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TECHNICAL REPORT

Is Better Patient Safety Associated with Less Malpractice Activity?

Evidence from California

Michael D. Greenberg • Amelia M. Haviland • J. Scott Ashwood • Regan Main

RAND INSTITUTE FOR CIVIL JUSTICE

The research described in this report was conducted under the auspices of the RAND Institute for Civil Justice (ICJ) and funded by pooled contributions from the ICJ and from several insurance companies, individuals, and nonprofit groups with interests in patient safety and medical malpractice policy.

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Preface

In recent years, policymakers and health care providers have become increasingly interested in the relationships between patient safety, preventable medical injuries, and medical malpractice claiming. Whereas the conventional logic behind malpractice liability in tort is based on the deterrence of negligence, the patient safety movement in the United States embodies a very different theory: that many preventable medical injuries result from complex systems failures; that most medical providers genuinely want to keep their patients safe; and that the combination of quality-improvement activities and root-cause analysis can be an effective tool for reducing the occurrence of injuries. By extension, improving safety performance also offers the potential for positive impact on the medical liability climate, and on the volume of malpractice litigation, across the United States.

The purpose of this report is to investigate the relationship between safety outcomes in hospitals and malpractice claiming against providers, using administrative data and measures. The results of our analysis are suggestive of a link between safety outcomes and malpractice liability, with important implications for public policy. This study is the first in a series of planned research projects seeking to address this relationship and its implications for policy. The current report will be of interest to anyone who is concerned with either patient safety or medical malpractice policy in the United States.

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Summary

In principle, improvements in health care quality, and in safety outcomes and practices in U.S. facilities, ought to have a positive impact on the volume of malpractice claims against physicians and institutions. Malpractice claims are supposed to spin out of legitimate injuries to patients, so reducing the occurrence of those injuries ought to have a corresponding effect on the volume of litigation. In practice, however, this association has not previously been demonstrated.

Despite its putative status, the link between safety outcomes and malpractice claims in U.S. hospitals and facilities is nevertheless potentially very important to policy. Such a link suggests that providers could improve their own malpractice risk by making health care safer; that the interests of patients and providers are potentially well aligned when risk is addressed in this way; and that policymakers might enact a new set of tools for reducing malpractice risk, focused on facilitating new patient safety interventions, quality-improvement activities, root-cause analysis efforts, and the like.

This report endeavors to test the hypothesis that the occurrence of adverse safety events is predictive of subsequent malpractice activity, and, by extension, that improved safety performance is associated with reduced malpractice claiming. Focusing on California, we examine a combination of malpractice and safety outcomes data from 2001 through 2005. Our results show a strong correlation between safety outcomes and the volume of malpractice claiming within California's counties.

Data and Approach

To assess the occurrence of clinical events with possible safety implications, we used the Healthcare Cost and Utilization Project (HCUP) state inpatient database for California, a comprehensive hospital encounter dataset, and we applied a version of the Patient Safety Indicators (PSIs) to that dataset. These indicators, which were developed by the Agency for Healthcare Research and Quality, capture 20 distinct classes of in-hospital events and complications with potential safety implications. These types of events range from obstetrical events to post-surgical events to nosocomial (in-hospital) infections. Statewide, we identified more than 365,000 PSI events during the study period, with a slight downward trend in frequency for the entire state over the five years. When analyzed by county and from year to year, however, the results showed considerable county-level variation over time.

To assess malpractice claiming activity, we constructed a database of malpractice claims from four of the largest physician medical liability carriers in California (Norcal, The Doctors

Company, SCPIE, and the Cooperative of American Physicians), which account for substantially more than 50 percent of the market of physicians who are not self-insured in the state. We collected approximately 27,000 claims based on alleged events that occurred from 2001 through 2005. As with our PSI measure, we found a modest, statewide decline in malpractice claiming over that time period, but with considerable year-to-year variation across counties within the general trend.

Our analysis involved building a series of regression models to examine the relationship between the annual frequency of adverse events and malpractice claims within California's counties, while controlling for stable demographic differences across counties.

Findings

Our results showed a highly significant correlation between the frequency of adverse events and malpractice claims: On average, a county that shows a decrease of *10 adverse events* in a given year would also see a decrease of *3.7 malpractice claims*. Likewise, a county that shows an increase of 10 adverse events in a given year would also see, on average, an increase of 3.7 malpractice claims. According to the statistical analysis, nearly three-fourths of the within-county variation in annual malpractice claims could be accounted for by the changes in patient safety outcomes.

We also found that the correlation held true when we conducted similar analyses for medical specialties—specifically, surgeons, nonsurgical physicians, and obstetrician/gynecologists (OB-GYNs). Nearly two-thirds of the variation in malpractice claiming against surgeons and nonsurgeons can be explained by changes in safety. The association is weaker for OB-GYNs, but still significant.

Policy Implications

From a policy perspective, the idea of a direct link between safety outcomes and the malpractice claims that spin out of them has several major implications. First is the premise that new safety interventions potentially can reduce the volume of malpractice litigation—a desirable result to seek out, even beyond the immediate impact of medical injuries avoided. Stated another way, improvements in safety performance have the potential to benefit both patients and providers and to align their interests while reducing litigation. A second implication is that the relationship between safety and malpractice is complex and not fully described by the simple notion of deterring acts of negligence through civil liability. Third is the observation that malpractice laws that place providers at risk for engaging in peer review risk-management activities, root-cause analysis, and the like, could have the perverse effect of detracting from broader patient safety efforts. In turn, that could increase the frequency of adverse events and preventable injuries and, indirectly, increase the volume of malpractice litigation itself.

These kinds of relationships and concerns represent an entirely different set of levers for policymakers to consider in regard to malpractice, quite apart from more conventional statutory tort interventions, such as caps on damages in tort claims. The recently announced federal initiative for a new portfolio of Medical Liability Reform and Patient Safety Demonstration projects is aimed at investigating, and expanding on, exactly these sorts of policy levers (White House, 2009a).

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Primum non nocere.

Abbreviations

AHRQ	Agency for Healthcare Research and Quality
HCUP	Healthcare Cost and Utilization Project
MICRA	Medical Injury Compensation Reform Act
OB-GYN	obstetrician/gynecologist
PSI	Patient Safety Indicator
SID	state inpatient database

CHAPTER ONE

Introduction

The Patient Safety Movement and Medical Liability

Patient safety within American health care facilities, and malpractice liability for American health care providers, are two of the most prominent public policy issues confronting the U.S. health care system today. The patient safety movement, which has gained tremendous momentum since the 2000 publication of *To Err Is Human* (Institute of Medicine, 2000), has demonstrated serious safety problems connected with the delivery of health care in U.S. facilities (Brennan et al., 1991; Greenberg et al., 2009; Leape et al., 1991; Studdert et al., 2000; Thomas et al., 2000; Thomas et al., 1999) and has generated enormous interest in new practices and technologies to reduce the occurrence of iatrogenic injury. Medical malpractice risk, meanwhile, remains a major concern for providers across the country (Mello, 2006; Mello et al., 2005; Mello et al., 2007a; Nelson et al., 2007; Studdert et al., 2004; Studdert et al., 2005). Although empirical evidence suggests that the national volume of malpractice claims has declined somewhat in recent years (Aon Risk Consultants, 2006; National Practitioner Data Bank, 2004, 2006), malpractice pressure on physicians has nevertheless remained a source of controversy and a focus for efforts to introduce new tort interventions, caps on damages, and the like (Kaiser Family Foundation, 2005; National Conference of State Legislatures, 2007).

In principle, improved patient safety practices with superior outcomes for patients ought to contribute to reductions in malpractice risk for physicians and facilities (Clinton and Obama, 2006; Studdert et al., 2004). In practice, it has not yet been systematically demonstrated that this is so. Recent studies have suggested that malpractice claims often involve patient safety "never events"—a term coined to describe serious and preventable adverse occurrences in care—and also that hospital mortality rates may be correlated with the rate of indemnity claims against affiliated providers, for at least some health care institutions (Aon Risk Consultants, 2006, 2008). Meanwhile, there is at least anecdotal evidence to suggest that some high-profile patient safety interventions have had a positive impact on the occurrence of preventable injuries in hospitals—as illustrated by the Institute for Healthcare Improvement's "Hundred Thousand Lives Campaign" (Berwick et al., 2006; Wachter and Pronovost, 2006). Nevertheless, a rigorous empirical demonstration of the cascading relationships between safety interventions, patient outcomes, and downstream malpractice claims has not yet been undertaken.

To the extent that the national patient safety movement is beginning to establish some traction, thereby improving quality of care and outcomes within facilities, and leading in turn to reduced malpractice claiming against providers, then this would represent an important achievement. It would suggest that patient safety interventions are having a salutary effect, not only for patients but also for the providers and institutions who care for them. More, it

would also offer an additional incentive to physicians and hospitals to work more aggressively on improving patient safety: an incentive in the form of reduced risk for malpractice liability.[1] Evidence concerning whether the patient safety movement really is achieving this kind of traction is mixed. Although recent reviews have observed no consistent national trend toward improved safety outcomes across a plethora of health care settings and procedures, safety outcomes notably have improved on some major performance measures even as they have deteriorated on others (Agency for Healthcare Research and Quality, 2009; Greenberg et al., 2009; Kuehn, 2009).

The Relationship Between Patient Safety and Malpractice Claiming

Meanwhile, of course, there are clearly many factors other than patient safety efforts that contribute to the occurrence of malpractice litigation. For example, some past studies have suggested that maladaptive provider communications contribute to malpractice litigation risk (Hickson et al., 1992; Hickson et al., 2009; Vincent et al., 1994), while others have observed an association between statutory tort interventions and the volume of litigation (Hickson et al., 1992; Hickson et al., 2009; Mello, 2006; Nelson et al., 2007; Vincent et al., 1994). Moreover, some of the seminal research that examines the link between malpractice claiming and provider negligence suggests that the sensitivity and specificity of that relationship is low (Brennan et al., 1991; Leape et al., 1991; Studdert et al., 2000). Studies such as these reinforce the notion that safety outcomes, or the occurrence of preventable injuries in hospitals, do not represent the only important precursor to malpractice claims.

Without addressing the other contributing factors to litigation in detail, it is nevertheless intuitive that there ought to be an underlying, basic relationship between the occurrence of preventable injuries and the subsequent malpractice claims that spill out of them. Unless one believes that malpractice claiming is fundamentally unrelated to injury, then the volume of the latter ought, in principle, to have some impact on the frequency of the former, holding other factors constant. In this study, we simply aimed to test the proposition that safety outcomes in hospitals do represent a precursor to malpractice claiming and, in turn, that we can use a broad administrative measure of such outcomes to predict changes in the volume of malpractice litigation over time.

Questions about the basic relationship between patient safety and malpractice claiming have become central in the recent national debates over health care policy, as illustrated by President Barack Obama's speech on health care reform in fall 2009, in which he highlighted the potential for patient safety efforts to serve as a preventative to medical injury, and therefore to malpractice litigation (White House, 2009b). This potential implies a new set of tools for policymakers to consider in reducing the ill effects of malpractice liability in tort—a set of tools based on reducing the footprint of preventable injuries at the front end, as a device to attenuate subsequent litigation at the back end. Put another way, policy options that promote better patient safety may offer a new avenue for reducing malpractice pressure on physicians, at the same time that they improve clinical outcomes. This study is the first in a series of planned research projects seeking to address this relationship and its implications for policy.

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[1] Note, however, that a recent empirical study found that the average costs to a hospital associated with the occurrence of an adverse event are modest and that only a fraction of those costs are born by the hospital itself (Mello et al., 2007b).

Organization of This Report

We detail the study's design and methodology in Chapter Two, and we present our findings in Chapter Three. In Chapter Four, we discuss the findings and their implications for public policy and future research.

CHAPTER TWO

Study Design and Methods

The purpose of this study is to investigate California patient safety and medical liability data from 2001–2005, in order to observe whether there is a relationship between (1) changes in the frequency of potential adverse safety events and (2) malpractice claims during that period. We also examined whether the relationship appears to vary across several broad groups of physicians, including surgical specialists, nonsurgeons, and obstetrician/gynecologists (OB-GYNs). We focus on California because that state enacted statutory tort reforms during the early 1970s under the Medical Injury Compensation Reform Act (MICRA), and the legal climate has remained stable in the state since that time: Thus, any recently observed changes in the volume of malpractice litigation occurring in California cannot be explained by the impact of tort reform within the state.

Study Design and Sample

We combined patient safety and medical malpractice claims data, aggregated at the county level in California, for each year from 2001 through 2005. To assess the occurrence of clinical events with possible safety implications, we used the Healthcare Cost and Utilization Project (HCUP) state inpatient database (SID) for California, a comprehensive hospital encounter dataset, and we applied to that dataset a version of the Patient Safety Indicators (PSIs), a set of AHRQ-sponsored quality measures that capture in-hospital events and complications with potential safety implications (Agency for Healthcare Research and Quality, 2007).

To assess malpractice claiming activity, we constructed a database of malpractice claims from four of the largest physician medical liability carriers in California from 2001 through 2005 (Norcal, The Doctors Company, SCPIE, and the Cooperative of American Physicians). According to statistics from A.M. Best, the first three of these carriers were the largest private-sector insurers by market-share in California during the period, while the Cooperative of American Physicians was also one of the largest coverage providers in California (and is also rated by A.M. Best). Collectively, these firms provided malpractice coverage for substantially more than 50 percent of the market of non-self-insured physicians in California, with deep penetration in counties throughout the entire state.

Measures and Data

In order to construct our county-level measures of potential safety events, we used the Patient Safety Indicators (PSIs), version 3.1—a set of administrative quality measures that capture in-hospital events associated with the occurrence of preventable injuries during care (Agency for Healthcare Research and Quality, 2007). The PSIs are defined by algorithms that can be applied to hospital encounter data, and they involve a series of ICD-9 (International Classification of Diseases, 9th Revision) diagnosis and procedure codes that identify both the population at risk for each indicator and the hospitalizations that meet the criterion for each indicator. The PSIs are a widely used set of administrative measures (Chang et al., 2008; Glance et al., 2008; Isaac and Jha, 2008; Rivard et al., 2008; Singer et al., 2009) and, since 2003, have been tracked nationally as an index of safety performance by AHRQ, as a part of its annual National Health Quality Reports (Agency for Healthcare Research and Quality, 2004, 2009). Notably, version 3.1 of the PSIs addresses some of the methodological weaknesses of earlier versions, by excluding clinical events present on hospital admission from the computation of the indicators (Bahl et al., 2008). The PSIs comprise a set of 20 different safety indicators, each identifying a distinct category of clinical events, ranging from obstetrical events to postsurgical events to nosocomial infections.

For technical reasons involving the architecture of the California SID database, we were unable to compute three of the PSIs using California encounter data.[1] For each of the remaining 17 PSIs, we computed county-level counts for the occurrence of each indicator in each year. We then aggregated across the indicators, to produce a total count for all PSI events for each California county in each year. This is the safety variable that we report on in our subsequent analyses. See Table 2.1 for a list of the 17 constituent PSI categories and basic descriptive data on the occurrence of the PSIs within our California dataset.

While we used the clinically specified denominators as an inclusion requirement for identifying PSI events for this study, we did not follow the typical practice of parameterizing the PSIs as rates, based on these denominators. The standard practice of using PSI rates, rather than event counts, is particularly appropriate where the comparisons of interest involve looking across sites or regions with very different at-risk populations. By contrast, our analysis focuses on looking at changes within counties over a short time period. We adjusted our PSI event counts to address the minor changes in eligible at-risk populations within counties, but across years, by standardizing on the at-risk population in 2001.

To construct our database of malpractice claims, we obtained data from four large malpractice carriers operating in California. The carriers provided us with records for all of their claims corresponding to alleged events of malpractice committed by physicians between January 1, 2001, and December 31, 2005. In each case, a "claim" represented a complaint of malpractice initiated by a patient against a physician, requesting financial compensation of the patient for putative harm, with subsequent legal involvement and response by the insurance company. Importantly, the insurer data included both open and closed claims, and it also included claims for which no damages were ever paid. Each claim record in the database included the specialty of the physician who was targeted, as well as the county in which the

[1] The three PSIs not calculable on the California SID are PSI 10 (Post-Op Metabolic Derangement), PSI 11 (Post-Op Respiratory Failure), and PSI 13 (Post-Op Sepsis). These indicators cannot be calculated because the California SID does not capture whether surgeries are elective, which is a defining element for those indicators.

Table 2.1
Frequency of Patient Safety Events by Indicator Type, California, 2001–2005

PSI Number	PSI Name	Percentage of Total
TPPS 19	Obstetric Trauma – Vaginal without Instrument	30
TPPS 18	Obstetric Trauma – Vaginal with Instrument	15
TPPS 04	Failure to Rescue	12
TPPS 15	Accidental Puncture or Laceration	12
TPPS 12	Postoperative Pulmonary Embolism or Deep Vein Thrombosis	6
TPPS 17	Birth Trauma – Injury to Neonate	6
TPPS 07	Selected Infections Due to Medical Care	6
TPPS 03	Decubitus Ulcer	5
TPPS 09	Postoperative Hemorrhage or Hematoma	4
TPPS 06	Iatrogenic Pneumothorax	2
TPPS 02	Death in Low-Mortality DRGs	1
TPPS 20	Obstetric Trauma – Cesarean Delivery	1
TPPS 14	Postoperative Wound Dehiscence	1
TPPS 05	Foreign Body Left During Procedure	<1
TPPS 08	Postoperative Hip Fracture	<1
TPPS 16	Transfusion Reaction	<1
TPPS 01	Complications of Anesthesia	<1

alleged malpractice took place. We used the malpractice data to compute county-level counts of malpractice events in California, for events that occurred in each year from 2001 through 2005. We also computed more selective county-level counts of malpractice events targeting surgical specialists, nonsurgeons, and OB-GYNs, respectively.

Statistical Approach

Our analyses involved a series of linear regression models, with fixed effects terms for California's counties. The assumptions for a linear model with fixed effects were met in our data—in particular, analysis of the residuals did not reveal any violation of the homoscedasticity assumption.[2] We used different sets of predictor variables in different models (as we describe below); all of our models were based on the dependent measures of county-level counts of malpractice claims occurring in each year.[3] In our primary analysis, the dependent measure involved the count of total malpractice claims. In secondary analyses, we focused on counts of malpractice claims against specific categories of physicians, as described immediately above. The regression equation in our models takes the form

$$y_{it} = \alpha + \beta_1 t + \sum_i \beta_{2i} I_i + \beta_3 PS_{it} + \varepsilon_{it} ,$$

where

- y_{it} is the count of malpractice cases for which the alleged incident took place in county i and year t
- I_i is an indicator for each county and the sum constitutes the set of county-level fixed effects
- PS_{it} is the difference between the adjusted PSI count in county i in year t and the average adjusted PSI count in county i across all five years
- the error term, ε_{it}, is independent with a normal distribution.

The primary quantities of interest from this model are the coefficient on the patient safety measure, β_3, and within the county R^2 value.

The main predictor variable in our models is the difference between county-level count of PSI events in each year and the average annual count of PSI events for that county over the five-year period—an adjusted measure that removes variation in county-level PSI frequencies due to stable demographic differences between the counties, such as population. In all of our regression models, we included year as a predictor, and fixed-effect terms for county—thus, we removed variation in the dependent measure attributable to stable differences between the counties and any average time trend. Standard errors in all models were adjusted to account for clustering by county.

For the entire state of California, our malpractice database included 27,244 claims based on alleged events that occurred during 2001–2005. On the safety side, our data included 365,834 PSI events (again, these represent potential in-hospital adverse events and complications with safety implications) observed during the same interval. Both the annual number of

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[2] As a further robustness check on our findings, we also ran Poisson regression models with parallel predictors.

[3] California has 58 counties, the 15 smallest of which have populations of less than 50,000 persons. Our patient safety and medical malpractice measures were 0 in all five years for four counties with very small populations (less than 19,000 persons), and we dropped those four counties from all of our models. For purposes of our analyses, we then pooled the patient safety and medical malpractice counts for the remaining 11 small counties. Note, however, that the modeling results we report here are insensitive to the inclusion of these small counties, and likewise to whether we incorporate the small counties into our models separately or by pooling.

malpractice claims in California and the annual number of PSI events trended gently downwards over the 2001–2005 period in our data.

Analyses were performed using SAS (version 9.1) and Stata (version 11) statistical software. We report statistical significance levels from two-sided tests without adjustment for multiple testing.

CHAPTER THREE

Results

Table 3.1 presents descriptive statistics for the variables used in the models. Table 3.1 also shows that, within each county, on average, the annual number of PSI events was above the five-year county mean during 2001 and 2002 and below the five-year county mean during 2004 and 2005, indicating a general decline in the frequency of patient safety events across California during this time period. However, the last two rows in Table 3.1 show that there is considerable variability in this trend across California counties: Approximately 37 percent of counties had an annual frequency of PSI events below their five-year mean during 2001, while 33 percent had an annual frequency of PSI events above their five-year mean during 2005. In somewhat similar fashion, Figure 3.1 depicts the change in annual county-level malpractice counts between 2001 and 2005 and shows that, while most counties experienced declines in the frequency of claims, some actually experienced increases in claims. These descriptive results suggest that there is considerable variation across California counties in how they trend from year to year, both in frequency of patient safety events observed and in the volume of malpractice claiming.

Table 3.1
Descriptive Statistics on PSI Events and Malpractice Claims by California County and Year

	Mean	Standard Deviation	Percentage
Number of total claims	100.78	234.61	
Number of nonsurgical claims	56.57	135.90	
Number of surgical claims	44.21	99.44	
Number of OB-GYN claims	9.45	19.76	
Total number of PSI events	686.37	1,429.32	
Difference between five-year average of PSI count and . . .			
Number of PSI events in 2001	47.92	119.51	
Number of PSI events in 2002	21.74	83.25	
Number of PSI events in 2003	–3.34	39.94	
Number of PSI events in 2004	–32.61	89.20	
Number of PSI events in 2005	–33.71	88.51	
Counties that were below their average PSI count in 2001			37.04
Counties that were above their average PSI count in 2005			33.33

Figure 3.1
County-Level Change in Volume of Malpractice Claims, 2001 Versus 2005

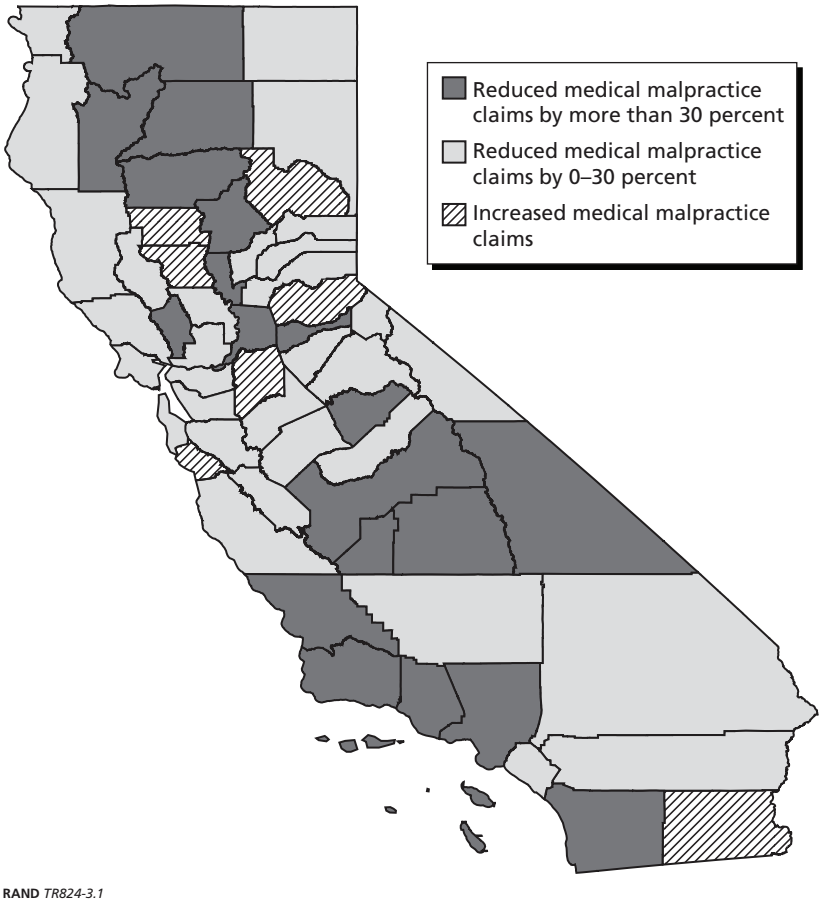

Table 3.2 shows results from our primary regression models. Model 1 shows that the average, annual county-level decrease in malpractice claims is approximately 11.1 (p = 0.009). Model 2 adds our main predictor variable: the difference between the annual, county-level frequency for PSI events, and the five-year mean for PSI events within the same county. That effect is highly significant, and suggests that a county that experiences a decrease of 10 PSI events over the course of a year would also see an associated reduction of 3.7 fewer malpractice claims (95 percent confidence interval (2.2, 5.1)).[1] The R^2 statistic for Model 2 is approximately 0.74, suggesting that within California counties, nearly three-fourths of the variation in annual malpractice claims volume is accounted for when we incorporate our measure of annual, county-level changes in PSI events as a predictor.

Table 3.3 shows results from our secondary analyses. In these analyses, we looked at the relationship between county-level changes in total aggregated PSI events and malpractice claims volume specifically targeting surgical specialists, nonsurgical physicians, and OB-GYNs. There is a significant annual decline over 2001–2005 in county-level malpractice claims targeting each group of physicians (surgeons: –4.7, p = 0.004; nonsurgeons: –6.3, p=0.016;

[1] As mentioned in the Methods section, we also ran Poisson regression models as an additional check on robustness. With the Poisson specification, the main predictor variable, change in PSI events, remains significant.

Table 3.2
Total Medical Malpractice Claims Models

Independent Variable	Model 1	Model 1 p-values	Model 2	Model 2 p-values
Year	–11.0727	P = 0.009	–1.2773	ns
	(4.0630)		(1.6004)	
Change PSI	—		0.3668	p < 0.001
	(—)		(0.0734)	
Intercept	123.8364	P < 0.001	123.8364	p < 0.001
	(0.0000)		(0.0000)	
$R^{2\dagger}$	0.1233		0.7388	
rho	0.9668		0.9898	

NOTE: Standard errors in this table are presented in parentheses below coefficient estimates.

NOTE: Malpractice claims and PSI events were pooled together in each year for 11 California counties with population under 50,000. Four counties were dropped from the analysis because they had zero malpractice claims and zero PSI events for every year between 2001 and 2005.

† Within-county R^2.

OB-GYNs: –0.8, p=0.015). Paralleling the main model results, within-county changes in the number of PSI events are significantly associated with changes in malpractice claims volume against each physician group: surgeons, nonsurgeons, and OB-GYNs. Changes in the number of PSI events account for nearly two-thirds of the variation in malpractice claiming against the two broader groupings of physicians (nonsurgeons: R^2 = 0.70; surgeons: R^2=0.67). Changes in the number of PSI events account for a lesser portion of the variance in malpractice claims targeting OB-GYNs, but the association nevertheless remains significant and substantial (OB-GYNs: R^2 = 0.30).

In the course of running these analyses, we also did several sensitivity checks, to investigate the robustness of our findings. One of those checks involved narrowing our predictor variable, to try to align more closely surgical hospitalizations (and related adverse events) with malpractice claims against surgical specialists, nonsurgical hospitalizations (and related adverse events) with claims against nonsurgeons, and so on. Our results from those model excursions are also highly significant and generally consistent with the findings that we report above. Note that because we are *not* trying to link specific adverse events with specific malpractice claims in a precise way, we believe that the main analyses we report above (which use the aggregate count of all PSI events as a predictor) are appropriate and more directly comparable, as applied to subsets of malpractice claims against surgeons, nonsurgeons, and OB-GYNs.

Table 3.3
Specialized Malpractice Claims Models

Model	Model 1	Model 1 p-values	Model 2	Model 2 p-values
Nonsurgical Malpractice Claims				
Year	–6.3273	p = 0.016	–0.2501	ns
	(2.5120)		(0.9974)	
Change PSI	—		0.2276	p < 0.001
	(—)		(0.0462)	
Intercept	69.5182	p < 0.001	69.5182	p < 0.001
	(0.0000)		(0.0000)	
R^{2a}	0.1022		0.7039	
rho	0.9603		0.9865	
Surgical Malpractice Claims				
Year	–4.7455	p = 0.004	–1.0272	ns
	(1.5736)		(0.6614)	
Change PSI	—		0.1392	p < 0.001
	(—)		(0.0273)	
Intercept	54.3182	p < 0.001	54.3182	p < 0.001
	(0.0000)		(0.0000)	
R^{2a}	0.1354		0.6657	
Rho	0.9694		0.9879	
Obstetrical Malpractice Claims				
Year	–0.8091	p = 0.015	–0.2261	ns
	(0.3191)		(0.1983)	
Change PSI	—		0.0218	p < 0.001
	(—)		(0.0042)	
Intercept	11.6091	p < 0.001	11.6091	p < 0.001
	(0.0000)		(0.0000)	
$R^{2\dagger}$	0.0688		0.2965	
rho	0.9521		0.9632	

NOTES: Malpractice claims and PSI events were pooled together in each year for 11 California counties with population under 50,000. Four counties were dropped from the analysis because they had zero malpractice claims and zero PSI events for every year between 2001 and 2005.

NOTE: Standard errors in this table are presented in parentheses below coefficient estimates.

† Within-county R^2.

CHAPTER FOUR

Discussion and Conclusions

Findings and Policy Implications

The findings from our study suggest that county-level safety performance in California, as reflected by changes in annual counts of PSI events, is significantly associated with changes in the volume of malpractice claims occurring in the same counties during the same years. Counties that achieved improvement in the frequency of PSI events during a given year tended also to achieve improvement in the volume of malpractice claiming, while those that experienced a deterioration in the frequency of PSI events tended also to see a deterioration in the volume of malpractice claiming as well. Notably, the correlation between county-level PSI events and volume of malpractice claims is observed across all counties and years, such that annual fluctuations in safety outcomes within a given county are associated with corresponding fluctuations in the number of malpractice claims. Similar patterns of results were obtained when we looked for the relationship across all malpractice claims, and more specifically when we looked at claims against surgical specialists, nonsurgeons, and OB-GYNs.

These findings are consistent with the basic hypothesis that iatrogenic harms are a precursor to malpractice claims, such that modifying the frequency of medical injuries has an impact on the volume of litigation that spills out of them. Although this is an intuitive relationship, it is not one that has been well validated previously. It suggests that safety interventions that improve patient outcomes have the potential to reduce malpractice claiming, and in turn, malpractice pressure on providers. It also suggests that the traditional legal doctrine of malpractice, which focuses on deterring negligence and related injuries, is at best incomplete in addressing the underlying problem of patient safety in U.S. health care facilities. The patient safety movement is notably based on a very different logic model: one in which injuries sometimes occur as a result of complex systems failure rather than negligence, and in which root-cause analysis and quality-improvement activities undertaken by providers are widely believed to have prophylactic effects. By extension, policies that facilitate the latter have the potential both to make patients safer and to reduce malpractice litigation to the benefit of providers.

From a policy perspective, several implications flow from the premise of a direct link between safety outcomes and the malpractice claims that spin out of them. First is that the relationship between safety and malpractice is complex, and not fully captured by the simple notion of deterring acts of negligence through civil liability. Second is the premise that new safety interventions potentially can have positive effects on the volume of malpractice litigation—a desirable result to seek out, even beyond the immediate impact of medical injuries avoided. Third is the observation that malpractice laws that place providers at risk for engaging in peer review risk-management activities, root-cause analysis, and the like, poten-

tially might also have the perverse effect of detracting from broader patient safety efforts. In turn, that could have a negative impact on the frequency of adverse events and preventable injuries, and indirectly, on the volume of malpractice litigation itself. Notably, these kinds of relationships and concerns represent an entirely different set of levers for policymakers to consider in regard to malpractice, quite apart from more conventional statutory tort interventions like caps on damages in tort claims. The recently announced federal initiative for a new portfolio of Medical Liability Reform and Patient Safety Demonstration projects is aimed at investigating, and expanding on, exactly these sorts of policy levers (White House, 2009a).

Safety Performance and Medical Liability Present Complex Challenges in Measurement

The current study also underlines some of the measurement complexities in thinking about the relationship between patient safety and medical malpractice. While we believe that the two phenomena are linked, we also believe that the alignment between our sets of measures is probably very imperfect. So, for example, it seems likely that there are some categories of malpractice claims (e.g., those corresponding to errors in reading diagnostic images) that have not been very focal in patient safety outcome measurement or interventions to date. Similarly, there are probably also categories of adverse safety outcomes (e.g., some types of nosocomial infections) that do not map very well into malpractice claims, either because it is difficult to define a salient "event," or to assign negligence to a specific provider, or because the magnitude of harms involved may be insufficient to drive much litigation. One avenue for future research will involve investigating in more detail the links between specific categories of safety outcomes and related types of malpractice claims. This kind of analysis could be useful for developing better measurement capabilities in the future and, more importantly, for tuning new safety interventions to address malpractice "patches" where litigation pressure is high.

Our findings also highlight another important point, specifically with regard to the use of the PSIs to generate state-level epidemiologic trends in safety outcomes. Typical practice in using the PSIs involves computing each of the indicators separately as an adjusted rate, based on a defined at-risk population. That methodology is often very appropriate, but it can also be misleading for understanding the aggregate trend in safety outcomes, across indicators and for large geographic regions. Recent reviews and reports have used PSI rates in painting a picture of national outcomes trends and have tended to assume that each PSI should be considered discretely and as equally important (see Agency for Healthcare Research and Quality, 2007; Greenberg et al., 2009; Kuehn, 2009). Based on that assumption, the conclusion has been that the PSIs do not show consistent evidence of broad, national improvement. Our examination of California data paints a somewhat different picture. When we aggregate event counts across PSIs, we do see a modest trend toward improvement, which is driven by the fact that some of the PSI categories (e.g., obstetrical events and "failure to rescue") are far more frequent than others (e.g., blood type mismatches), and that the former categories are where improvement seems to be taking place. Notably, the reported national trends on the PSIs are consistent with the possibility that similar patterns may be occurring across the country as well. For purposes of national trending in safety outcomes, the implication is that there are multiple ways to aggregate trends across the PSIs, and that AHRQ may want to review how it analyzes and interprets these indicators.

Strengths and Limitations of This Study

The current study is noteworthy for several methodological strengths, including the use of a unique malpractice dataset that includes both paid and unpaid claims, a statistical design that controls for fixed county-level effects, and our focus on California as an especially important state for looking at the safety-malpractice relationship. In particular, the malpractice data used in this study are, in some respects, superior to those of the National Practitioner Data Bank, which captures information only on paid malpractice claims (and thereby represents only a small fraction of all malpractice activity, ignoring the substantial "tail" of open and unresolved claims). Moreover, California is a particularly important state for investigating the safety-malpractice relationship, in part because of its size, and in part because statutory tort reform in California has been in place for many years, so that observed changes in malpractice claims activity are unlikely to have resulted from changes in the legal climate.

Weaknesses of the current study include our reliance on administrative data and the PSIs to identify potential adverse safety events, as well as the fundamentally correlational nature of our findings. With regard to the former, the PSIs have sometimes been criticized as administrative measures with only modest specificity and sensitivity, and as neglecting to capture true adverse events with much precision. Recent studies addressing the validity and technical characteristics of the PSIs have come to mixed conclusions about their robustness (Rivard et al., 2008; Schwartz and Komesar, 1978; Utter et al., 2009; White et al., 2009; Raleigh et al., 2008; Romano et al., 2009; Rosen et al., 2005; Rosen et al., 2006; West et al., 2008). Nevertheless, and consistent with the intent of the expert panel that developed the indicators, it is important to point out that the PSIs, by design, do not directly capture medical errors, but instead clinical situations in which the potential for iatrogenic origin and preventable injury is heightened. In this sense, our use of annual changes in PSI event counts might best be viewed as a broad indicator of safety climate, that is, as an aspect of quality of care, within California counties. The fact that our PSI measures are predictive of malpractice activity, despite any imprecision in those measures, arguably strengthens the findings of this study.

With regard to the correlational nature of our analyses, the fact that our models rely on adjusted annual frequencies in county-level malpractice claims, and that these annual frequencies are closely tracked by PSI counts at many time points and locations, strengthens the suggestion of a possible causal relationship. Nevertheless, our regression results are only suggestive, rather than dispositive, in supporting this interpretation.

We also acknowledge that the relationship between malpractice claiming and patient safety is a complex and dynamic one, and the current study focuses on only one aspect of that relationship. So, for example, classical deterrence theory would suggest that, over time, the volume of malpractice litigation and magnitude of liability risk also feeds back into provider behavior, in the form of a punitive incentive to avoid negligence (Schwartz and Komesar, 1978). That is a putative relationship that is simply outside the scope of this study to address. By focusing on the more immediate connection between high-risk clinical events in a specific time period and malpractice litigation associated with those events, the current study aims simply to establish that the former truly are a meaningful precursor to the latter. This is a link that has some major policy ramifications in itself.

One of the most striking aspects of our results is the fact of a very strong correlation between our PSI safety measure and the volume of malpractice claiming, such that changes in the former account for the substantial majority of variation that we observe in the latter. The

magnitude of this correlation is particularly noteworthy, in light of the well-known empirical finding that malpractice claiming is not highly correlated with the occurrence of provider negligence (Studdert et al., 2000). When considered in this light, our results invite two questions. First, how do we reconcile the results with the earlier findings of Studdert and colleagues on malpractice and negligence? Second, how do we explain the magnitude of the unusually strong correlations that we do observe in the current study?

With regard to Studdert's groundbreaking research on malpractice claims and negligence in Utah and Colorado, we would point out that the current study is focused on a different relationship and set of variables (adverse safety events to malpractice claims) than was the earlier study (negligence to malpractice claims). It will come as no surprise to patient safety advocates that there are many adverse events in care that result in patient harm but that nevertheless do not meet the legal criteria for negligence. The current study does not attempt to examine the concept of "negligence." By contrast, our own finding of a correlation between adverse events and malpractice claiming is somewhat more reminiscent of other work that Studdert and colleagues have done, in which a set of malpractice claims were found to be strongly associated with the occurrence of adverse outcomes for patients who filed them (Studdert et al., 2006).

With regard to the fact that we do observe a very strong correlation between our PSI measure and malpractice claiming, several considerations deserve mention. First is a reminder that our statistical models seek to explain changes in malpractice claiming within California counties. Many factors that contribute to variation in malpractice activity across geographic regions are essentially being held constant in our modeling approach. As a result, we are not attempting to explain overall levels of malpractice activity across counties, which might be a far more difficult thing to do. In a different vein, we have observed that our PSI outcome measure perhaps might be viewed as an indirect indicator of broad changes in safety climate (i.e., safety awareness, investment, process improvement efforts, etc.) within the counties. To the extent this is correct, it could easily be the case that changes in within-county safety climate are also associated with other sorts of within-county changes, which in turn might also play into malpractice claiming. For example, provider communications are well known to be a mediating factor in patients' decisions about whether to file a malpractice claim; it seems plausible that counties that improve on safety performance might also tend to improve in their provider communications behavior at the same time. Although not formally investigated in our models, this kind of effect could also make stronger the observed correlations between safety outcomes and malpractice claiming.

Finally, the strength of our observed correlations is also influenced by the specification of our statistical models. In our fixed effects linear regression model, large counties, which have larger numbers of claims and adverse events, exert more influence on estimated correlations than do smaller counties. Moreover, the observed correlations reflect both (1) the extent to which the within-county highs and lows in malpractice claiming occur in the same years as the within-county highs and lows in our patient safety measure *and* (2) the extent to which the magnitudes of the highs and lows on each measure track each other. In turn, the extent to which the magnitudes of the highs and lows track each other is affected by both within-county *and* between-county differences in magnitudes. Conditional on the highs and lows on both measures occurring in the same years within county, the between-county differences in magnitudes (of the highs and lows) may raise the correlation levels. As noted earlier, in sensitivity tests we ran additional models employing a Poisson specification, which relies on different model assumptions and does not have either of the attributes of the linear model just discussed.

The Poisson specification also results in significant findings and similar conclusions, but has a lower associated adjusted R^2 value.

Conclusions

As has been pointed out by prominent policymakers in the United States, the association between safety and malpractice activity over time is potentially quite important, in part because it suggests that providers and institutions may experience some direct benefit from improved safety performance, in the form of reduced malpractice risk (Clinton and Obama, 2006). Ultimately, it would be desirable to link specific safety practices and interventions not only to bottom-line improvements in safety outcomes for patients, but also to reductions in malpractice activity against providers—an aim that has recently been identified by the President as a target for new large-scale demonstration projects (White House, 2009a). In turn, improved safety practices and quality in the delivery of care could provide a reward to the provider community, in the form of reduced malpractice activity and costs, perhaps thereby spurring further investigation of new safety interventions and avenues for improving care.[1] The current study represents an initial step in helping to establish these sorts of links and incentives for providers.

Finally, with regard to the long-standing debate over malpractice laws and policy in the United States, the current study suggests a different thread for policymakers to consider. Advocates on both sides of the debate have argued strenuously on behalf of patients who suffer iatrogenic injuries, on the one hand, and on behalf of providers who are sometimes targeted frivolously, on the other. Presumably, the one thing that all parties to the debate can agree on is that reducing malpractice activity by reducing the number of iatrogenic injuries is a good idea. Arguments about the merits of statutory tort intervention will surely continue in the future, but to the extent that improved safety performance can be shown to have a demonstrable impact on malpractice claims, that offers another focal point for policymakers in seeking to address the malpractice crisis. Based on the results of the current study, we would suggest that that focal point may be more immediately relevant than has previously been recognized.

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[1] Note again, however, that Mello et al. (2007b) recently found that the average direct costs to hospitals associated with the occurrence of an adverse event are fairly modest and, by implication, that the institutional savings associated with reducing the occurrence of such events might be similarly modest.

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