might affect the risk estimates and other responses of different physicians quite differently.

factors. So, those amounts do not necessarily correlate well with physicians' risk of being sued. If premiums fail to correlate with safety outcomes, that might be because that measure is a weak indicator of the litigation risk.

Average size of paid claims reflects, primarily, the amount of the injury victim's losses and the quality of the evidence of causation and negligence. A small number of serious permanent injuries could lead to costly settlements or awards and a high average payment amount. A smaller average amount could reflect a large number of less serious injuries being filed and paid. Thus, smaller average claims amounts could reflect *more*, rather than less, risk of being sued. The assumption about what high average paid claims reflect might be backwards, depending on what underlies those numbers.

Another measure of litigation risk in many studies has been *tort reform*. All such reforms are assumed to reduce exposure risk.[35] Some reforms benefit the healthcare industry because they tend to reduce the amount that must be paid to reimburse victims for their losses. But those same reforms do not necessarily reduce the probability that any given healthcare provider might become a defendant in a suit. Reforms such as abolition of punitive damages, abolition of mandatory prejudgment interest, collateral source rule reform, and mandatory periodic payments might make the healthcare industry a bit more profitable, and might reduce insurance premiums slightly, yet do little or nothing to reduce the probability of a claim being filed.[36]

A tort reform that tends to *increase* the risk of providers being sued is the abolition of joint and several liability. Under traditional law, each tortfeasor who is liable is responsible to reimburse the victim fully. That rule allows a defendant who is responsible for, say, 80% of the harm, to be required to pay for 100% of it. By abolishing the rule of joint and several liability, that defendant would be responsible for paying only 80%. This law reform might be attractive to the primary defendant's insurer, who gets to pay less in damages. But, under the reform, the only way the plaintiff can recover all that the plaintiff is owed is to bring those responsible for the remaining 20% into the suit.[37] That means more healthcare providers are likely to become defendants rather than fewer.[38] Thus,

---

35. The one tort reform that appears to have been more successful than any other in reducing the incidence of suits and therefore litigation risk is the capping of damages, that is, limiting the payment of compensation that would otherwise be owed to the most seriously harmed patients. For reviews of the evidence, see BERNARD S. BLACK ET AL., MEDICAL MALPRACTICE LITIGATION: HOW IT WORKS, WHY TORT REFORM HASN'T HELPED (2021); Allen Kachalia & Michelle M. Mello, *New Directions in Medical Liability Reform*, 364 NEW ENG. J. MED. 1564, 1566 (2011); SAKS & LANDSMAN, *supra* note 1; FRANK A. SLOAN & LINDSEY M. CHEPKE, MEDICAL MALPRACTICE (2008).

36. *See* Sage & Underhill, *supra* note 32.

37. Imagine that four other participants in the incident were each found to be five percent responsible.

38. Data suggest that the familiar quip that lawyers sue everyone in sight—and therefore anyone and everyone who could plausibly become a defendant has already always been a defendant—is not accurate. Evidence suggests that lawyers are selective in choosing defendants. Mohammad Rahmati et al., *Screening Plaintiffs and Selecting Defendants in Medical Malpractice Litigation: Evidence from Illinois and Indiana*, 15 J. EMPIRICAL LEGAL STUD. 41, 55 (2018), found that in

a reform increasing the risk that providers will become defendants in litigation is mistakenly treated as a reform that decreases the risk.[39]

In sum, a variety of measurement pitfalls might interfere with obtaining valid measures of liability risk. Some of the measures in common use might not reflect actual differences in liability risk, might be difficult to interpret, or even give readings that are the reverse of the actual state of risk. A finding of no correlation for such measures would not really equate to "no evidence of deterrence" and vice versa.

2. *Awareness of Risk*

As noted earlier, even real and meaningful differences in litigation risk cannot produce differences in outcomes unless those differences are perceived with reasonable accuracy by providers. Subjective perception of the risk of liability is more important than the actual risk—whether or not the measurement of actual risk is valid or freighted with error—because that is what drives behavior.

Efforts to measure those perceptions suggest that healthcare providers generally are insensitive to actual levels and variations in risk. One study, by members of the Harvard Medical Practice Study project, found that physicians greatly overestimated the risk of being sued.[40] They believed that 45% of ad-

---

serious cases of medical malpractice in Illinois, sixty-six percent of cases were against a single defendant. "So, a 'sue everybody in sight' strategy does not describe the behavior of most Illinois med mal plaintiffs' lawyers." *Id.* at 56. Rahmati and his coauthors' study of Indiana found that thirty percent of cases were filed against single physicians and many more were against single physicians plus the physician's professional corporation. *Id*. at 65–66. Selectivity in choosing defendants is unsurprising once one pauses to consider that each named defendant requires more research, more expert evaluation, more depositions, more motions, more everything, all of which cost more in time and money. There is no reason to go after additional defendants unless the expected return will more than make up for the additional cost.

Claudia E. Lavenant, Craig L. Hayward & Paul Jesilow, *Tort Reform and Physician Sanctioning*, 24 LAW & POL'Y 1, 11–13 (2002), found that states where joint liability was abolished subsequently saw increases in the number of physicians against whom sanctions (suspensions, loss of license, etc.) were brought by state medical disciplinary authorities. The authors explain as follows:

> Individuals and organizations can only be held responsible for the portion of damages they caused. As a result, attorneys may press cases against physicians that, prior to reform, would have resulted in settlements with hospitals [or a physician more central to the harm]. The ensuing findings of malpractice are passed along to medical boards and the National Practitioner Data Bank, which then makes the information available to all licensing boards. Increased physician sanctioning is an expected outcome.

Id. at 12.

39. At the same time, some research suggests that patients might benefit. *See, e.g.,* Janet Currie & W. Bentley MacLeod, *First Do No Harm? Tort Reform and Birth Outcomes*, 123 Q.J. ECON. 795, 826 (2008) ("Our strongest and most robust finding is that [joint and several liability] reform reduces C-sections, and complications of labor and delivery. By aligning malpractice risk more closely with the physician's own actions, JSL reform causes physicians to take more care and avoid unnecessary and potentially harmful procedures. In addition, JSL reform may cause hospitals to undertake systematic reforms that are beneficial to patients generally in order to avoid being held responsible for a large share of the damages in medical malpractice cases.").

40. Ann G. Lawthers et al., *Physicians' Perceptions of the Risk of Being Sued*, 17 J. HEALTH POL. POL'Y & L. 463, 473 (1992).

verse events led to malpractice litigation (the actual rate was no more than 4%) and that 65% of negligent adverse events led to litigation (actual rate, not more than 13%).

In another study, Carrier and her colleagues found that levels of malpractice concern among doctors were generally high and unrelated to the actual level of lawsuit risk in the state where they practiced.[41] They noted: "We found high levels of malpractice concern among both generalists and specialists in states where objective measures of malpractice risk were low. We also found relatively modest differences in physicians' concerns across states with and without common tort reforms."[42] Sage and Hyman noted that physicians

> seem unaffected by evidence regarding the actual likelihood of a lawsuit or the level of potential damages. . . . [P]hysicians in states with strong tort reforms and in states lacking those reforms articulated identical views regarding malpractice risk. Even physicians practicing in low-liability-risk environments display high levels of anxiety about the malpractice system.[43]

If providers are insensitive to the actual litigation risks under which they practice, and if they do not keep track of which versions of which reforms exist where they practice, then they cannot adjust their subjective estimation of malpractice risk to accord with the objective risks. If those findings remain accurate and general descriptions, then an enormous challenge confronts research testing for a relationship between liability risk (in the legal environment) and patient safety. Given practitioner insensitivity to variations in actual risk, how can any study looking for an effect of actual liability risk on patient safety be expected to find any impact?

Physicians' generalized, vague, and exaggerated fear of becoming malpractice defendants suggests the possibility that the fear of malpractice liability is more like a binary switch that is either on or off. Once a level of risk exposure is sufficient to flip that switch on, it makes no difference whether the risk is just enough to turn it on or is far more than enough to do so. Studies that look at varied risk levels that are all above the minimum threshold needed to turn the deterrence switch "on" are all methodologically destined to find "no effect."

This is analogous to dose-response relationships in studies of chemical and drug effects.[44] For example, as depicted in Figure 1, imagine that a set of studies all compared agonists[45] at doses ranging from 10 to 10,000. All of those dose levels produce the same response. In this context, it would be a mistake to conclude that the agonist "has no effect" because the varying doses of the agonist

---

41. Emily R. Carrier et al., *Physicians' Fears of Malpractice Lawsuits Are Not Assuaged by Tort Reforms*, 29 HEALTH AFFS. 1585, 1585 (2010).

42. *Id.*

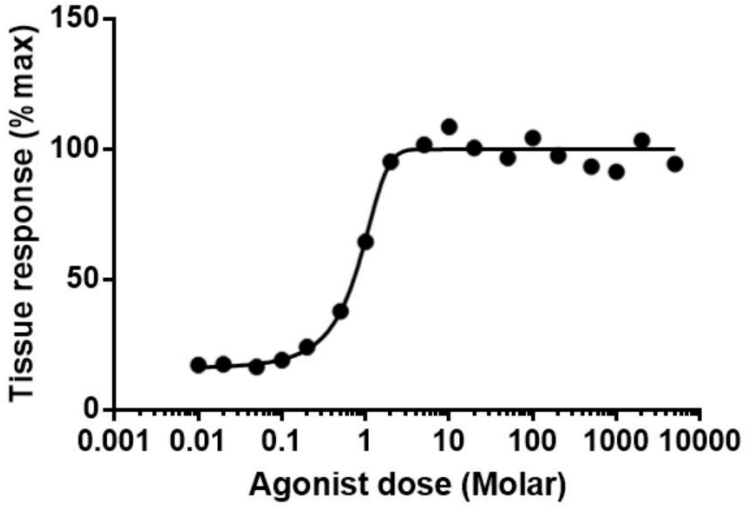
43. William M. Sage & David A. Hyman, *Do Health Reform and Malpractice Reform Fit Together?* 20 (Am. Enter. Inst. Health Pol'y, Working Paper No. 2011-02, 2011), https://www.aei.org/wp-content/uploads/2011/10/2011-04-Hyman-Sage.pdf.

44. JIXIAN WANG, EXPOSURE-RESPONSE MODELING: METHODS AND PRACTICAL IMPLEMENTATION (2015).

45. An agonist is a chemical substance that initiates a physiological response when it joins to a receptor.

show no differences when tested against each other. Let's take the analogy one step further. Imagine that the chemical being tested happened to exist in the general environment (the air, the water, many foods) at a sufficient dose to produce the response. Under that circumstance, any dose administered by researchers would appear to produce no response.

Figure 1. A Dose Response Curve Showing the Tissue Response to Stimulation by an Agonist. Doses below some threshold are insufficient to generate a response; doses above that threshold all generate the maximum response. Figure created by James Goodman (June 17, 2019), https://en.wikipedia.org/wiki/Dose%E2%80%93response_relationship#/media/File:Dose_response_curve_stimulation.jpg.



And, finally, let's carry the point back into the context of research on possible safety effects of liability. We need not imagine that the legal "substance" being tested exists in the larger environment and is always acting on healthcare providers. We know it is there, and they know it is there. Studies that compare jurisdictions with a little more tort law versus a little less tort law, or somewhat different tort law, will be unable to detect differences so long as all of the liability risks are above the threshold required to trigger a response.[46] All the while, hovering above in the larger environment, there exists the general, overarching malpractice system. Providers are aware of that overarching system, and it might be the main (and vague) liability risk they are aware of, and behave in light of.

46. One quasi-experiment is an exception and is worth taking note of. *See* Frakes & Gruber, *supra* note 27.

Comparing a bit less to a bit more, in the midst of that predominant legal environment, cannot detect the possible effects of the larger environment's tort law. And *that* is the important effect, which needs to be studied.

3. Actions

An important consideration is what actions are taken, could be taken but are not taken, or cannot be taken by potential tortfeasors to reduce their risk of liability by increasing patient safety. If a healthcare provider perceives a risk of tort liability, and is motivated to take constructive action, but is unable to do so, then the chain of causation from liability risk to safety is broken. This would be another explanation for the failure of liability risk to affect patient safety.

For example, if a practitioner wanted to use Pronovost's highly effective five-step procedure to prevent central line associated bloodstream infections, but worked at one of the numerous hospitals that did not stock chlorhexidine, then the safer practice could not be implemented.[47] Such examples underscore the notion that most of the potential for improving patient safety is controlled by those higher in the organizational structure than clinical caregivers.

For research on the question under examination, the choice of which actions to measure can have an impact on the possibility of finding an effect or overlooking it. Those choices of what to measure might be driven by one's theory of how liability risk and patient safety work.

For example, consider the role of defensive medicine. Elsewhere, we extensively reviewed research on various aspects of defensive medical practice.[48] We noted, among other things, that the methodologically weakest studies of defensive medicine (surveys asking physicians to estimate the amount of defensive practice they or their colleague engage in) found huge amounts of defensive medicine,[49] while other kinds of research (scenario studies, multivariate analyses of actual events) found more limited indications of defensive practices.

We concluded that true defensive practices were much less common than usually supposed. Much more common was the use of additional diagnostic tests, observation, and consultation in cases where being wrong carried a high risk of serious harm to the patient. Perhaps *those* are the kinds of safety steps that can be and are taken by individual practitioners. A familiar example is head injury that initially appears not to be serious:

> [A] scenario [that] aligns well with existing empirical evidence . . . is consistent with an image of healthcare providers as thoughtful professionals who are properly concerned about their patients' well-being, rather than routinely sacrificing their patients' interests for their own. This scenario is that sick patients fall along a continuum ranging from clearly suffering from a condition

47. *See generally* PETER J. PRONOVOST & ERIC VOHR, SAFE PATIENTS, SMART HOSPITALS (2010). When fully instituted at over 100 hospitals in Michigan, in three months the five-step protocol of clinical best practices brought the median infection rate down from 2.7 infections per 1,000 catheter-days to nearly zero. *Id.* at 142.

48. Saks & Landsman, *supra* note 22.

49. We also found that sometime in the 1970s responses to such self-report surveys abruptly flipped from massive denial of defensive practices to massive admission. *Id.* at 53.

> that requires a particular treatment strategy, at one extreme, to clearly not suffering from the condition at the other extreme. For those clear cases, no defensive practices need be employed. Cases near the middle, characterized by the greatest uncertainty and high risk of error, will be more likely to prompt "defensive" behavior, especially for a condition where an erroneous diagnosis could lead to a disastrous outcome. Under such circumstances, non-cost-beneficially-optimal, "wasteful," diagnostic testing is most likely to be undertaken. Whether that is done to protect the physician or the patient might be impossible to disentangle. Doctors might say that they thought they were acting defensively. But they were simultaneously making sure that the patient was being protected against the consequences of error. Under such circumstances, the line that divides defensive medicine from good medical practice becomes impossible to discern.
>
> An example of that kind of situation would be a head injury. If the patient suffered a potentially dangerous head injury that could have been detected with more testing and observation, but is not caught, the result for the patient could be devastating. That's what the doctors responding to OTA's head-injury-case scenario were almost certainly thinking about when they proposed to order "excessive" testing. That is certainly what Atul Gawande was worrying about when his son was taken to the ER after a fall. Furthermore, it is consistent with research finding that "the strongest effect of greater malpractice pressure is in increased use of imaging services, with somewhat smaller effects on the use of other discretionary, generally low-risk services such as physician visits and consultations, use of diagnostic tests, and minor procedures."
>
> If that is what most "defensive medicine" looks like, then it is not irrational, not particularly wasteful, and not something many patients would wish to put a stop to.[50]

If the preceding example is a more accurate description of what "defensive" practices are, researchers should want to capture such actions as a measure of possible safety effects of liability risk. They are good candidate measures because they are steps that providers have within their power to take, if they wish, in situations where such steps would prevent avoidable serious injury if the initial diagnosis and assessment turned out to be mistaken. On the other hand, researchers who believe that defensive medicine is rampant, and that such actions are merely worthless defensive practices, might choose not to include those measures in their studies. As a result, those researchers might be passing up an opportunity to detect effects of liability risk on patient safety that do exist.

Those same differences in one's understanding of defensive medicine would lead reviewers of studies to exclude from consideration measures that capture what they regard as worthless defensive practices.[51] If they are right,

---

50. *Id.* at 82–83 (footnotes omitted).

51. As Mello and her coauthors state:

> Studies that examined the relationship between liability risk and measures that are more reflective of costs than quality were excluded. For these reasons, studies focusing on . . . most types of diagnostic tests were excluded. Such services are considered overused due in part to defensive medicine. Unless studies accounted for clinical circumstances that distinguished appropriate from inappropriate use . . . they were deemed unhelpful in assessing deterrence. If a study examined multiple outcome measures, we included only analyses of outcomes that met our criteria.

they have not looked because there is nothing to look at. If they are wrong, they've missed an opportunity to detect beneficial effects.[52]

Finally, a distinction needs to be made between actions and their safety effects. Actions that can be taken in an effort to try to improve safety, and are taken, could be indications of positive effects of liability risk, whether they work or not. Thus, a study using PSIs (patient safety indicators) might be using a much more sensitive measure of positive actions that might be associated with liability risk than a study that skips right to how many of those patients die from their healthcare.[53]

That the final link in the chain—connecting constructive actions to safe outcomes—is missing would be the consequence of insufficient medical knowledge concerning what actions do in fact protect patients from harm and which do not. Creating that final link would require a different kind of research than we are discussing in this Article, namely, conventional medical research that evaluates the efficacy and safety of alternative clinical actions.

This distinction illustrates, again, the value of "looking under the hood," examining the intermediate links in the chain, and trying to figure out what is going on.

4. *Outcomes*

Many of the outcome variables examined by this line of research include measures of quality of care as well as safety, as though all are expected to respond equally to liability risk. And if they do not, the implication is that liability risk—assuming its impact traveled this far down the causal chain—did not reach all the way to the beneficial end.

Finding and constructing quality metrics has been challenging in healthcare, quite apart from their use in studies of the possible safety effects of malpractice liability. As the medical literature develops over time, providing better quality and safety metrics, medical liability research might evolve right along with it, thanks to it.

Mello et al., *supra* note 13, at 353. By contrast, diagnostic procedures could be distinguished as high value versus low value; if liability pressure led to more use of high-value diagnostics but not of low-value diagnostics, that would seem to be indicative of a safety effect of the law. *Id.*

52. This would not be the first time that different literature reviews of the same body of empirical research reached conflicting conclusions. See, for example, the recent dueling systematic reviews of the anti-parasite drug ivermectin, repurposed to treat Covid-19. Two meta-analyses of empirical studies of its efficacy, reported within weeks of each other, reached opposite conclusions. *Compare* Andrew Bryant et al., *Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-Analysis*, *and Trial Sequential Analysis to Inform Clinical Guidelines,* AM. J. THERAPEUTICS e434 (2021) (announcing the conclusion that the drug works to prevent and cure Covid-19) *with* Yuani M. Roman et al., *Ivermectin for the Treatment of COVID-19: A Systematic Review and Meta-Analysis of Randomized Controlled Trials,* 74 CLINICAL INFECTIOUS DISEASES 1022 (2022) (finding no effect). An important difference between the two reviews was the inclusion criteria used by the two teams.

53. *See, e.g.*, Zenon Zabinski & Bernard S. Black, *The Deterrent Effect of Tort Law: Evidence from Medical Malpractice*, J. HEALTH ECON., July 2022, art. no. 102638, at 1.

Another problem, as noted earlier, is that safety is not necessarily the same thing as quality.[54] Malpractice liability is not aimed at aspects of quality outside of harm produced by what the National Patient Safety Foundation refers to as "errors and deviations."[55] Quality would be a valuable fringe benefit of liability risk, if liability risk had some effect on quality, but that is not what liability for harmful error has evolved to address.

The methodological implication is that studies of the effects of liability risk on iatrogenic harm would do better to focus on iatrogenic harm. The failure to find effects on other aspects of healthcare should not be mistaken for a failure of liability risk to affect the incidence of iatrogenic harm. Thoughtful research will keep these distinctions well sorted.

C. Organizations and Systems

At several points, this Article alluded to organizations or systems being better situated than individual healthcare workers to implement safety improvements. Most of the examples given of positive impact of tort liability on safety were focused on organizations—not individuals—assessing the cost of liability and evaluating whether and what investments to make in safety.[56]

In many contexts, major aspects of the ability to make practices safer, and decisions about whether and how to do so, rest with people higher in the organizational structure than individual providers of care. If enhancing patient safety requires action at the level of the system—if the organization is where control over patient safety is centered and where most decisions on investments in safety are made—then that is where the focus of accountability would presumably be most usefully aimed. Unfortunately, because of the way the healthcare industry has organized itself, much liability lands on providers and their insurers rather than on larger organizations.

---

54. *See supra* text accompanying note 17.

55. *See* Szalados, *supra* note 17, at 226.

56. Those examples included: worker's compensation, disclosures to investors, medical device product liability, and facilitating the use of Pronovost's five-step method to reduce central line infections. Another, well-known, example is worth mentioning also: Explicitly responding to malpractice suits (and high malpractice insurance premiums) resulting from high rates of serious harm to patients, anesthesiologists launched a project to make anesthesiology safer. *See* Cheney, *supra* note 28; Pierce, *supra* note 28. The project team made important discoveries about what anesthesiologists were doing wrong and what needed to change to reduce those dangers. Before long, the incidence of death from anesthesia errors fell from about 1 in 5,000 to less than one in 250,000. SAKS & LANDSMAN, *supra* note 1, at 86. As safety went up, litigation and premiums plunged, as hoped and expected. As Cheney observed: "The relationship of patient safety to malpractice insurance premiums was easy to predict. If patients were not injured, they would not sue, and if the payout for anesthesia-related patient injury could be reduced, then insurance rates should follow." Cheney, *supra* note 28.

In the organizational setting, like that of Nelson & Pritchard, *supra* note 11, not only are potential defendants more sophisticated about risk, potential plaintiffs are also more sophisticated. So both sides of the equation are more aware of their risks and their options. Perhaps when plaintiffs are more dependably alert to their own interests and more often exercise their rights, out of necessity defendants also pay more attention.

If that organizational view is correct, then studies of the physician-focused model of liability would not be expected to find much of a relationship between liability risk and safe caregiving by individuals. Their null findings could be interpreted as confirmation of the systems model. Furthermore, it lends support to the argument that making *systems* more amenable to liability would produce more safety.[57] Though individuals cannot or do not, organizations are quite capable of tracking data on liability risk and costs, and of making sophisticated decisions about which investments in safety, or other organizational changes, are worth undertaking to reduce the costs of liability.[58]

Under existing arrangements, most hospitals deflect what liability they can onto physicians and other independent contractors. The result is somewhat paradoxical: the entity most able to make the systems changes needed for greater safety is sheltered from liability, while the individuals who cannot make those changes are exposed to liability. Legal changes, such as the adoption of enterprise liability[59] or enterprise insurance,[60] would be expected to make tort liability more effective at promoting safety by facilitating the liability of organizations, where safety improvements are more likely to be achievable.[61] This is not to say that there are no individual providers who cause more than their share of iatrogenic harm.[62] But they, too, would likely receive more help, or be moved to jobs where they might do less harm, if the costs of their errors were borne by the organizations for which they worked.

Thus, a difficulty with individual-provider focused studies is that they are looking to the wrong places for solutions—reflecting a model of safer medical care as an individual-provider phenomenon, rather than of prevention as systemic and susceptible (presumably) to being encouraged by liability directed at the collectivity. Of course, the "correct" place to look has yet to be brought into existence.

---

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

58. Among the cost-benefit concerns to be overcome, iatrogenic harm to patients generates additional profit, while investments in safety cost money to implement and, if successful, reduce future revenue. Sunil Eappen et al., *Relationship Between Occurrence of Surgical Complications and Hospital Finances*, 309 J. AM. MED. ASS'N 1599, 1602 (2013); Dan C. Krupka et al., *The Impact on Hospitals of Reducing Surgical Complications Suggests Many Will Need Shared Savings Programs with Payers*, 31 HEALTH AFFS. 2571, 2575 (2012); Marlene R. Miller et al., *Patient Safety Events During Pediatric Hospitalizations*, 111 PEDIATRICS 1358, 1361 (2003). Something is needed to offset those perverse incentives if there is to be a business case for safety. Tort liability has been the traditional counterforce, but other economic counterforces have been developed in recent years, notably denial-of-payment programs by the Centers for Medicare and Medicaid Services.

59. Abraham & Weiler, *supra* note 57.

60. Tom Baker, *Medical Malpractice Insurance Reform: "Enterprise Insurance" and Some Alternatives*, *in* MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 267, 289 (William M. Sage & Rogan Kersh eds., 2006).

61. Abraham & Weiler, *supra* note 57.

62. *See, e.g.*, David A. Hyman et al., *Medical Malpractice and Physician Discipline: The Good, The Bad and The Ugly*, 18 J. EMPIRICAL LEGAL STUD. 131, 160 (2021); David Studdert & Michelle M. Mello, *In from the Cold? Law's Evolving Role in Patient Safety*," 68 DEPAUL L. REV. 421, 437 (2019).

III. CONCLUDING REMARKS

Iatrogenic harm is the leading cause of accidental injury and death in the United States, every year, without respite, exceeding all other causes of accidental harm combined.[63] That fact alone makes it an important subject of interest for researchers of various kinds, including empirical legal researchers. Apart from isolated or narrow developments, the healthcare industry has not succeeded in reducing the magnitude of the problem, despite urgent calls for doing so starting two decades ago.[64]

Tort law's contribution to reducing healthcare harm is debatable. That debate has been the point of departure for the present Article. If malpractice liability does have safety effects, but most research has not been adequate to detect those effects, we should be loath to eliminate it before more convincing work has been conducted. If liability is one of the main things preventing the number of iatrogenic deaths and injuries from rising even higher, we should not be eager to abolish it, or weaken it further, on inadequate or misinterpreted evidence.

On the other hand, if malpractice liability generates no safety effects, the chief reason for preserving it vanishes. Still, before abolition can be seriously argued, we should want more and tighter research than exists at present. If malpractice liability offers no safety-promoting benefits, then the law needs to find other ways to foster safety, because a permanent epidemic of iatrogenic harm should be acceptable to no one.[65] Moreover, even if malpractice liability makes a positive contribution to patient safety, it plainly is not good enough, considering the persistent volume of iatrogenic harm. And so, the law still has to find additional ways to foster safety, and empirical legal research will have an important role to play in testing those legal innovations.

Somewhere between no benefit and widespread benefit, the reality might be that malpractice liability advances safety in some ways and in some contexts but not in others. Research designed to sort out such possibilities is needed, the findings of which would support policy-making that tailors the application of liability to appropriate circumstances.

The principal goal of this Article has been to explore possible methodological weaknesses in this research area and to suggest improvements that might benefit future research. We now summarize the suggestions and implications that grow from the Article's analysis and discussion.

Threshold. A critically important possible explanation for the pattern of findings in this literature could be the existence of a threshold for liability risk—that all levels of risk above some threshold are responded to similarly, and therefore no differences in response exist among above-threshold risk levels. If that is a generally accurate description of responses to liability risk, then only the

63. Relevant data are reviewed in SAKS & LANDSMAN, *supra* note 1, ch. 4.

64. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Linda T. Kohn et al. eds., 2000).

65. *Epilogue: The Path Forward*, *in* SAKS & LANDSMAN, *supra* note 1, at 259–60 (noting some of those other avenues, and inviting a wider conversation on that subject).

below-versus-above threshold difference can be meaningful and detectable.[66] A major focus of interest of future research should be an effort to determine whether such a critical threshold exists and, if it does, quantifying where it is on the continuum of risk.

Feasible Actions. Studies need to take account of what actions are within the power of individual providers to enact to enhance patient safely versus what steps require systemic changes that must be made at the organizational level. Only the former are plausible choices for use as indicators of effects of liability risk at the level of individual providers. Some or most of those plausible choices might include actions often regarded as wasteful defensive practices. Research needs to assess whether they are, indeed, useless or if they, or some of them (such as high-value diagnostics), confer health and safety benefits. If the latter, they are dependent variables that should be included in studies assessing the effects of liability risks.

System-Level Responses. To the extent that improving patient safety requires actions at the organizational level, and that organizations are better able to evaluate liability risk and the associated costs and benefits of responses to the risk, research should be undertaken to shift the focus from the impact of liability risk on the behavior of individuals to its impact on the behavior of healthcare organizations.

Measures of Litigation Risk. Many measures of litigation risk have been employed in deterrence research, and many of them seem to have been chosen more because they are available and superficially plausible. More effort needs to go into developing and validating measures of litigation risk. One aspect of such measures deserving thought is that they consist of events and metrics of events that are capable of being perceived with sufficient accuracy by those who are expected to be reacting to them.

Perception of Liability Risk. Risk can have no sensible impact on downstream behavior without passing through the filter of perception and being interpreted with reasonable accuracy. Improved understanding is needed of perceptions of liability risk, what entities are doing the perceiving (individuals versus organizations) and with what accuracy. These issues need to become part of research on the effects of liability risk on safety.

Causal Pathway. Research would benefit from examining measures of the intermediate steps on the path from litigation risk to safety outcomes, among them risk perception, motivation, ability to act, and actions taken. Treating those intermediate steps as being locked inside an opaque box is to miss opportunities to learn much more about responses to liability risk. How far along the causal pathway do the effects, if any, of liability risk extend? Where is the chain bro-

66. Consistent with this threshold possibility are the findings of the study by Frakes & Gruber, *supra* note 27. They examined a situation in military healthcare where the same physicians in the same facilities treated patients (active service members) who were barred from bringing malpractice claims alongside other patients (family members and retirees) who did have a right to sue. This allowed comparisons of the behavior of providers in treating the two different types of patients. On several different measures of treatment intensity, patients who could not sue received four-to-five percent less care than those who could sue.

ken, if it breaks? Is that break remediable? Those and other such questions could be asked and answered.

Actions and Their Effects. A distinction needs to be made between actions and their effects. If a relationship exists between liability risk and caregiver actions, but not between risk and outcomes, a reasonable inference would be that the problem is not that providers are unresponsive to risk, but that knowledge is lacking as to what actions have beneficial impacts on safety. A related distinction needs to be made between measures of quality versus measures of safety.

Research Designs. Researchers should be alert for opportunities to conduct experimental or quasi-experimental studies, since they are inherently more interpretable and facilitate stronger inferences.[67] Assuming correlational studies will continue to dominate this literature, those studies should be conducted with the thoughtfulness and care that such approaches require, given the inferential risks inherent in nonexperimental work. That includes errors of inferring the direction of causation when relationships are found. And, whichever research designs are employed, care needs to be taken when analyzing highly skewed variables such as are often employed in this area of research. Finally, replication or partial replication needs to be more highly valued so that the literature can grow sufficiently for meta-analyses to be performed. We think it is no exaggeration to suggest that any field without enough studies on which to perform sound meta-analyses is not yet ready to be offering the world much guidance.

To date, all efforts to bring iatrogenic harm within tolerable bounds have been plainly insufficient. Even when the role of individual tort liability is eventually, convincingly determined—be it a substantial contribution to patient safety or none at all—the law will still have more work to do if massive numbers of avoidable deaths and injuries are not to remain a permanent feature of American healthcare.[68] Empirical legal research will have an important role to play in testing those varied initiatives. And the quality of that future research will be essential in accurately determining which changes in law are having what effects, if any.

67. Again, consider the study by Frakes & Gruber, *supra* note 27.

68. As Schuck has noted, "All systems . . . have had to adopt auxiliary measures—information, education, administrative regulation, instinct for self-preservation, technology, market effects (including reputation), professional discipline, and other behavioral influences—to augment the call for accident prevention." Peter H. Schuck, *Tort Reform, Kiwi-Style*, 27 YALE L. & POL'Y REV. 187, 200 (2008). SAKS & LANDSMAN, *supra* note 1, discuss a variety of possibilities, many of them involving legal changes away from individual liability, and even away from litigative policies more generally.