

Medical Malpractice:

Evidence on Reform

Alternatives and Claims

Involving Elderly Patients

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**Medical Malpractice: Evidence on Reform Alternatives
and Claims Involving Elderly Patients**

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EXECUTIVE SUMMARY

This report examines recent trends in malpractice claiming—by elderly Medicare beneficiaries and by all claimants—and the available evidence concerning the effects that a range of medical liability reform options might have on Medicare beneficiaries, other patients, and healthcare providers.

The first part of the report characterizes patterns in paid lawsuits involving elderly patients during the 2005-2015 period using data from the National Practitioner Data Bank (NPDB) Public Use File. We find that:

- For elderly individuals, the number of paid claims reported to the NPDB annually remained fairly stable over the 2005-2015 period. In contrast, for nonelderly individuals, the number declined markedly.
- The distribution of paid claims by age is right skewed, with the frequency peaking in age groups 40-49 and 50-59.
- Paid claims involving patients aged 70 or above were significantly more likely to involve severe injuries, and nearly twice as likely to involve a death, than claims involving patients under age 60.
- Paid claims involving elderly patients were significantly more likely than claims involving younger patients to involve injuries that occurred in the inpatient setting.
- Claims involving elderly patients were less likely than claims involving younger patients to be diagnosis related, and more likely to be related to medication, anesthesia, treatment, or monitoring.

The second part of the report synthesizes the evidence and theoretical predictions regarding the potential of several leading medical malpractice reform ideas to positively affect the performance of the medical liability system, its impact on healthcare delivery, and the interests of Medicare beneficiaries. For most reforms, the report analyzes evidence from well-designed, controlled studies. Where such studies are unavailable, the analysis encompasses anecdotal reports, case studies, and descriptive findings regarding the operation of proposed systems or close analogues in the U.S. and foreign countries. For reforms that have not yet been tested, the report describes theoretical predictions about the likely effects of the reforms based on relevant scholarship in medicine, law, and economics.

The analysis covers eight “traditional” reforms that have been widely implemented by states: caps on noneconomic damages, pretrial screening panels, certificate-of-merit laws, attorney fee limits, joint-and-several liability reform, collateral source rule reform, periodic payment, and shortening of statutes of limitation or statutes of repose. It also examines seven “innovative,” less tested reforms: “health courts,” communication-and-resolution programs, safe harbors for adherence to evidence-based practice guidelines, mandatory pre-suit notification laws, apology laws, state-facilitated alternative dispute resolution, and judge-directed negotiation programs.

The reforms are evaluated for their effects on the following outcomes: claims frequency and costs, patient compensation, overhead costs, providers’ liability costs, healthcare spending/defensive medicine, physician supply/access to care, quality of care, unintended consequences, and differential impact on Medicare beneficiaries.

We find that the evidence base for evaluating most traditional state tort reforms is substantial and mature. The evidence is sufficient to support the following conclusions:

- Noneconomic damage caps are associated with reduced claims frequency, lower compensation award amounts, lower liability insurance premium costs for physicians, reductions in some types of defensive medicine, higher physician supply, and shorter time to settlement—but may have disproportionately large effects on claiming by the elderly.
- Pretrial screening panels have no significant effect on claims frequency or compensation amounts.
- Attorney fee limits have no significant effect on claims frequency, compensation amounts, liability insurance premiums, or physician supply.
- Joint-and-several liability reform has no significant effect on compensation amounts, liability insurance premiums, physician supply, or quality of care.
- Collateral-source rule reform has no significant effect on claims frequency, compensation amounts, liability insurance premiums, defensive medicine, physician supply, or health insurance coverage rates.
- Periodic payment has no significant effect on claims frequency, compensation amounts, physician supply, or patient care outcomes.
- Shorter statutes of limitation/repose have no significant effect on compensation amounts, but are associated with lower liability insurance premiums.

The evidence base is too small, or study findings are too mixed, to support inferences regarding the relationship of the traditional reforms to other outcomes.

The evidence base for evaluating the innovative tort reforms is very small, as most have not been tested in the U.S. or have been tested so recently that robust outcomes data are not yet available. Analogous systems are not clearly predictive of how they would function, and much depends on the choices made about system design. However, based on theoretical predictions and the limited evidence available, they likely merit further experimentation in the U.S.

Exhibit 1 below summarizes the evidence reviewed in this report concerning the effects of the various reforms. Where conclusions can be drawn, the table includes an impressionistic rating of the strength of evidence available, considering the quantity and quality of research studies: high (H), medium (M), or low (L). When a reform's effect on a particular outcome measure has not been studied, if there is a plausible, substantial theoretical relationship between the two, we comment on its nature and direction.

Exhibit 1. Summary of the Evidence and Potential Effects of Traditional and Innovative Liability Reforms

	Outcome Measures and Overall Strength of Evidence	Other Plausible Relationships for Which Little or No Evidence is Available
Traditional Reforms		
Caps on noneconomic damages	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Reduction in claims frequency for both paid claims and all filed claims (M) • Disproportionate effect on filing of claims by elderly patients (L) • Substantial reduction in average compensation amounts (H) • Substantial reduction in time to settlement (L) • Moderate constraint on growth of liability insurance premiums (M) • Reductions in some types of defensive medicine (H) • Modest increase in physician supply (H) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Overall healthcare spending • Health insurance coverage rates • Quality of care and patient outcomes • Whether reductions in awards disproportionately burden elderly claimants 	<ul style="list-style-type: none"> • Defense costs (could increase or decrease on average)
Pretrial screening panels	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • No reduction in claims frequency (H) • No change in compensation amounts (H) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Litigation costs • Liability insurance premiums 	<ul style="list-style-type: none"> • Time to compensation (could increase) • Defensive medicine and healthcare spending (could decrease)

	Outcome Measures and Overall Strength of Evidence	Other Plausible Relationships for Which Little or No Evidence is Available
Certificate of merit laws	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Claim frequency (could decrease) • Time to compensation (could increase) • Litigation costs (could increase for plaintiffs and decrease for defense)
Attorney fee limits	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • No change in claims frequency (M) • No change in compensation amounts (H) • No change in liability insurance premiums (M) • No change in physician supply (M) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Litigation costs (could increase on average if attorneys are less inclined to bring small cases) • Differential impact on Medicare patients (could disproportionately burden patients with low damages)
Joint-and-several liability reform	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • No change in compensation amounts (M) • No change in liability insurance premiums (M) • No change in physician supply (H) • No change in quality of care (H) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Defensive medicine and healthcare spending • Litigation costs • Health insurance coverage rates/costs 	<ul style="list-style-type: none"> • Access to compensation (could reduce plaintiffs' ability to recover compensation)

	Outcome Measures and Overall Strength of Evidence	Other Plausible Relationships for Which Little or No Evidence is Available
Collateral-source rule reform	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • No change in claims frequency (M) • No change in compensation amounts (H) • No change in liability insurance premiums (M) • No change in defensive medicine/healthcare spending (M) • No change in physician supply (H) • No change in health insurance coverage rates (L) • No change in quality of care (H) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Differential impact on Medicare patients (reducing liability awards could disproportionately burden elderly claimants)
Periodic payment	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • No change in claims frequency (M) • No change in compensation amounts (M) • No change in physician supply (M) • No change in patient care outcomes (L) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Liability insurance premiums • Defensive medicine/healthcare spending 	<ul style="list-style-type: none"> • Insurers' overhead costs (could increase or decrease) • Differential impact on some Medicare patients (persons with short lifespans and/or low savings may prefer a lump-sum payment)
Shorter statute of limitations/repose	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • No change in compensation amounts (M) • Reduction in growth of liability insurance premium costs (M) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Claims frequency 	<ul style="list-style-type: none"> • Time to compensation (short statutes of limitation/repose could unduly bar valid claims) • Insurers' overhead costs (could decrease)

	Outcome Measures and Overall Strength of Evidence	Other Plausible Relationships for Which Little or No Evidence is Available
Innovative Reforms		
Health courts: Medical courts model	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Claims frequency (could increase or decrease) • Number of claims paid (could increase or decrease) • Defensive medicine and healthcare spending (could decrease)
Health courts: Administrative model	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Lower overhead costs (M) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Claims frequency (could increase, if claimants perceive easier access to compensation) • Number of claims paid (could increase, if broader compensation standard used) • Compensation amounts (could decrease) • Provider liability costs (could increase or decrease) • Defensive medicine and healthcare spending (could decrease) • Quality of care (could improve)
Communication and resolution programs (CRPs)	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • Substantial reduction in claims frequency (L) • Reduction in claims payments (L) • Reduction in time to compensation/resolution (L) • Reduction in litigation costs (for patients and providers) (L) • Reduction in liability premiums (L) <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Defensive medicine and healthcare spending (could decrease, if providers perceive CRPs as protecting them). • Quality of care (could improve)

	Outcome Measures and Overall Strength of Evidence	Other Plausible Relationships for Which Little or No Evidence is Available
Safe harbors for adherence to evidence-based practice guidelines	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Total and paid claims (could decrease) • Total liability costs for insurers (could decrease) • Litigation costs (could decrease) • Defensive medicine and healthcare spending (could decrease) • Quality of care (could improve)
Mandatory pre-suit notification laws	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Number of claims filed (could increase or decrease) • Compensation amounts (could increase or decrease) • Time to compensation (could decrease) • Defense costs (could decrease) • Could support the growth of CRPs
Apology laws	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Total claims filed (could increase or decrease) • Compensation amounts (could decrease, if more early resolution results) • Time to compensation (could decrease) • Overhead costs (could decrease, if more early resolution results) • Could support the growth of CRPs
State-facilitated alternative dispute resolution	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Total claims filed for compensation (could increase or decrease) • Compensation amounts (could be lower due to early resolution) • Time to compensation (could decrease) • Overhead costs (could decrease) • Quality of care (could improve)

	Outcome Measures and Overall Strength of Evidence	Other Plausible Relationships for Which Little or No Evidence is Available
Judge-directed negotiation	<p><i>Evidence sufficient for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None <p><i>Evidence too mixed for conclusions to be drawn:</i></p> <ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Compensation amounts (could decrease) • Time to compensation (could decrease) • Overhead costs (could decrease, if less trials result) • Defensive medicine and healthcare spending (could decrease)

1. Introduction

For over 40 years, there has been significant debate about whether and, if so, how best to reform the medical liability system. Discussion has long centered on traditional liability reforms—such as damages caps—but more recently has increasingly moved into consideration of alternative, innovative approaches that often seek or support broader modifications to the liability system (Exhibit 2). This report evaluates the potential of several traditional and innovative reform proposals to improve the performance of the medical liability system and the quality of healthcare delivered. We also give specific information on the potential implications of these reform options for Medicare beneficiaries. We start by providing a snapshot of trends in malpractice claiming over the past decade, using data from the National Practitioner Data Bank (NPDB) Public Use File, testing for differences between elderly Medicare beneficiaries and non-beneficiaries.

In 2009, the Agency for Healthcare Research and Quality (AHRQ) funded a number of demonstration projects that sought to improve not only medical liability outcomes, but also patient safety. In light of the growing evidence base on traditional and newer reforms, completion of the AHRQ demonstration projects, and ongoing questions of how liability reforms may differentially affect Medicare beneficiaries, MedPAC commissioned this report.

This analysis builds upon and updates the 2010 MedPAC commissioned report, “Evaluation of Options For Medical Malpractice System Reform: A Report to the Medicare Payment Advisory Commission (MedPAC).”¹ We describe the essential features and design options of leading proposed traditional and innovative reforms and synthesize the best available evidence about the likely effects of each of 9 outcome variables:

1. **Claims frequency and costs:** number of malpractice claims and average compensation costs
2. **Patient compensation:** malpractice claim outcomes, including the speed, ease, and equity with which patients receive compensation
3. **Overhead costs:** malpractice system administrative costs, including patient and provider litigation costs and insurers’ overhead expenses
4. **Providers’ liability costs:** malpractice liability costs for healthcare providers (i.e., malpractice insurance premiums)
5. **Healthcare spending and defensive medicine:** defensive medical practices and overall healthcare spending and utilization
6. **Physician supply/access to care:** healthcare provider supply and patient access to care, including health insurance coverage and cost
7. **Quality of care:** potential to foster evidence-based care and improve patient safety
8. **Unintended consequences:** potential or known unintended effects of reforms, if any
9. **Differential impact on Medicare beneficiaries:** potential for the reform to impact Medicare beneficiaries differently than the general population

Exhibit 2. Reform Options Evaluated

Reform	Basic Description
<i>Traditional State Reforms</i>	<i>Reforms that have long been in use among U.S. states and are among the set of reforms customarily included in empirical studies of tort reforms.</i>
Caps on noneconomic damages	Limit the amount of money that a plaintiff can take as an award for noneconomic losses, or “pain and suffering,” in a malpractice suit. The cap may apply to the plaintiff, limiting the amount she may receive, or to each defendant, limiting the total amount for which each may be liable.
Pretrial screening panels	Panel reviews a malpractice case at an early stage and provide an opinion about whether a claim has sufficient merit to proceed to trial. Typically, a negative opinion does not bar a case from going forward, but can be introduced by the defendant as evidence at the trial.
Certificate of merit requirements	Requires a plaintiff to present, at the time of filing the claim or soon thereafter, an affidavit certifying that a qualified medical expert believes that there is a reasonable and meritorious cause for the suit.
Attorney fee limits	Limits the amount of a malpractice award that a plaintiff’s attorney may take in a contingent-fee arrangement. The limitation is typically expressed as a percentage of the award; it may also incorporate a maximum dollar value.
Joint-and-several liability reform	In cases involving more than one defendant, such as a physician and a hospital, this reform limits the financial liability of each defendant to the percentage fault that the jury allocates to that defendant. Without this reform, the plaintiff may collect the entire amount of the judgment from one defendant if the other(s) default on their obligation to pay, even if the paying defendant bore only a small share of the responsibility for what happened to the plaintiff.
Collateral-source rule reform	Eliminates a traditional rule that if an injured plaintiff receives compensation for her injury from other sources, such as health insurance, that payment should not be deducted from the amount that a defendant who is found liable for that injury must pay.
Periodic payment	Allows or requires insurers to pay out malpractice awards over a long period of time, rather than in a lump sum. This enables insurers to purchase annuities (sometimes called “structured settlements”) from other insurance companies which cost less than paying the whole award up front. Insurers are also able to retain any amounts that the plaintiff does not actually collect during her lifespan.
Statutes of limitations/repose	Limits the amount of time a patient has to file a malpractice claim. Statutes of limitations bar lawsuits unless they are filed within a specified time after the injury occurs or is discovered. Statutes of repose bar lawsuits unless they are filed within a specified time after the medical encounter occurred, regardless of whether an injury has yet been discovered.

<i>Innovative Reforms</i>	<i>Reforms that are relatively new in use, or have had limited or no implementation, in the U.S.</i>
“Health courts”	<p>Medical court model: A model of a “health court” that replaces a lay judge and fact finder (either a judge or jury) with a judge and fact finder who has both medical and legal training.</p> <p>Administrative model: A more commonly proposed “health court” model today that routes medical injury claims into an alternative, typically administrative, adjudication process that can include a combination of specialized judges, decision and damages guidelines, neutral experts, and a compensation standard that is broader than the negligence standard.</p>
Communication-and-resolution programs (sometimes termed disclosure, apology, and offer programs)	Institutional programs that support clinicians in discussing unanticipated care outcomes (and their causes) with patients and families and in taking rapid steps towards resolution, including proactively offering compensation when appropriate.
Safe harbors for adherence to evidence-based practice guidelines	Provide legal protection against medical malpractice claims if a defendant healthcare provider can show that an applicable and approved clinical practice guideline was followed in the care in question
Mandatory pre-suit notification laws	Require plaintiffs to provide advance notice (typically ranging 1 to 6 months) to a physician or healthcare organization of their intent to sue.
Apology laws	Protect providers from having apologies or expressions of sympathy (and sometimes admissions of responsibility) made after an adverse event from being admitted into evidence in a lawsuit. The protection can be sometimes lost if contradictory statements are later made.
State-facilitated alternate dispute resolution	The state provides an agency or other body that can receive reports of potential errors or adverse events from patients or providers. The state then helps the parties come to resolution through a confidential mediation process.
Judge-directed negotiation	Malpractice litigants are required to meet early and often with the presiding judge to discuss settlement. Litigants must appear with knowledge of the case and full authority to settle. A single judge retains responsibility for the case over its entire lifecycle and takes an unusually active role in mediating negotiations. A neutral attorney (hired by the court system) with clinical training supports the judge in understanding clinical matters.

Our evaluation is based on existing empirical studies of state tort reforms, including several literature reviews and syntheses by recognized experts in the field;¹⁻⁸ case studies and anecdotal reports of particular federal, state and institutional programs; legal scholarship on the structure and theoretical basis of reforms; and, where no evidence is available, our own judgments. In synthesizing extant empirical research, we do not include the large “grey literature” of reports issued by advocacy

organizations, relying instead on academic, government, and foundation reports that meet accepted standards of scientific rigor. For studies evaluating the effects of tort reforms implemented in the states, this meant exclusion of study findings based solely on univariate or bivariate analysis, rather than a well-controlled multivariate regression analysis. A summary of data sources consulted is presented in Exhibit 3. For this update to the 2010 report, we reviewed an additional 109 studies and other papers on traditional and innovative tort reforms.

Exhibit 3. Scope of Literature Search

Source	Sources and Scope of Search
Legal literature	Westlaw’s “Journals & Law Reviews” combined library, Jan 1990-Mar 2016; Social Science Research Network (unrestricted date search)
Health and medical literature	PubMed, Jan 1990-Mar 2016
Economics literature	EconLit, Jan 1990- Mar 2016; Social Science Research Network (unrestricted date search); older articles cited in more recent works
Government reports	Reports collected on websites of the Congressional Budget Office, General Accountability Office, Office of the Assistant Secretary for Planning and Evaluation, Office of Technology Assessment (archive), and Agency for Healthcare Research and Quality, Jan 1990-Mar 2016; websites of the Washington State Task Force on Noneconomic Damages and Oregon Patient Safety Commission
Foundation reports	Reports collected on websites of the National Academy of Medicine, Robert Wood Johnson Foundation, Kaiser Family Foundation, Commonwealth Fund, and Pew Charitable Trusts (unrestricted date search)
Other	RAND Compare Dashboard ⁹

2. Analysis of Paid Malpractice Claims Involving Elderly Patients

2.1. Methods

2.1.1. Data and Limitations

Using data in the National Practitioner Data Bank (NPDB) Public Use File (PUF),¹⁰ we analyzed paid malpractice claims involving elderly patients that were reported to the NPDB between January 1, 2005 and December 31, 2015. Pursuant to the federal Health Care Quality Improvement Act of 1986, the Health Resources and Services Administration (HRSA) requires that liability insurers and certain other entities report to the NPDB all payments made on malpractice claims in the name of a healthcare practitioner. Reports must be made within 30 days of a payment.

A restricted set of data fields is made available to the public in the PUF. The claims listed in the PUF for each year generally represent claims that closed with a payment in that year, although claims with a January reporting date may have closed in December of the previous year. The filing dates for these claims may have been as short as a few months earlier, or as long as a few years earlier. The dates of the incidents of alleged malpractice are still earlier: among the claims we analyzed, the mean lag time between the incident and reporting dates was 4.9 years (median: 4.0 years).

For simplicity, we confined our analytical sample to claims against MDs or DOs (PUF practitioner codes 010, 015, 020, and 025). Both trainees and non-trainees were included. We adjusted indemnity payments to 2015 dollars using the annual Consumer Price Index.¹¹

Though it is the standard dataset used in the field of medical liability research for analysis of trends in malpractice claims, the PUF has several limitations. One set of shortcomings relates to what is collected by HRSA. The NPDB elicits information about claims only when they result a payment, so it cannot be used to explore trends in the total number of claims filed (including those dropped, dismissed, tried to verdict for defendant, and settled without an indemnity payment). Further, the NPDB does not collect information about payments made in the name of healthcare facilities.

There is also believed to be some degree of underreporting to the NPDB, stemming in part from the practice of “corporate shielding,” in which an institutional defendant (for example, a large medical center) pays a claim in its own name only, dropping the physician so as not to trigger the NPDB reporting requirement for the physician.¹² The magnitude of the underreporting problem is not known. However, there is no theoretical reason to think it is either disproportionately high or disproportionately low for claims involving elderly patients.

Other limitations relate to how data are recorded in the PUF. First, in order to reduce the likelihood that a particular claim can be identified, indemnity payments are reported in the PUF as the midpoint of a dollar value range near their actual amount. For example, a payment of \$318,000 would be recorded as the midpoint of the nearest \$10,000 increment, or \$315,000. This introduces measurement error into calculations of mean, median, and total payments—probably only a modest amount, because the dollar value ranges are fairly narrow.

Second, some of the critical fields for this analysis, including patient age, were not made available in the PUF until end of January 2004. For that reason, our analysis is limited to 2005-2015.

Third, patient age is reported in ranges rather than precise years. This complicates estimates of the volume of claims brought by Medicare beneficiaries, because the age band 60-70 spans the onset of Medicare eligibility on the basis of age. Our strategies for addressing this challenge are described below.

Fourth, the variable representing total indemnity payments on a claim does not bundle together payments made by defendants’ insurers and payments made by state-run patient compensation funds (PCFs) for the same incident. Nine states have patient compensation funds, which function as a secondary layer of liability insurance, paying judgments and settlements above a certain amount. The PUF lists PCF payments separately, but does not provide a means of directly linking them to the primary payment in the same case via a case identifier. We used a probabilistic matching method employed by Studdert and colleagues to link PCF payments to insurer payments relating to the same incident, but this algorithm may have linked payments imperfectly.¹³

2.1.2. Definition of “Medicare” Group

Because we could not precisely identify Medicare beneficiaries within the PUF, we constructed two different groups of elderly claimants. The main analysis compares patients 70 years and older at the time of the incident underlying the claim to patients under age 60 at the time of the incident. (Claimants aged 60-69 at the time of the incident are omitted from the analysis because that group

contains both Medicare enrollees and non-enrollees.) A sensitivity analysis compares patients 60 years and older to those under 60.

It should be noted that End-Stage Renal Disease patients are likely misclassified in our analysis. Though Medicare eligible, they are likely to be disproportionately under the age cutoffs that define the “Medicare” groups in our analysis. Thus, our analysis treats them as non-Medicare patients unless they exceed the age thresholds. Persons who qualify for Medicare as Disabled but are not elderly are also erroneously classified as non-Medicare beneficiaries in our analysis.

ESRD and Disabled patients are not identifiable in the NPDB, making it impossible to correct any potential misclassification. Because ESRD patients represent less than 1% of Medicare beneficiaries¹⁴ and about 45% of those patients are over age 65,¹⁵ the number of persons misclassified—and thus the effect of the misclassification on our results—is small. In contrast, non-elderly Disabled persons comprise more than 16% of Medicare beneficiaries. We have no way of determining what proportion of NPDB reports they represent, and thus what the magnitude of the potential misclassification bias in our analysis might be. To account for these issues, throughout the report we have referred to our Medicare group as representing “elderly” Medicare enrollees, rather than all enrollees.

2.1.3. Analytical Methods

We used ordinary least squares (OLS) regression, chi-square tests, and t-tests to examine the relationships between key outcome variables and Medicare enrollee status. In regression models predicting indemnity payments, payments were logged to reduce nonnormality.

To examine time trends, we modeled year as a continuous variable (coded 1 through 12) and used OLS regression. We also ran Cuzick’s nonparametric test for trend across ordered groups on the 12-point time variable. This test, which is implemented in Stata using the **nptrend** command, is an extension of the Wilcoxon rank-sum test. It tests the hypothesis that the values of a variable with a natural ordering systematically increase or decrease over levels of another variable. All analyses were run in Stata version 13.1.

We included state PCF payments in calculations of indemnity payment levels, but excluded them from all other analyses, such as frequency counts, to avoid double counting of cases relating to the same incident.

Our analysis shows the distribution of claims by age group, but does not independently control for differences in health status or healthcare utilization. Because of their greater utilization of medical care, the elderly will, on average, have greater exposure to malpractice (though that may not hold true in the realm of missed and delayed diagnoses). We do not test for whether age *in itself* makes a person more or less likely to appear in the NPDB (for example, because older persons are more or less likely to sue or prevail in lawsuits than younger persons).

2.2. Results

2.2.1. All Claims

2.2.1.1. Sample Characteristics

Our analytical dataset contained 116,965 paid claims reported between January 1, 2005 and December 31, 2015 (Exhibit 4). About 94.2% of these (110,199 claims) were payments made by insurers, and the remaining 6,766 payments (5.8%) were made by state PCFs.

Among the non-PCF payments, 92.2% were paid in the name of a non-trainee MD, 7.1% were paid on behalf of a non-trainee DO, and less than 1% were paid on behalf of a trainee. Nearly all (95.7%) were made pursuant to a settlement. Nearly a third (32.2%) of claims involved deaths and almost another third (30.6%) involved serious, permanent injuries. The majority (56.6%) of incidents occurred in the inpatient setting.

Across all payments, the median total payment was \$211,046 in 2015 dollars. Twenty-five percent of payments were \$73,834 or less and 75% were \$500,321 or less. The 99th percentile of payments was \$2.75 million.

The most common clinical classifications of the incidents underlying paid claims were diagnostic related (31.5%), surgery related (27.0%), and treatment related (19.7%). Among diagnostic-related claims, 53.5% concerned an alleged failure to diagnose, 26.6% a delayed diagnosis, 5.2% an alleged misdiagnosis, and the remainder were distributed among a large number of other types of allegations. Among surgery-related claims, the leading types of allegations were improper performance (47.5%), improper technique (7.7%), failure to recognize a surgical complication (6.6%), retained foreign object (5.1%), improper management (4.3%), and unnecessary procedure (3.4%). Among treatment-related claims, the most common allegation types were improper management (15.1%), improper performance (13.4%), failure to treat (12.4%), delayed treatment (11.5%), failure to diagnose (4.5%), failure to recognize a complication (3.6%), and failure to order an appropriate test (3.6%).

2.2.1.2. Trends over Time

The median payment dropped from \$220,114 in 2008 to \$214,312 in 2009 and continued to drop thereafter, to \$197,096 in 2014, but increased again in 2015 to \$225,000 (Exhibits 5,6). Mean payments displayed a similar pattern, declining from \$426,366 in 2005 to a low of \$368,702 in 2011 before rising to \$404,627 in 2015 (Exhibit 5).

Time was not a significant predictor of indemnity payment amounts in Cuzick's nonparametric test for trend ($z=-1.65$, $p=0.099$) or in a simple regression of the natural log of payments on time ($\beta=-0.0017$, $s.e.=0.0013$, $t=-1.30$, $p=0.19$).

Exhibit 4. Sample Characteristics: Paid Malpractice Claims Involving MDs and DOs Reported to the NPDB, 2005-2015 (n=116,965)

	<i>n</i>	%		<i>n</i>	%
Year reported			Injury setting		
2005	13,034	11.8	Outpatient	45,602	43.4
2006	11,710	10.6	Inpatient	59,554	56.6
2007	10,755	9.8			
2008	10,377	9.4	Practitioner type		
2009	10,149	9.2	MD	101,549	92.2
2010	9,532	8.7	DO	7,831	7.1
2011	9,320	8.5	MD resident	706	0.6
2012	8,911	8.1	DO resident	113	0.1
2013	9,003	8.2			
2014	8,828	8.0	Patient age at time of injury		
2015	8,580	7.8	<1	7,844	7.1
			1-9	2,907	2.6
Injury severity			10-19	4,347	3.9
Emotional only	1,857	1.7	20-29	9,123	8.3
Insignificant	1,901	1.7	30-39	15,609	14.2
Minor temporary	11,147	10.2	40-49	20,235	18.4
Major temporary	12,001	11.0	50-59	19,990	18.1
Minor permanent	13,687	12.5	60-69	14,570	13.2
Significant permanent	16,545	15.2	70-79	8,673	7.9
Major permanent	11,582	10.6	80-89	2,788	2.5
Quadriplegic, brain damage, lifelong care	5,309	4.9	90-99	264	0.2
Death	35,089	32.2			
Clinical classification:			“Medicare beneficiaries”		
Diagnosis related	37,956	32.0	Main analysis (70+)	11,725	12.8
Anesthesia related	3,180	2.7	Sensitivity analysis (60+)	26,295	24.7
Surgery related	31,763	26.8			
Medication related	6,109	5.2	Payment type		
IV / blood products related	221	0.2	Settlement	105,487	95.7
Obstetrics related	8,873	7.48	Judgment	2,980	2.7
Treatment related	23,298	19.6	Before settlement	327	0.3
Monitoring related	3,619	3.1	Context unknown	1,405	1.3
Equipment / product related	702	0.6			
Behavioral health related	458	0.4	Indemnity payments		
Other	2,516	2.1	Mean	\$393,005	
			s.d.	\$671,877	
			Median	\$211,046	
			25 th percentile	\$73,834	
			75 th percentile	\$500,321	

Counts exclude patient compensation fund payments; indemnity payment amounts include these payments. Percentages may not sum to 100 due to rounding. Denominators for proportions are observations that are not variable. Approximately 3.5% of the sample was missing age data.

Exhibit 5. Mean and Median Payments Among Full Sample, by Year (in 2015 dollars)

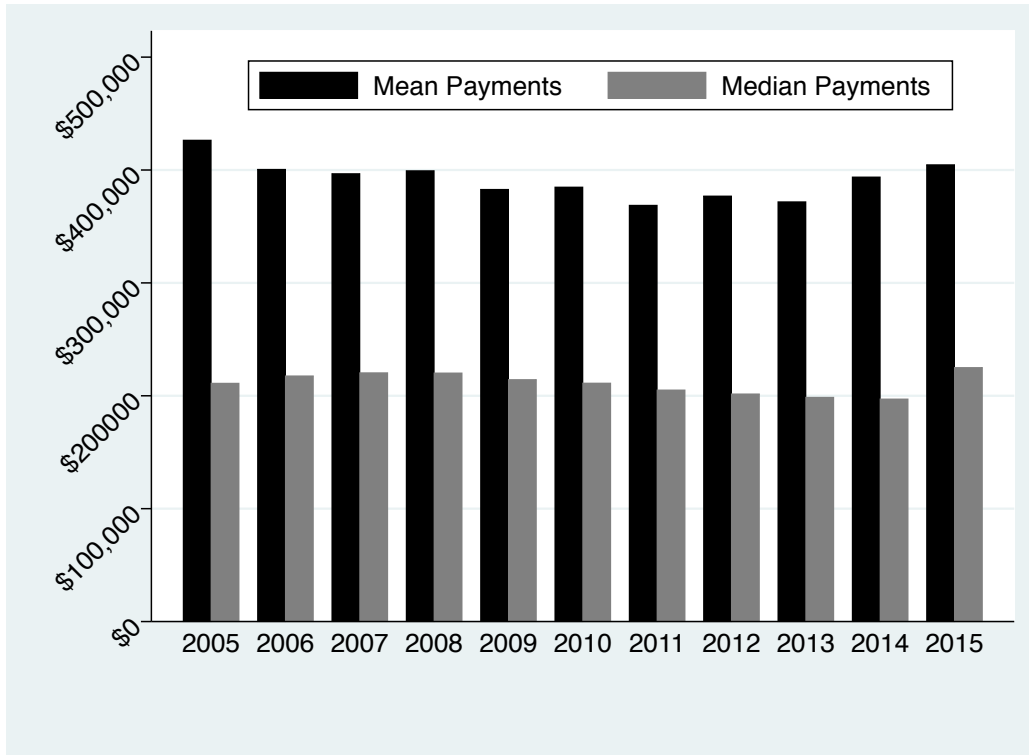
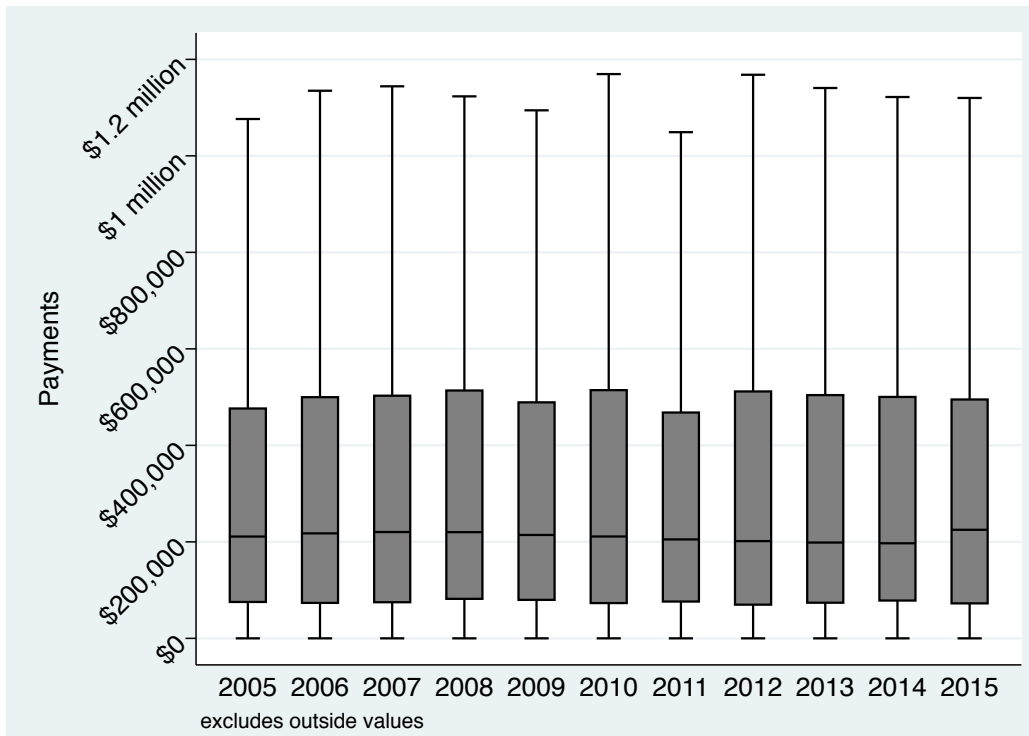


Exhibit 6. Box-and-Whiskers Plot of Payments Among Full Sample, by Year (in 2015 dollars)



Top and bottom edges of boxes represent 75th and 25th percentiles, respectively. Horizontal line within box is the median. Top and bottom whiskers represent adjacent values as defined by Tukey (1977), which are (for top) the largest value that is less than or equal to the upper quartile plus 1.5 times the interquartile range, and (for bottom) the smallest value that is greater than or equal to the lower quartile minus 1.5 times the interquartile range. Values exceeding the upper and lower adjacent values (“outside values”) are not shown in order to reduce clutter in the visual presentation.

Overall, the number of claims reported annually dropped steadily over the study period, from a high of 13,034 in 2005 to 8,580 in 2015 (Exhibit 7). There were no notable differences in average injury severity across the study period.

The trend in number of paid claims over time looked very different for Medicare enrollees and non-enrollees, however. In contrast to the decline for claims involving individuals under age 60, the number of paid claims involving Medicare enrollees remained essentially stable over time. Exhibit 8 shows this phenomenon, with the Medicare enrollee group defined as age 70 or above; the plots using a broader definition of Medicare enrollees (aged 60 and above) looked similar.

Exhibit 7. Number of Paid Claims, by Year

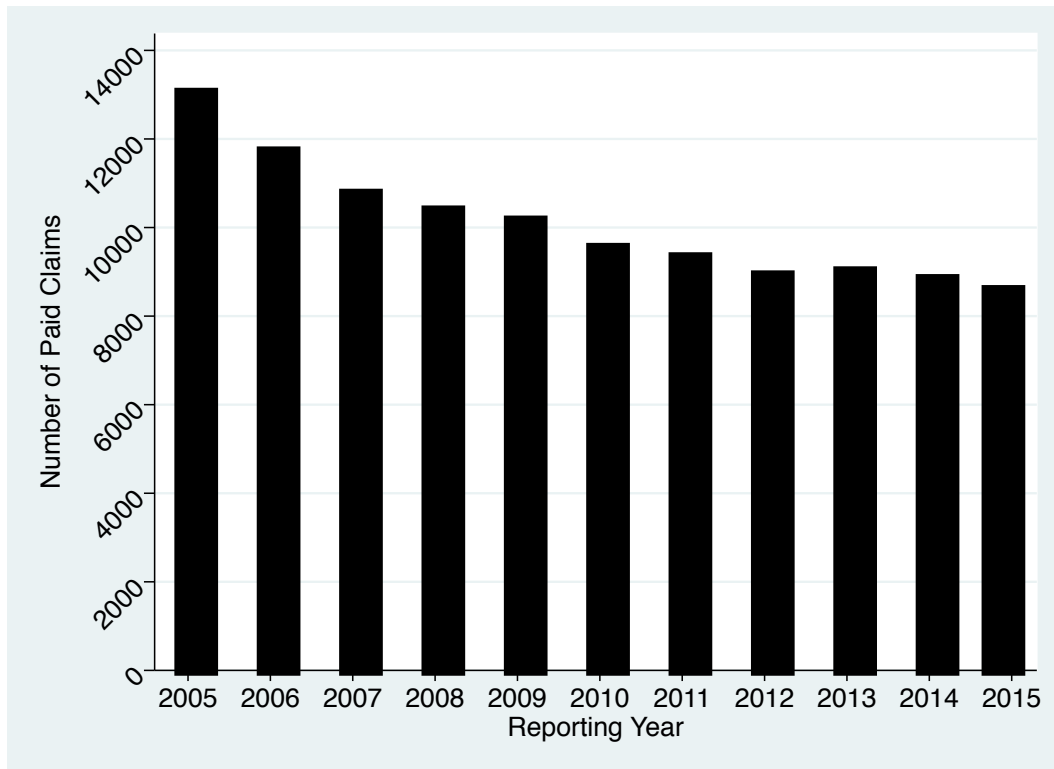
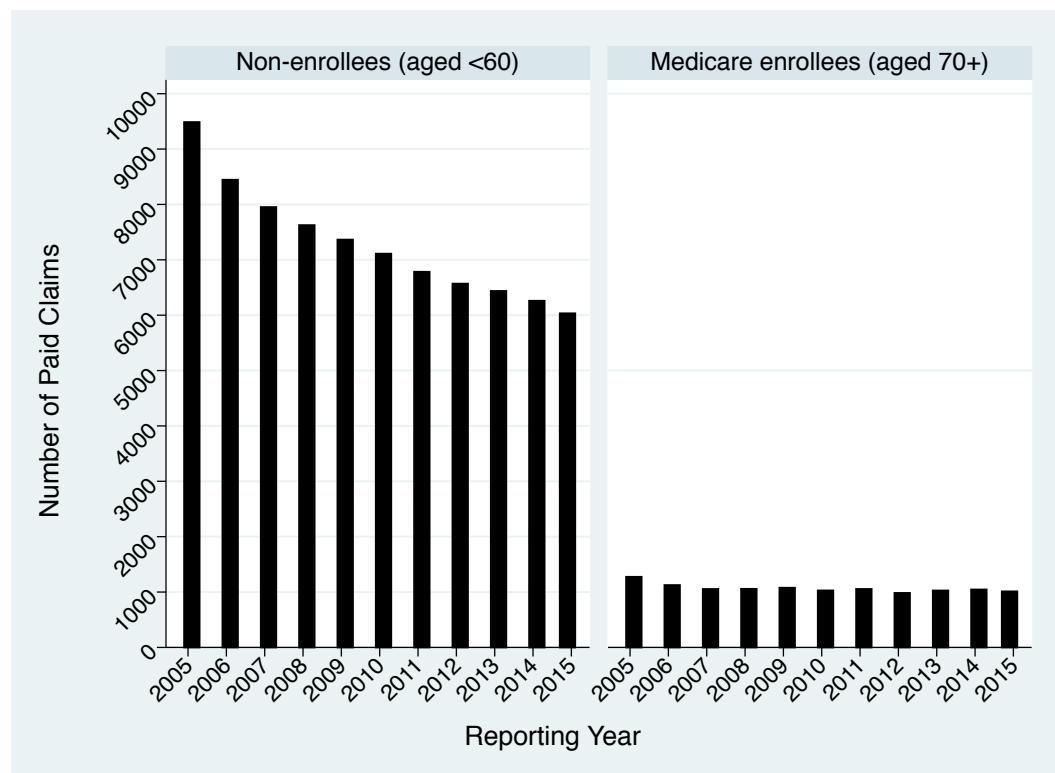


Exhibit 8. Number of Paid Claims, by Year and Medicare Enrollee Status



2.2.1.3. Distribution of Claims by Age Group

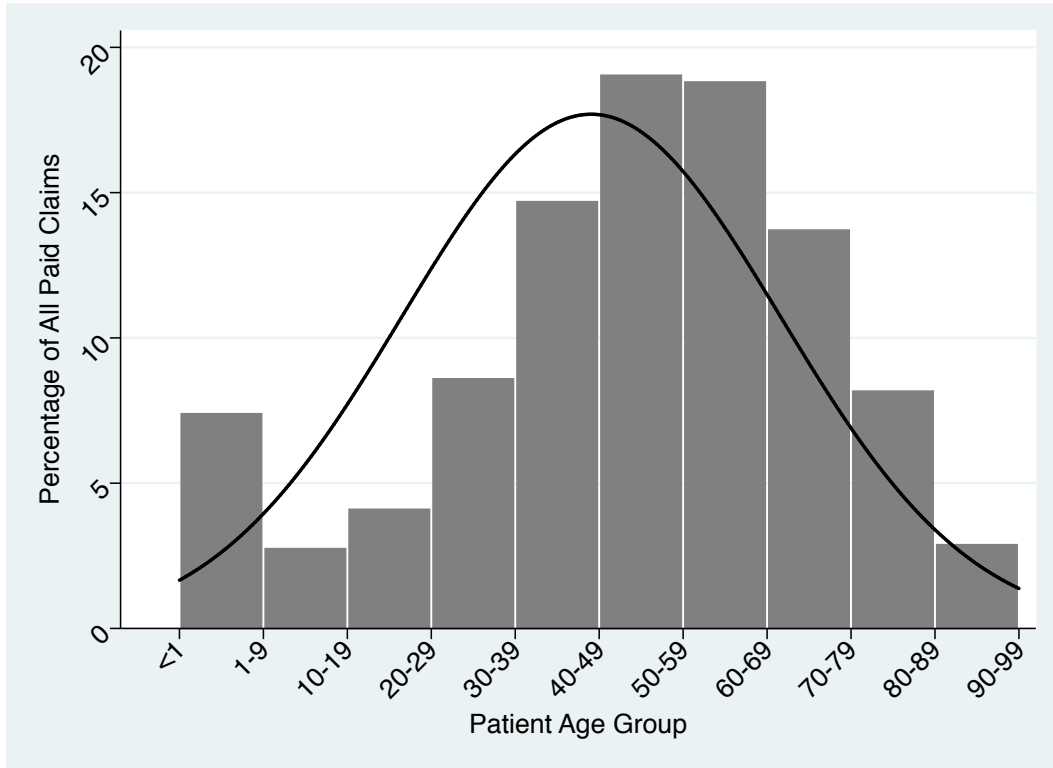
The age distribution of the number of paid claims was right skewed (Exhibit 9). Patients aged 70 or above at the time of claim reporting accounted for 10.6% of all claims over the study period, and patients aged 60 or above accounted for 23.9% of claims. The majority of claims (58.9%) involved adults aged 20-59, while about 13.7% involved children, infants, and fetuses.

When interpreting the distribution of paid claims by age group, it is difficult to assess whether the elderly are over- or under- represented. To fully understand that, one would need to understand inter-age-group differences in individuals' exposure to medical malpractice. Although such an exploration is beyond the scope of this report, we did examine one measure of potential exposure to malpractice: hospital care utilization. We examined the age distribution of both the number of hospital stays and hospital costs in the U.S., using data on stays in community hospitals from the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project (HCUP) for 2004-2013.

Hospital costs are more sensitive to the intensity of services received than number of admissions, but both stays and costs are imperfect proxies for individuals' actual exposure to malpractice. That exposure also depends on the reason for hospitalization, which likely varies across age groups. Moreover, it is important to bear in mind that about 4 in 10 NPDB claims relate to malpractice that allegedly occurred in an outpatient setting. Despite these shortcomings, hospital care utilization provides some information on the comparative exposure of different age groups to malpractice.

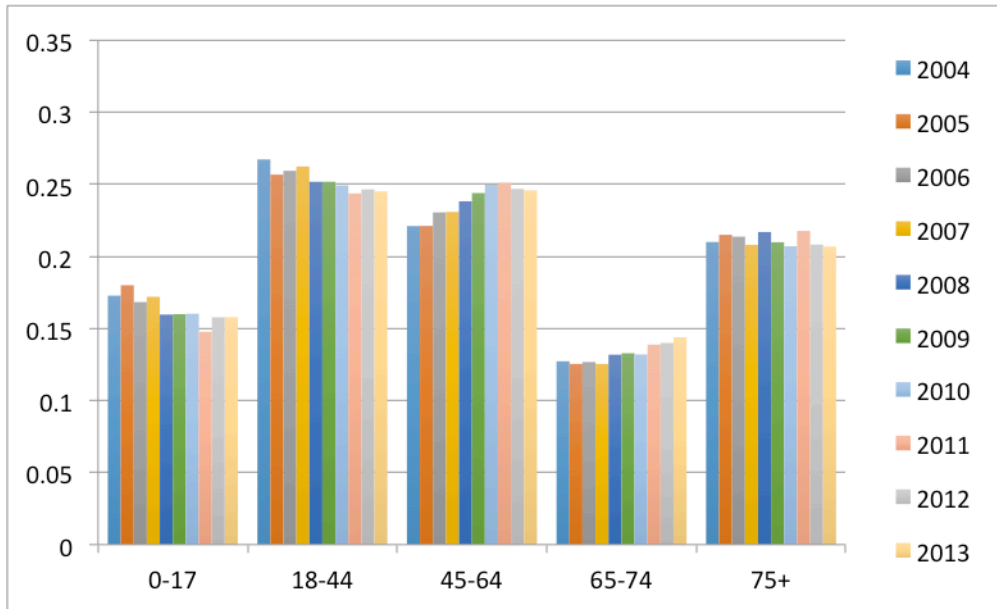
HCUP categorizes age groups somewhat differently from the PUF, but discrepancies between the age distributions of paid claims and hospital stays are nonetheless clear. Patients aged 65 and older account for about a third of hospital stays each year (Exhibit 10) and more than 40% of inpatient costs (Exhibit 11). Yet the broader group of elderly including those as young as 60 account for less than a quarter of all paid malpractice claims.

Exhibit 9. Paid Claims, 2005-2015, by Age Group



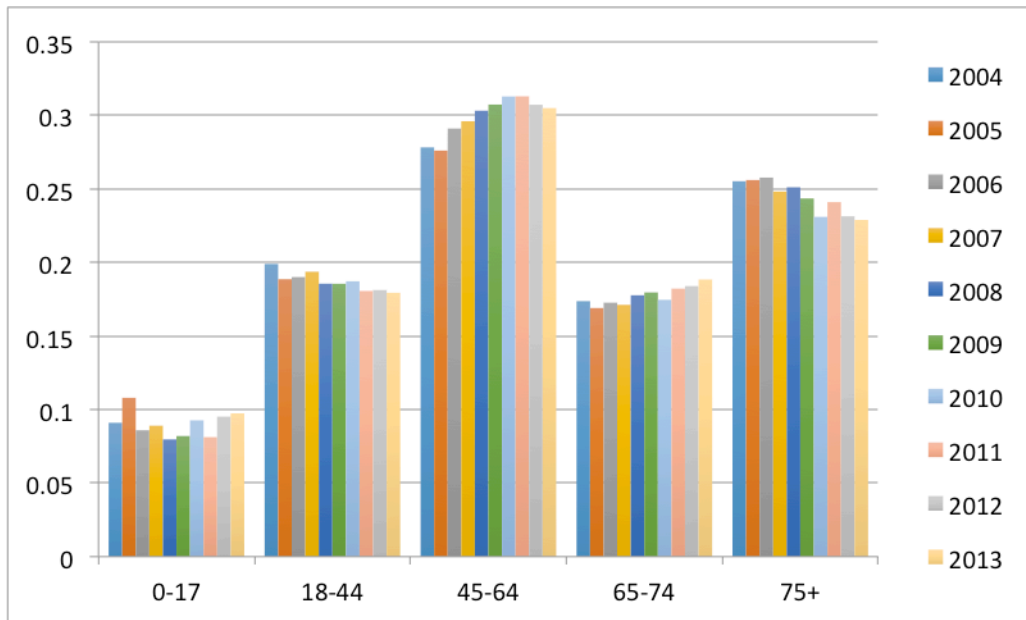
Curved line represents the normal distribution. Labels for each age group sit at the left side of the bar representing that group. The bar for ages 90-99 is too low to be visible (less than one quarter of 1%).

Exhibit 10. Proportion of all U.S. Hospitalizations, by Age Group and Year



Data source: Healthcare Cost and Utilization Project, <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsServlet>

Exhibit 11. Proportion of all U.S. Inpatient Costs, by Age Group and Year



Data source: Healthcare Cost and Utilization Project, <https://www.hcup-us.ahrq.gov/faststats/NationalTrendsServlet>

2.2.2. Comparison of Medicare Enrollees and Non-Enrollees

In this analysis we compared claims involving Medicare enrollees (defined as aged 70 or above) to claims involving non-enrollees (defined as aged 59 or below).

2.2.2.1. Indemnity Payments

Average and median indemnity payments were significantly lower among Medicare enrollees than among non-enrollees (Exhibit 12). The mean award over the entire study period was \$231,723 (s.e. \$2,812) among Medicare enrollees and \$420,615 (s.e. \$2,256) among non-enrollees ($p < 0.001$ in two-sample t -test) (Exhibit 13). The medians were \$139,548 for Medicare enrollees versus \$227,419 for non-enrollees.

Exhibit 12. Box-and-Whiskers Plot of 2005-2015 Payments, Medicare Enrollees (Aged 70+) vs. Non-Enrollees

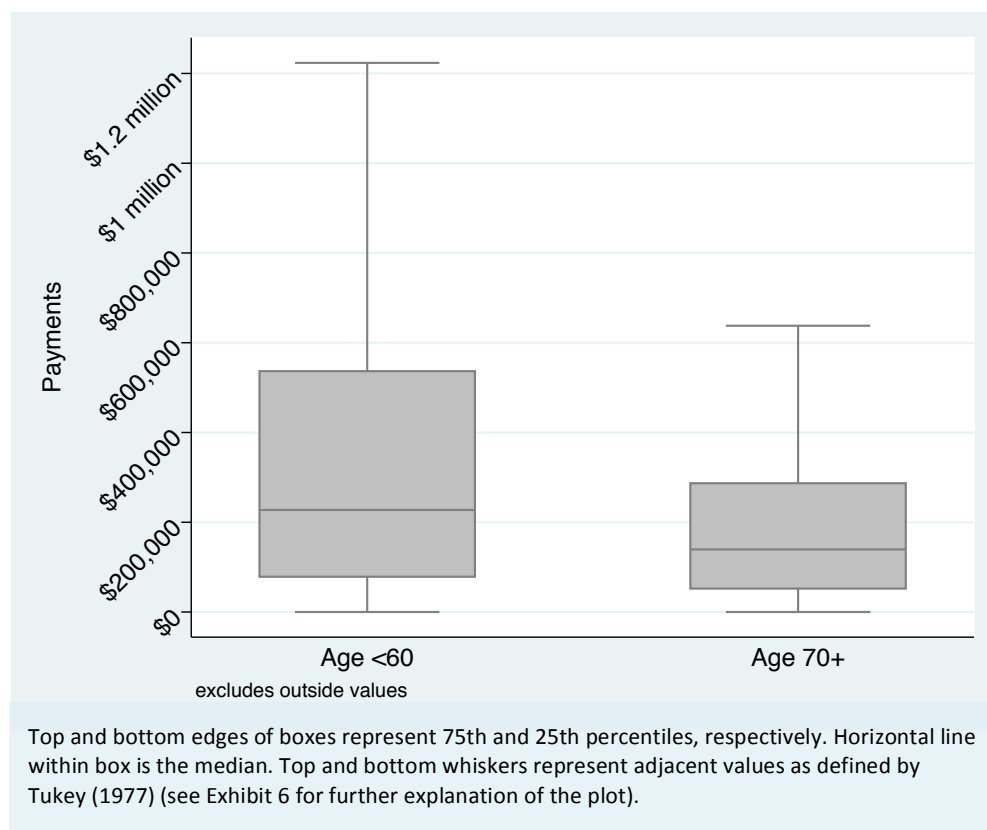


Exhibit 13. 2005-2015 Mean Payments, Medicare Enrollees (Aged 70+) vs. Non-Enrollees (Aged <60)

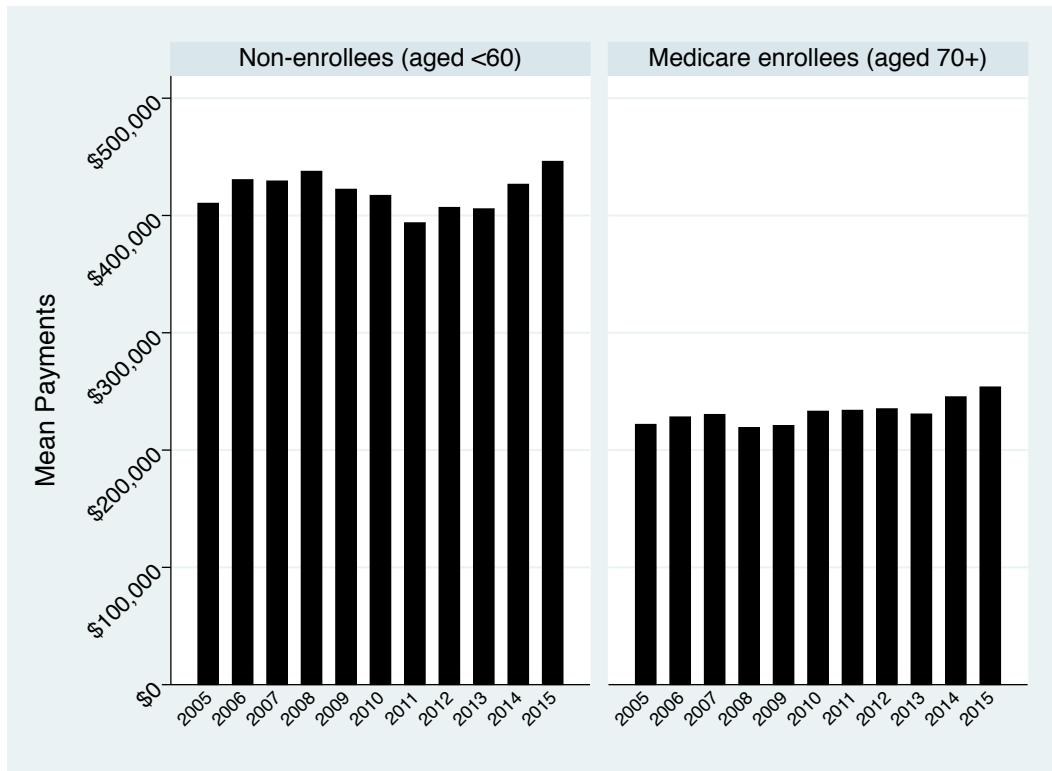


Exhibit 14 presents the results of an ordinary least squares regression model predicting the natural log of indemnity payments as a function of the 11-category age group variable described in Exhibit 4, controlling for injury setting (inpatient or outpatient) and year of injury. The age variable was a highly significant, negative predictor ($p < 0.001$).

Exhibit 14. Ordinary Least Squares Regression: Natural Log of Indemnity Payments (n=93,925)

	β	s.e.	t	p	95% CI	
Constant	13.0908	2.96	4.43	<0.001	7.30	18.89
Age group	-0.48	0.014	-33.89	<0.001	-0.509	-0.45
Inpatient injury	0.31	0.0095	32.98	<0.001	0.29	0.33
Year of injury	-0.00056	0.0015	-0.38	0.705	-0.0034	0.0023

2.2.2.2. Injury Severity

Injuries involving Medicare enrollees were significantly more likely than injuries to younger patients to be severe (“significant-permanent” injury or worse) (70.8% vs. 60.7%, $p < 0.001$). In an ordinary least squares regression model predicting injury severity as a function of age group, the age variable was significant, positive predictor at the $p < 0.001$ level ($\beta = 0.78$, s.e. = 0.023, $t = 34.72$).

Within injury severity categories, the largest differences were in the proportion of deaths: 50.6% of claims involving Medicare enrollees related to a patient death, compared to 28.2% of claims involving

younger patients. Younger patients, in contrast, had nearly four times the proportion of claims involving emotional injuries only, compared to Medicare enrollees.

2.2.2.3. Incident Characteristics

Setting. Injuries involving Medicare enrollees were significantly more likely than injuries to younger individuals to have occurred in the inpatient setting (63.3% vs. 55.4%, $p < 0.001$).

Clinical Category. Overall, the distributions of claims by clinical category looked fairly similar for Medicare enrollees aged 70 or above and patients under age 60 (Exhibit 15). Medicare enrollees' claims (for obvious reasons) rarely involved obstetrical events; and Medicare enrollees' claims were nearly twice as likely as claims involving patients under 60 to be medication- or monitoring- related. A few other statistically significant differences were observed, but they were smaller in magnitude. Specifically, claims involving Medicare enrollees were significantly more likely to be classified as related to treatment or anesthesia, and less likely to be related to diagnostic processes or behavioral health concerns.

We tested for differences in the prevalence of three specific malpractice allegations that our clinical judgment suggested might be more common among the elderly: unnecessary care, breach of informed consent, and poor communication with the patient. We found that claims involving Medicare enrollees indeed were more likely than claims involving younger patients to involve allegations of unnecessary care, but were less likely to involve allegations of a breach of informed consent (Exhibit 15).

Exhibit 15. Clinical Classifications and Alleged Error Types in Paid Claims, 2005-2015

	Medicare enrollees (aged 70+) %	Non-enrollees (aged <60) %	<i>p</i>
Main classification:			
Diagnosis related	28.39	32.20	<0.001
Anesthesia related	3.03	2.53	0.002
Surgery related	26.61	26.61	1.00
Medication related	8.54	4.63	<0.001
IV / blood products related	0.16	0.18	0.72
Obstetrics related	0.05	9.53	<0.001
Treatment related	25.09	18.51	<0.001
Monitoring related	5.16	2.69	<0.001
Equipment / product related	0.72	0.60	0.15
Behavioral health related	0.13	0.47	<0.001
Other	2.11	2.05	0.68
Selected alleged errors:			
Unnecessary care	2.70	2.23	0.002
Breach of informed consent	0.87	1.32	<0.001
Poor communication with patient	1.26	1.23	0.79

Exhibit presents a non-exhaustive list of alleged error types, highlighting those most salient to elderly persons. Two-tailed *p*-values are based on Pearson chi-squared analysis.

2.2.3. Sensitivity Analysis

In a sensitivity analysis, we repeated the above analyses on a sample of 26,295 claims involving Medicare enrollees (defined as age 60 or above) compared to 80,055 claims involving non-enrollees (age 59 or below). (Analyses of indemnity payments were conducted on a sample of 27,503 enrollees versus 85,384 non-enrollees). The findings were similar to the main analysis.

2.2.3.1. Indemnity Payments

As in the main analysis, average and median indemnity payments were significantly lower among Medicare enrollees than among non-enrollees (Exhibits 16, 17). For the entire study period, the mean payment was \$286,067 among enrollees, compared to \$420,615 for non-enrollees ($p < 0.001$ in two-sample t -test). The median payments were \$173,528 for Medicare enrollees versus \$227,419 for non-enrollees. The absolute differences in means and medians between the age groups were smaller in the sensitivity analysis than in the main analysis due to the higher mean and median awards among the broader (sensitivity analysis) group of Medicare enrollees.

Exhibit 16. 2005-2015 Mean Payments, Medicare Enrollees (Aged 60+) vs. Non-Enrollees (Aged <60)

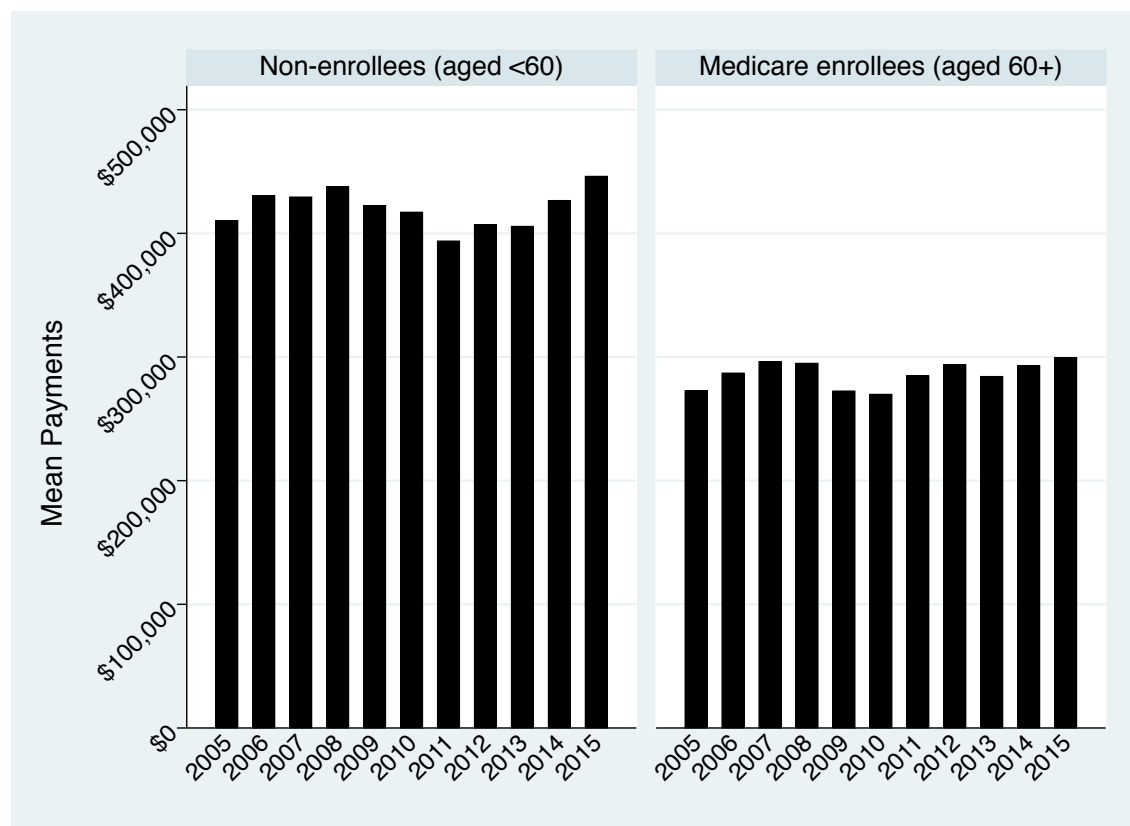
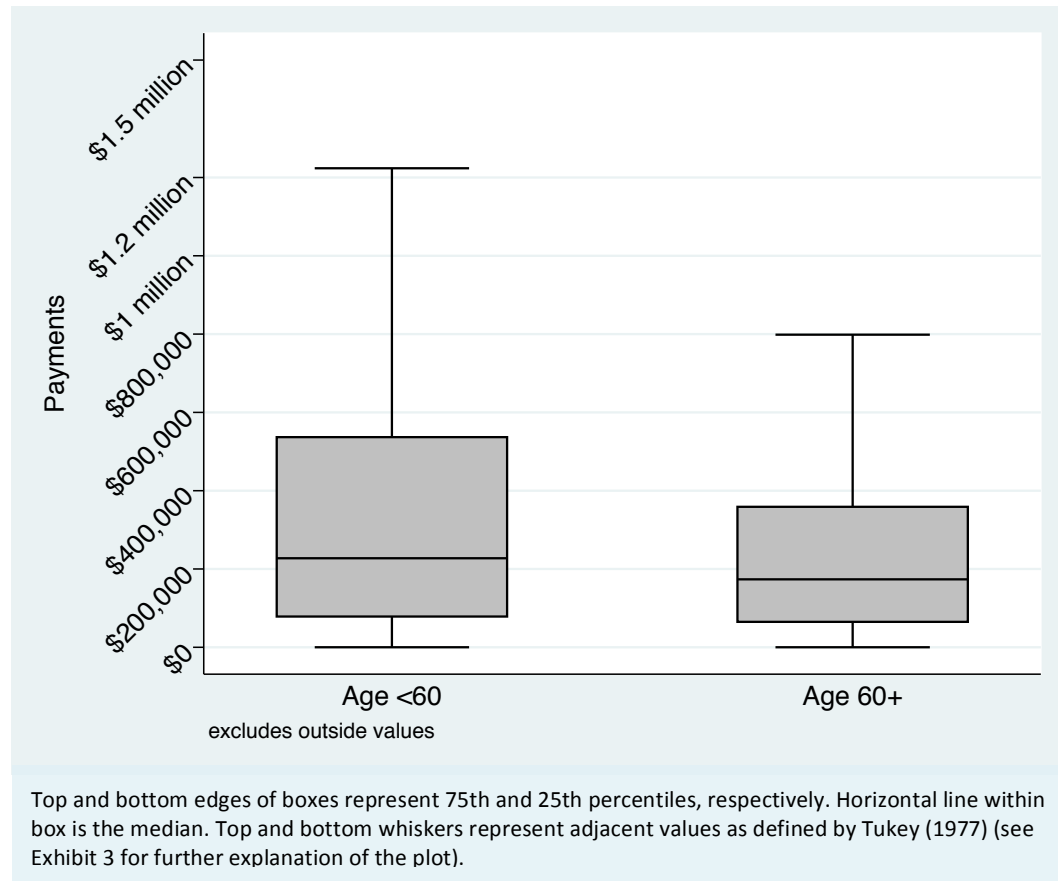


Exhibit 17. Box-and-Whiskers Plot of 2005-2015 Payments, Medicare Enrollees (Aged 60+) vs. Non-Enrollees (Aged <60)



In a multivariate regression model predicting logged indemnity payments (Exhibit 18), results were similar to the main analysis. Age remained a highly significant, negative predictor ($p < 0.001$).

Exhibit 18. Sensitivity Analysis: Ordinary Least Squares Regression: Natural Log of Indemnity Payments (n=108,683)

	β	s.e.	t	p	95% CI	
Constant	12.688	2.734	4.64	<0.001	7.329	18.046
Age group	-0.285	0.0101	-28.08	<0.001	-0.305	-0.265
Inpatient injury	0.280	0.0088	31.93	<0.001	0.263	0.298
Year of injury	-0.000350	0.0014	-0.26	0.798	-0.00205	0.00276

2.2.3.2. Injury Severity

Injuries involving Medicare enrollees aged 60 or above were significantly more likely than injuries to younger patients to be severe (“significant-permanent” injury or worse) (68.5% vs. 60.7%, $p < 0.001$). Both the magnitude and the statistical significance of the difference were similar to the main analysis. In an ordinary least squares regression model predicting injury severity as a function of age group, the age variable remained a significant, positive predictor at the $p < 0.001$ level ($\beta = 0.6048$, s.e. = 0.0162, $t = 37.35$).

Within injury severity categories, the largest difference between the Medicare and non-Medicare groups was in the proportion of deaths (45.1% of Medicare enrollees vs. 28.2% of non-enrollees), though it was slightly smaller in magnitude than in the main analysis. As before, younger patients had nearly quadruple the proportion of claims involving emotional injuries, compared to Medicare enrollees. Younger patients also had nearly treble the proportion of claims involving a specific subtype of serious injury—quadriplegia or comparably severe injuries (5.8% vs. 2.0%).

2.2.3.3. Incident Characteristics

Setting. As in the main analysis, injuries involving Medicare enrollees were significantly more likely than injuries to younger individuals to have occurred in the inpatient setting (59.7% vs. 55.4%, $p < 0.001$). The absolute magnitude of the difference was slightly smaller than in the main analysis.

Clinical Category. Compared to claims involving patients under age 60, claims involving Medicare enrollees were significantly more likely to be classified as related to surgery, medication, treatment, monitoring, or anesthesia (Exhibit 19). Medicare enrollees’ claims were significantly less likely to be related to behavioral health concerns and obstetrical care. Small but statistically significant differences were also observed in the prevalence of allegations of unnecessary care and allegations of a breach of informed consent.

These results were similar to the main analysis, with two exceptions: in the main analysis, the surgery difference was not significant but the difference in the proportions of diagnosis-related claims was.

Exhibit 19. Sensitivity Analysis: Clinical Classifications and Alleged Error Types in Paid Claims

	Medicare enrollees (aged 60+) %	Non-enrollees (aged <60) %	<i>p</i>
Main classification:			
Diagnosis related	31.91	32.20	0.392
Anesthesia related	3.01	2.53	<0.001
Surgery related	27.95	26.61	<0.001
Medication related	6.73	4.63	<0.001
IV / blood products related	0.18	0.18	0.863
Obstetrics related	0.07	9.53	<0.001
Treatment related	22.93	18.51	<0.001
Monitoring related	4.29	2.69	<0.001
Equipment / product related	0.63	0.60	0.629
Behavioral health related	0.14	0.47	<0.001
Other	2.16	2.05	0.304
Selected alleged errors:			
Unnecessary care	2.67	2.23	<0.001
Breach of informed consent	0.92	1.32	<0.001
Poor communication with patient	1.32	1.23	0.271

Exhibit presents a non-exhaustive list of alleged error types, highlighting those most salient to elderly persons. Two-tailed *p*-values are based on Pearson chi-squared analysis.

2.2.4. Time Trends Among Claims Involving Medicare Enrollees

We analyzed trends over time among claims involving Medicare enrollees. Looking first at the group defined as aged 70 and above, the number of paid claims involving Medicare beneficiaries dropped from 1,273 in 2005 to 1,053 in 2007 and remained fairly constant through 2015 (Exhibit 20).

We examined the proportions of claims in each year that related to each of the several different types of alleged errors. Although there was some fluctuation from year to year, no clear patterns emerged. The proportion of claims involving inpatient injuries, and the proportion involving severe injuries, also varied significantly across the years in the study period, but there was no discernible time trend.

The median and mean payments among Medicare enrollees showed some annual fluctuation over the study period. The means increased over time to a somewhat greater extent than medians (Exhibit 21). Time significantly predicted payment amounts in Cuzick's nonparametric test for trend ($z=2.17, p=0.030$) and in a regression of the natural log of payments on time ($\beta=0.00957, s.e.=0.00367, t=2.61, p=0.009$).

Exhibit 20. Number of Paid Claims Among Medicare Enrollees (Aged 70+), by Year

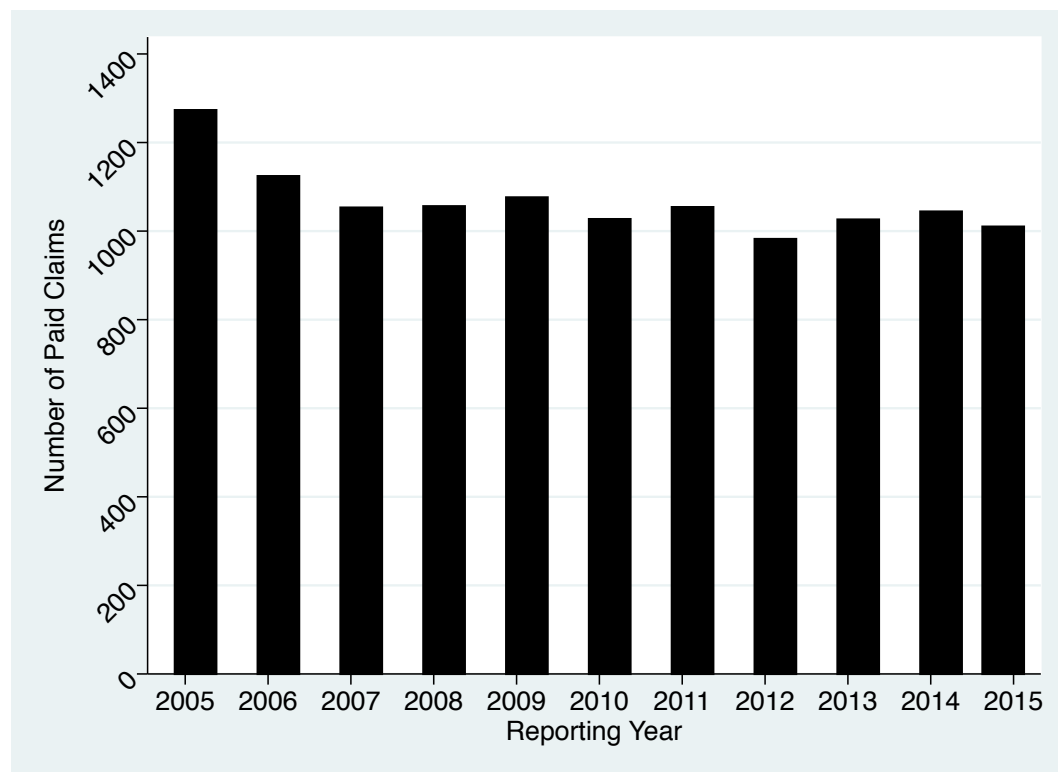
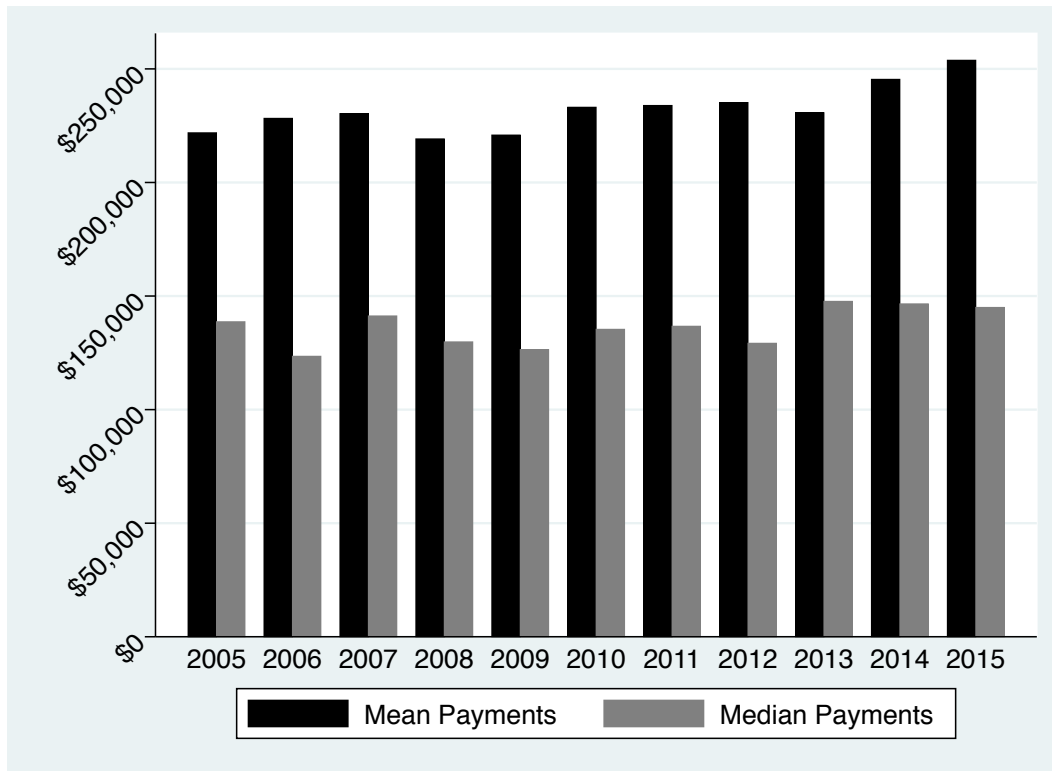


Exhibit 21. Mean and Median Payments Among Medicare Beneficiaries Aged 70+



2.2.5. Sensitivity Analysis

In the sensitivity analysis of claimants aged 60 and older, the frequency of claims over time showed a pattern similar to that for the main analysis: a drop through 2007 followed by fairly stable counts through 2015 (Exhibit 22).

As before, no patterns were apparent in the proportions of claims involving different types of alleged errors or the proportions involving inpatient injuries. However, the proportions involving severe injuries declined over time more consistently than in the main analysis, from a high of 72.7% in 2007 to 65.9% in 2015.

The trends over time in mean and median payments looked very similar to the main analysis (Exhibit 23). Time was borderline-significant as a predictor of payment amounts among Medicare beneficiaries in Cuzick's nonparametric test for trend ($z=1.79$, $p=0.073$). As in the main analysis, it reached statistical significance in a regression of the natural log of payments on time ($\beta=0.005108$, $s.e.=0.002531$, $t=2.02$, $p=0.044$).

Exhibit 22. Number of Paid Claims Among Medicare Enrollees (Aged 60+), by Year

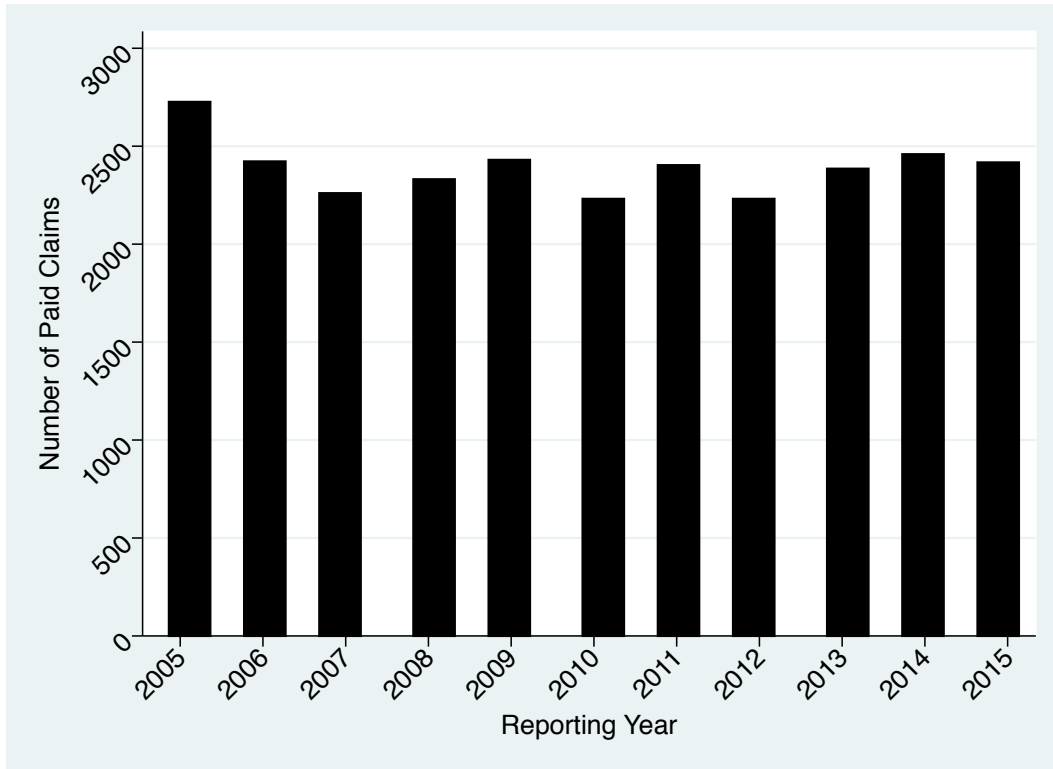
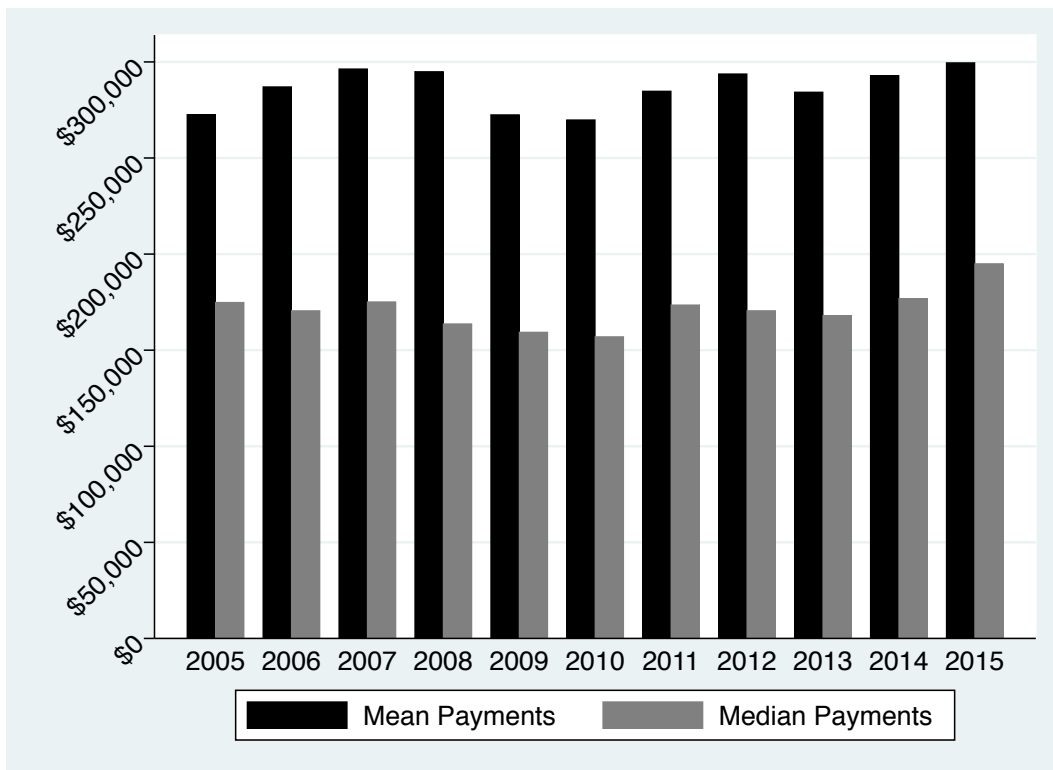


Exhibit 23. Mean and Median Payments Among Medicare Beneficiaries Aged 60+



2.3. Discussion

Several findings from the foregoing analyses merit highlighting. First, for elderly individuals, the number of paid claims reported to the NPDB annually remained fairly stable over the 2005-2015 period. In contrast, for nonelderly individuals, the number declined markedly. That difference is not easily explained. But what is clear is that there has not been upward pressure on paid claims frequency for either age group over the last decade.

The last malpractice insurance “crisis” is generally characterized as having ended around 2003-2004, with a concomitant calming of claims rates, payment levels, and insurance premium costs. Such crises are cyclical, and historically have recurred about every 10-15 years.¹⁶ Although that time period has almost elapsed, there is no sign in the NPDB data of recurrence based on claims closed through 2015. (Our analysis cannot discern whether claim *filings* have increased or decreased over time.)

Second, there are observable differences in the nature and severity of injuries among elderly versus non-elderly claimants. Paid claims involving patients aged 70 or above were significantly more likely to involve severe injuries, and nearly twice as likely to involve a death, than claims involving patients under age 60. Injuries to elderly patients were also significantly more likely to have occurred in the inpatient setting than claims involving younger patients. They were less likely to be diagnosis related, and more likely to be related to medication, anesthesia, treatment, or monitoring, than claims involving younger patients.

Third, indemnity payments in paid claims involving the elderly are significantly lower than in claims involving younger claimants. As noted above, this cannot be attributed to lower injury severity. Rather, it likely reflects the lower economic losses of retirees compared to individuals still in the workforce. It may also reflect lower noneconomic damages payments for claimants with shorter life expectancies.

Finally, the distribution of paid claims by age is right skewed. It peaks at ages 40-59 but individuals in their 60s and 70s are also highly represented in the data. There are three potential reasons for the skew. The first is that there may be a higher incidence of malpractice among patients older than young adults. That may be the case simply because older adults have greater quantity and intensity of healthcare utilization (i.e., higher exposure to malpractice) or because of differences in the quality of care delivered to patients of different ages. The second explanation is that older patients may have a higher propensity to file a malpractice claim if they experience an unexpected care outcome. The third is that older patients may be disproportionately likely to receive a payment, conditional upon filing a malpractice claim.

Our analysis cannot definitively evaluate the respective roles of these three factors, but higher exposure to malpractice due to greater use of medical services seems the most likely explanation. The HCUP data show that the elderly as a group may have greater exposure to adverse events because they have a greater number of hospitalizations, and other research has shown that the elderly are at significantly higher risk of suffering preventable adverse events during hospitalizations than non-elderly patients.¹⁷

With regard to the second potential explanation, higher propensity to claim, other research suggests this dynamic is probably not in play. To the contrary, several well-regarded studies have found that elderly patients are disproportionately less likely to file a claim relating to a malpractice injury.¹⁸⁻²² One possible explanation is that their lower expected damages awards and/or higher comorbidity (which makes proving causation more difficult) made them relatively unattractive clients for plaintiffs’

attorneys. Other contributors may be a lower propensity to recognize that they have suffered an injury due to negligence; an unwillingness to alienate healthcare providers on whom they depend; and a lower tolerance for lengthy litigation.²³

With regard to the third potential explanation, likelihood of recovering damages conditional on filing a claim, we are not aware of evidence suggesting that claims involving older adults are more or less likely than claims involving younger patients (besides infants) to result in a payment. At least one study has found no association between age and the probability of receiving a payment.²⁴

3. Evaluation of Traditional State Reforms

This section synthesizes the literature on the effects of traditional state tort reforms, including caps on noneconomic damages, pretrial screening panels, certificate-of-merit laws, attorney fee limits, joint-and-several liability reform, collateral source rule reform, periodic payment, and shortening of statutes of limitation or statutes of repose. This literature dates back to the mid-1970s, but was thin until the late 1980s and did not really begin to blossom and strengthen in rigor until the early 2000s.

For this 2016 update to our original 2010 report, we incorporate information below on an additional 34 controlled studies that tested the effects of one or more of these tort reforms.

3.1. Caps on Noneconomic Damages

Caps on noneconomic damages limit the amount of money that a plaintiff can take as an award for noneconomic losses, or “pain and suffering,” in a malpractice suit. The rationale for this reform is to reduce the number of very large awards, which are difficult for liability insurers to plan for and pay and which may pose special difficulties for healthcare facilities that are self-insured. It is also motivated by a desire to reduce the high degree of variation²⁵ and perceived arbitrariness in jury awards for “pain and suffering.” About half the states currently impose a cap on noneconomic damages and 6 cap total damages.

3.1.1. Key Design Features and Decisions

Key design choices for noneconomic damages caps include the following:

- **Amount:** Although the oldest and most widely publicized example of a noneconomic damages cap, California’s, is \$250,000, most states have found it politically difficult to implement such a stringent cap in more recent attempts at reform. It is more common for states to set the cap at \$500,000 or more, and to opt for a tiered cap in which different amounts apply to different kinds of injuries. The appeal of a flat cap is its simplicity and, when set at a low amount, greater potential for cost control. The appeal of a tiered cap is its greater vertical equity—that is, more severe injuries are eligible for a higher award.
- **Indexing:** Some states adjust their caps for inflation, while others do not. If California’s cap had been adjusted for inflation, it would be over \$1.1 million today. Indexing maintains the intent of the legislature adopting the cap as to the appropriate valuation of noneconomic damages in real dollars, while declining to index provides greater long-term ability to constrain costs.

- Applicability to claims: Most states apply their cap to all medical malpractice injuries, but some limit it to particular kinds of claims—for example, wrongful death claims or claims relating to emergency department care. A decision to carve out particular types of claims may reflect legislative concern about liability stress within a certain clinical specialty or the potential for unpredictable, large damages awards for certain kinds of injuries.
- Applicability to litigants: A cap may be applied to the plaintiff, limiting the amount he may receive, or to each defendant, limiting the total amount for which each may be liable. The latter choice reflects a particular notion of equity, though it may result in inequitable awards in cases where multiple defendants have different shares of fault for causing the plaintiff's injury.
- Judicial waiver: Caps rules may allow a judge the discretion to waive the damages cap in cases where its application would seem especially unjust. The price of avoiding injustice in this fashion is lesser predictability around damages awards.

3.1.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

The evidence increasingly suggests that noneconomic damages caps are associated with a statistically significant decrease in the frequency of claims, whether the measure used is paid claims or all claim filings. Six studies have returned such findings,^{22,26-31} while two have found no association.^{32,33} Mechanistically, the link is that caps discourage plaintiff's attorneys from filing claims by lowering the expected value of the case, which in a contingent-fee system affects the attorney's expected return on investment.

With limited exceptions, studies of the effects of caps on claims payouts consistently find a significant effect, typically on the order of a 20 to 30 percent reduction in average indemnity payments.^{22,26,27,29,34-42} One simulation analysis of the \$250,000 cap adopted by Texas in 2003 differentiated its effects on payouts from jury verdicts and settlements, finding that the proportional reduction was larger for the former (27 percent average reduction) than the latter (18 percent average reduction).³⁹ A related set of studies has examined caps' effect on total insurer losses, which are a function of both the volume and costs of claims; most models have identified a significant, downward effect.^{43,44} Finally, 3 studies did not find an effect of caps on payouts,^{27,33,45} and one found an effect on claims payments in a regression model that used individual claims as the unit of analysis, but not in a model using states as the observational units.⁴⁵

A null finding is difficult to explain, since the literal effect of caps is to reduce awards. It is typically explained by theorizing that caps change the mix of cases that are brought, such that the reduction in average awards due to the cap is offset by an increase in the average award due to an increase in the average severity of the injuries represented. Another possibility is that caps affect too small a proportion of cases to make a significant difference overall. This is more likely to be the case where the cap is set at a relatively high level, but one study found that even Texas's \$250,000 noneconomic cap would be triggered in just 18% of cases.³⁹ Overall, the weight of evidence strongly favors the conclusion that caps affect payouts.

- Patient Compensation.

One study found that noneconomic caps have no significant effect on the proportion of claimants who recover damages in malpractice cases.⁴¹ Two studies have found that time to settlement decreases after adoption of a noneconomic cap;^{22,40} the effect sizes were quite large, from 28% to 50% for adults, depending on the particular age group and study. The theoretical rationale is that caps reduce uncertainty about what the case is worth, bringing the parties' positions at the bargaining table closer together.

However, the dampening effect of caps on filing rates suggests that caps may make it more difficult for some claimants to access the civil justice system. Caps also have implications for the vertical and horizontal equity of payouts. Vertical equity refers to the extent to which awards increase with the severity of injury, while horizontal equity concerns the degree of homogeneity in awards for injuries of similar severity. Depending on the level at which they are set, and how this level compares to public judgments about appropriate compensation for very severe injuries, caps may undermine vertical equity. They may make awards for the highest-severity injuries the same as awards for less severe injuries.

With respect to horizontal equity, caps are likely to make awards for the highest-severity injuries more uniform—they should fall at or near the cap. However, caps may have a disproportionate effect on the elderly, as discussed below.

- Overhead Costs.

One study has examined the effects of caps on defense costs in malpractice litigation, finding that caps were associated with a significant cost increase.⁴⁶ This is counterintuitive to the dominant theory about the effect of caps, which is that they encourage more rapid settlement by increasing certainty about the value of the case. However, the authors offered an alternative explanation: higher defense costs could reflect a greater propensity among insurers to allow cases to go all the way to trial, since the downside risk of trial is lower in jurisdictions that cap awards.

- Providers' Liability Costs.

The effect of damages caps on malpractice insurance premiums has been the subject of intense controversy. The issue has been exhaustively studied, with mixed findings among well-designed studies.⁴ Here, we focus on controlled studies of the effect on the average premiums paid by physicians. Other studies have examined caps' relationship with the total amount of premium dollars collected by insurers, but these findings are less useful because the total amount depends on both the price of insurance and how many physicians buy insurance.

Five studies have found that caps are associated with a statistically significant decrease in premiums,^{38,47-50} while four older studies found no effect on premiums,^{33,37,45,51} and in one study the significance level varied across models.⁵² A reasonable conclusion based on strong, recent studies is that caps moderately constrain the growth of premiums over time, with producing a difference of 6 to 13 percent, on average, in a given year.² One study found larger effects—17 to 25 percent, depending on the specialty—but did not make an important market-share adjustment to its premium data.⁴⁹

In 2009, the Congressional Budget Office (CBO) estimated the cost of a package of 5 reforms implemented together in all states: a \$250,000 noneconomic damages cap, a punitive damages cap of \$500,000 or twice the economic damages award, collateral-source offsets, a 1-year statute of limitations for adults and 3-year limit for children, and joint-and-several liability reform. Recognizing that many states already have some or all of these reforms in place, the CBO estimated the marginal impact of the package as a 10 percent reduction in total national premiums for malpractice insurance.⁵³

- Healthcare Spending and Defensive Medicine.

There is some evidence that damages caps are associated with reduced defensive medicine behaviors, but studies are diverse in both their measures and their findings. The conventional wisdom has long been that caps effect reductions in utilization of services that are considered to be indicators of defensive medicine, based on a well-known 1996 study by Daniel Kessler and Mark McClellan.⁵⁴ Kessler and McClellan found that states with one or more “direct reforms” (including damages caps, abolition of punitive damages, no mandatory prejudgment interests, and collateral-source rule reform) had significantly lower Medicare hospital payments for ischemic heart disease and myocardial infarction. Although their study did not isolate damages caps from other direct reforms, subsequent work finding little effect of the other direct reforms on other outcome measures gave rise to the inference that caps drove the effect.

The Kessler and McClellan study examined only a narrow set of outcomes, and subsequent studies sought to test the defensive medicine reduction hypothesis using a much broader range of indicators. These indicators have included other services that tend to connote defensive practice (such as cardiac procedures, cesarean section, episiotomies, and low utilization of vaginal birth after cesarean section); general categories of healthcare utilization (inpatient admissions, inpatient days, surgeries, specialist referrals, and outpatient visits); and overall healthcare spending.

Study findings regarding cesarean section—which would be expected to decrease if defensive medicine is reduced—are mixed.² Among the most recent studies, two strong analyses found caps to be predictive of lower rates of cesarean section^{55,56} while two others found no overall differences in these rates across states with and without caps.^{57,58}

Similar diversity is found with regard to other types of utilization. Studies have identified significant decreases in rates of specialist referrals,⁵⁹ episiotomies,⁵⁸ and cardiac procedures for heart attack patients;⁶⁰ and significant reductions in hospital admissions,⁶¹ inpatient days,⁵⁸ and surgeries.⁶¹ Another study found that health insurers paid providers significantly less for some procedures in states with caps than in states without them.⁶² One analysis (albeit one with methodological weaknesses) found a significant relationship between caps and healthcare expenditures per capita, estimating that caps resulted in a 3 to 4 percent savings.⁶³ But other study findings suggest that caps do not lead to reductions in Medicare Part A or overall spending⁶⁴⁻⁶⁶ or outpatient visits.⁶¹ Curiously, one study identified a *positive* association between caps and Medicare Part B spending.⁶⁶

The CBO’s most recent conclusion—now several years old—about the association between tort reforms (including but not limited to damages caps) and the use of healthcare services is that “the weight of the empirical evidence now demonstrates a link.”⁵³ This finding supersedes its earlier conclusion that the evidence of a link between tort reforms and healthcare spending was quite limited and was confined largely to spending in the Medicare program.⁶⁷ Its most recent cost model estimates that nationwide

implementation of the package of 5 reforms listed above would result in a 0.5 percent decrease in total national healthcare expenditures.⁵³ This model did not incorporate estimates from several quite recent analyses of Medicare spending, however.

A reasonable conclusion to draw from this group of studies is that noneconomic damages caps have been shown to be associated with reductions in some, albeit not all, indicators of defensive medicine. The evidence about effects on healthcare spending is too varied to support a strong conclusion.

- Physician Supply / Access to Care.

The weight of a fairly large evidence base suggests that noneconomic damages caps effect statistically significant increases in the supply of physicians in a state—though some evidence suggests the effect may be concentrated among high-risk specialist physicians, rural areas, and/or caps at the most stringent level (around \$250,000).² Among 13 controlled studies, 10 have found significant increases in physician supply in at least some models.⁶⁸⁻⁷⁷ One found a decrease⁷⁸ and 2 found no significant differences.^{79,80} Examining the studies with positive findings, the effect sizes have varied dramatically, but have clustered around 2-5%.

Physician supply is one indicator of access to care; health insurance coverage rates and prices are others. These measures are less studied and conclusions are difficult to draw based on the available evidence. The theory underlying a relationship between caps (and all other liability-limiting tort reforms) and health insurance coverage is that the reforms will decrease defensive medicine, thereby lowering healthcare costs, thereby lowering health insurance premiums, thereby increasing the number of people who can afford insurance. This connection is quite remote, and not substantiated by existing research.⁹ The leading study in this area found that results were quite sensitive to model specification, but in what was arguably the best model (one which controlled for other tort reforms), noneconomic damages caps did not significantly predict health insurance coverage rates overall or among the most price-sensitive groups—the young and single and the self-employed.⁸¹ Two studies have examined the relationship between damages caps and employer-sponsored health insurance premiums. One found no significant association,⁸² while the other found that caps were associated with significantly (1.3 percent) lower premiums for self-insured plans, but no significant differences for fully insured plans, most of which were HMOs.⁸³ One unpublished study found that caps reduced the percentage of state residents under the age of 65 without health insurance, but the study did not control for the presence of other tort reforms.⁸⁴

Overall, the evidence concerning the effects of damages caps on physician supply indicates a positive effect, likely of modest size, while the evidence concerning health insurance coverage and cost is too limited and equivocal to draw a conclusion.

- Quality of Care.

In theory, damages caps and other liability-limiting tort reforms could enhance the quality of care by reducing defensive practices that pose risks to patients, such as invasive procedures. On the other hand, there is greater concern that reducing malpractice liability could undermine tort deterrence—that is, the incentives created by the threat of being sued to take due care in providing medical care. To examine these potential relationships, researchers in a modest body of studies have examined both patients' health outcomes and, more recently, accepted indicators of quality and safety of care.

Health outcomes are a crude measure of quality of care. Mortality, the outcome variable in most health outcomes studies of damages caps, is an extreme outcome that is insensitive to most gradations in the quality and safety of care. Mortality and other health outcomes are also subject to a host of other influences besides the physician's quality of care.

With that caveat in mind, the results of several studies of health outcomes can be examined. Most such studies have not identified a statistically significant relationship between damages caps and health outcomes, whether the outcome studied is mortality,^{64,76} birth outcomes,^{56,85-88} or cardiac care outcomes.⁵⁴ One study found that noneconomic damages caps significantly *decreased* mortality from all accidental causes except motor vehicles,⁸⁹ but little credence can be given to the association given that most of these deaths probably did not relate to medical care. One other study also found a link to lower mortality, this time among persons with coronary heart disease; the effect size was 1.4% and was entirely concentrated among patients aged 45-64.⁶⁰ Finally, one study found damages caps to be associated with higher mortality due to complications of medical care (but not all-cause mortality).⁶¹

Studies using more proximal measures of quality of care—a preferable approach—have returned mixed results concerning the effects of damages caps. One found that noneconomic damages caps are associated with a statistically significant reduction in preventable complications of labor,⁵⁶ while 2 other, more recent studies of the same construct (several AHRQ Patient Safety Indicators in labor and delivery) found no significant association.^{86,87} One of those also found no significant associations with avoidable hospitalizations or cancer screening rates.⁸⁷ There is one, as yet unpublished, study that bucks the trend, having found caps to be significantly associated with an increase in PSI events (i.e., worse safety) for most PSIs studied.⁸⁸

Overall, the evidence base is not sufficient to draw strong inferences about the relationship between caps and quality of care, but most study findings have not found a significant link. The results appear to be sensitive to the particular measure of quality employed, and also to model specification choices.

- Unintended Consequences.

Damages caps likely have the effect of limiting access to compensation for patients whose claims are meritorious but would return insufficient damages to give the plaintiff's attorney a reasonable return on investment in the case. Arguably, such an effect is unintended, although for some reformers the goal of reducing the total number of claims may overshadow concerns about whether the deterred claims are meritorious or frivolous. Although tort reformers hope that cap adoption will reduce liability costs, the primary mechanism through which they are intended to do so is reducing award and settlement size. As we discussed above, mounting evidence suggests that they also do so by deterring claim filings.

Clear-cut cases of harm due to negligence are generally easier to settle than cases with unclear causation or reasonableness of care, making it likely that the effect is more modest for clearly meritorious cases than for cases of uncertain or no merit. Although this is somewhat reassuring, it remains the case that caps' effect on claim filing may also affect many meritorious cases involving small economic damages.

- Differential Impact on Medicare Beneficiaries.

There has long been controversy in the literature about whether noneconomic damages caps disproportionately burden particular population subgroups, most notably women and the elderly, who have relatively low economic damages because of their lower workforce participation. Two studies that analyzed data on jury verdicts concluded that this was not a major concern—one because the percentage reductions in awards did not significantly differ⁹⁰ and one because although plaintiffs 65 years and older had a relatively high proportion of their award reduced by the cap, they had the smallest median dollar reduction of any age groups (because few awards exceeded the cap amount).⁹¹ These studies controverted findings from a methodologically weaker analysis⁹² which did identify disproportionate effects on elderly plaintiffs.

More recent studies have expanded this inquiry beyond jury verdicts, shedding more light on the operation of caps across all paid claims. These studies of the effects of noneconomic damages caps on payouts find unequal effects across age groups, but the findings are inconsistent as to direction. One study of Texas's \$250,000 cap found that deceased, unemployed, and elderly claimants saw the largest proportional reductions in payouts: 19% reductions, on average, for the elderly, compared to 10% for infants, 14% for nonelderly adults, and 21% for children.⁹³ The same group of researchers, in a second study, reported that payouts dropped 10-14% more for elderly than adult nonelderly claimants.²² But another study of Texas found the proportional reduction was marginally *smaller* for the “young” elderly (ages 60-69) than for most younger age groups except 0-2 year olds.⁴⁰ The difference was modest, however: a 23.5% reduction for claimants in their 60s versus about 25% across all age groups.

Our analysis of NPDB PUF data found that the mean and median total awards to claimants aged 70 and up (\$231,723 and \$139,548, respectively) over the study period were below the trigger point for the most stringent damages cap applied by states (\$250,000)—and most states apply that cap only to the noneconomic portion of the award. This is not necessarily inconsistent with a conclusion that caps disproportionately burden the elderly if the burden is measured as the *proportionate* reduction in awards among claimants whose awards are reduced by the caps. But it seems clear that the elderly are not disproportionately burdened in the sense of have a *higher likelihood of having their award reduced* because of caps.

There is reason to believe that the effect of caps on claim filing may be particularly pronounced among the elderly, because their economic damages tend to be lower than those of younger claimants. Substantiating this possibility, one study found that Texas's cap has had a disproportionate effect on paid claim rates involving the elderly.²² The elderly had long been underrepresented in the population of Texas malpractice claimants, controlling for their inpatient healthcare utilization, but leading up to the adoption of the cap in 2003 the ratio of elderly to adult, non-elderly paid claims had been converging. After the cap was adopted, the number of claims per 100,000 elderly population dropped sharply. The percentage drop was similar to that for adult, nonelderly claimants, but had more substantial implications for the elderly if one assumes that otherwise, the previous trend of mounting claim rates would have continued. The researchers pointed out that one bright spot of Texas's cap for the elderly was that it expedited time to settlement by an even greater percentage for them than for adult, nonelderly plaintiffs (41% vs. 28%).

On the defensive medicine front, much of the available evidence comes from analysis of Medicare claims, so there is good information about specific effects on the elderly. Unfortunately, however, the findings do not point in a clear direction. Overall, they suggest that Medicare beneficiaries may receive

fewer hospital services in states with caps than in states without them. Whether this is associated with worse outcomes, however, is controversial—and the available results are not based on data specific to elderly patients.

3.1.3. Summary

There is a large, robust evidence base regarding the effects of damages caps, particularly concerning their effects on claims costs, defensive medicine, and physician supply. The weight of the evidence suggests that caps reduce claims frequency, achieve substantial savings in average claims payments, modestly constrain the growth of malpractice insurance premiums, moderately improve physician supply, and reduce at least some defensive medical practices. Evidence concerning their effects on health insurance and quality of care is too limited or equivocal to support firm conclusions, but does not presently support an association. On some but not all measures, caps disproportionately burden the elderly. They are likely have a particularly large effect on claiming by the elderly, but elderly claimants are less likely to have damages high enough to trigger the cap.

3.2. Pretrial Screening Panels

The function of pretrial screening panels is to review a malpractice case at an early stage and provide an opinion about whether or not the claim has sufficient merit to proceed to trial. Typically, a negative opinion does not bar a case from going forward, but can be introduced by the defendant as evidence at the trial. The rationale for this reform is to reduce the number of nonmeritorious malpractice claims, and the litigation expenses incurred in defending them, by bringing expert judgment to bear before a large amount of legal expenses are incurred. Additionally, panel decisions can provide juries with a neutral source of expertise in cases that go to trial.²⁵ About 20 states currently have pretrial screening panels of some kind. Screening panels have been repealed in at least 7 states and overturned by courts on constitutional grounds in at least another 5.²⁵

The literature regarding the effects of pretrial screening panels is smaller and older than the literature on damages caps. Because few of the early studies identified any significant effects of screening panels, researchers in later studies typically opted to exclude screening panels from the models being tested, in order to make those models simpler. For example, in the past 6 years, only one study has provided useful information about the effects of screening panels.⁴²

3.2.1. Key Design Features and Decisions

Key design choices for pretrial screening panels include the following:

- **Timing of review:** There is some variation across states in the length of time between the filing of a claim and review by the panel. Longer time periods permit the plaintiff a longer period in which to obtain information in support of the claim, but result in higher litigation expenses as the discovery period progresses.
- **Composition of the panel:** All states have included physician representation on the screening panel, but states vary as to whether nonphysicians (for example, judges, lawyers, and laypersons) are represented.

- Matters evaluated: Most screening panels evaluate only the merit of the case, but a handful of states have panels that also suggest a recommended amount of damages for meritorious cases.
- Effect of the decision: Among the alternative consequences of the panel’s decision that a claim is nonmeritorious are (1) the claim is precluded from advancing; (2) the claim can proceed, but evidence of the panel’s decision may be introduced by the defendant at trial; and (3) the claim can proceed, but the plaintiff must post a bond or in some other way provide an up-front payment that is forfeited to the defendant if the plaintiff does not prevail in the litigation.
- Mandatory vs. voluntary: Some states have opted for voluntary rather than mandatory pretrial screening. The rationale for voluntary screening is to create a venue for the parties to get an early, expert opinion about the case, which may encourage settlement or abandonment of the claim.
- Financing: The costs of running the screening panel could be borne by the state or federal government, or could be borne by the parties to litigation through user fees. Some states have adopted a “loser pays” system, in which the party that does not prevail in the lawsuit covers both parties’ legal expenses.
- Discovery powers: In order to ensure that plaintiffs have access to sufficient information to present their case before the panel, some states allow the plaintiff to conduct discovery prior to the panel hearing; some also require that the defendant(s) comply in a timely fashion with discovery requests.

3.2.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Theoretically, screening panels should decrease the number of claims that progress to a mature stage and the number and cost of payouts in nonmeritorious cases. However, there is no evidence that they accomplish these objectives. No controlled studies have identified statistically significant, unconditional effects on claim frequency or average payouts, while 7 have found no association.^{27,33-36,94,95} One study found that screening panels did not independently predict payout amounts, but did show statistically significant interaction effects with damages caps.⁴² Specifically, panels were significantly associated with an *increase* in average payouts in states without damages caps and with a *decrease* in payouts in states that have any type of damages cap. It is not clear why this should be the case.

Some single-state, descriptive studies have actually identified a higher rate of claiming in the years following implementation of screening panels than in the years prior.²⁵ The reasons that claiming is not reduced are unclear. It may be that screening panels simply do not issue an adverse decision in many cases, or it is possible that plaintiff’s attorneys pursue claims notwithstanding adverse panel decisions because they view panels as biased and unreliable.

- Patient Compensation.

Aside from the studies of claims discussed above, research has not examined the effect of screening panels on patients’ timely access to compensation or the equity of payouts. Because screening panels

impose an additional procedural hurdle, their logical effect is to increase the average time to obtaining compensation. It is not known whether they screen out cases that were actually meritorious, or would have been shown to be so had the plaintiff been allowed to proceed and further build his/her case. There is no obvious theoretical relationship between screening panels and vertical or horizontal equity in awards.

- Overhead Costs.

Screening panels involve costs. Even if panel members serve on a volunteer basis, there are overhead expenses for convening panel meetings. In states where full hearings are held, both the panels and the litigants incur additional expenses for preparation, which may include substantial discovery activities. It is unknown whether these extra costs are offset by cost savings associated with (1) the termination of some cases following the panel's decision, or (2) earlier settlements reached after a panel decision indicating the claim likely has merit.

Most expert commentary expresses the view that panels likely increase litigation costs overall.²⁵ Single-state, descriptive studies of screening panels have also reached this conclusion. They have found that although panels decrease the number of claims that go to trial, they cause significant increases in average time to claim resolution.⁹⁶ Two multivariate studies of the issue have been conducted. One found that mandatory pretrial screening was associated with a significant reduction in defense costs.⁴⁶ The other, which had methodological limitations, found that defense costs and the time from incident to resolution of a malpractice claim did not differ in states that had no screening panels, optional panels, or mandatory panels.⁹⁴ Overall, the evidence concerning insurers' defense costs is inconclusive, though it is fairly clear that screening panels involve administrative costs to run.

- Providers' Liability Costs.

Three studies have examined the relationship between screening panels and malpractice insurance premiums. One study found a significant, beneficial effect,⁵¹ while the others (one of which was methodologically stronger³³ and one of which was weaker⁹⁴) did not. Overall, there is not a strong basis for concluding that premiums are affected. Theoretically, one would not expect a strong effect, since the effects on claiming and litigation expenses appear to be weak or adverse.

- Healthcare Spending and Defensive Medicine.

The effect of screening panels on defensive medicine or healthcare spending has not been extensively investigated. Theoretically, the relationship seems remote. Only if physicians believed screening panels were an effective bulwark against nonmeritorious claims would an effect on defensive medicine be plausible. One study found that states with pretrial screening panels had significantly lower rates of cesarean section and higher rates of vaginal birth after cesarean section, suggesting that physicians may indeed perceive the panels as protective.⁵⁵

- Physician Supply / Access to Care.

No information is available regarding the effect of screening panels on physician supply. The relationship would seem to be very remote. An effect would only be seen if physicians believed strongly enough in screening panels to migrate to states that had them, which seems implausible in light of the

prevalence of screening panels and continued high levels of malpractice fear among physicians in most states.

- Quality of Care.

No information is available regarding the effect of screening panels on quality of care, although one unpublished study found no effect on any of six birth outcomes.⁸⁵ There is no theoretical reason to believe a relationship exists.

- Unintended Consequences.

Although it has not been studied, in theory, screening panels could have the unintended effect of identifying “false positives”—that is, screening out cases that, in fact, have merit. Particularly when conducted at a very early stage in the litigation, screening panel reviews may not be fully informed. Possibly, cases screened out might have been proven to have merit if the plaintiff had been permitted to further build the case.

- Differential Impact on Medicare Beneficiaries.

There is no reason, either empirical or theoretical, to believe that screening panels have a differential impact on the elderly.

3.2.3. Summary

A handful of well-designed studies have examined the effects of pretrial screening panels, and the weight of the evidence suggests that they are not effective in reducing claim frequency, claims costs, or malpractice insurance premiums. They may help reduce defensive medicine. The evidence concerning their effects on defense costs, physician supply, health insurance premiums, and quality of care is too limited or equivocal to support conclusions about those relationships. Panels involve their own administrative costs.

3.3. Certificate of Merit

Certificate of merit (COM) reforms require the plaintiff in a malpractice suit to present, at the time of filing the claim or soon thereafter, an affidavit certifying that a qualified medical expert believes that there is a reasonable and meritorious cause for the suit. Like pretrial screening panels, the rationale for COM requirements is to reduce the number of nonmeritorious malpractice claims and associated expenses by bringing expert judgment to bear early in the litigation.²⁵ At least 11 states have adopted COM requirements, but Washington State’s COM law was struck down on constitutional grounds.⁹⁷

Like the literature regarding the effects of pretrial screening panels, the body of work on COM reforms is smaller and older than the literature on damages caps. They have been included in only one study published in the past 6 years.²⁹

3.3.1. Key Design Features and Decisions

Key design decisions for COM reforms include the following:

- Time to filing of certificate: State laws vary in the time allowed to file the COM, with some requiring simultaneous filing with the initial complaint and others allowing a few weeks or months.
- Definition of qualified expert: Some state statutes specify requirements concerning who may serve as an expert witness for purposes of a COM—for example, a requirement that the individual must spend most of his or her professional time practicing or teaching medicine, a maximum amount of time that may be spent on expert witness work, a requirement that the expert be certified in the same specialty as the defendant, or a requirement that the expert be licensed in the state in which the claim is filed.
- Nature of the affidavit: An affidavit sworn by the expert could be required, or it could be acceptable for the plaintiff's attorney to sign an affidavit attesting that he or she has obtained an expert's opinion that there is reasonable cause for filing the complaint. For expert affidavits, varying levels of substantive detail could be required, from a simple statement that the expert has reviewed the medical record and found there to be evidence of substandard care to a detailed opinion concerning the deviation from the standard of care and how it led to the plaintiff's injury.
- Nature of the attestation: At the outset of litigation, many facts concerning the plaintiff's care may be unclear. For this reason, some states have required experts to attest only that the plaintiff has a reasonable cause to file the claim, or that a reasonable investigation gave the plaintiff a good faith belief that grounds exist to file the claim. Others, however, require the expert to state that after conducting a review, they conclude that the standard of care was not met.⁹⁸ This may be difficult to do early in the litigation when discovery has not yet been completed and some facts are unclear.²⁵
- Exceptions: Statutes may be drafted to carve out an exception for *res ipsa loquitur* claims—claims relating to injuries that ordinarily would not have occurred in the absence of a deviation from the standard of care (for example, wrong-site surgery). Arguably, an expert witness affidavit is not necessary to establish that such claims have sufficient merit to proceed. However, whether a particular injury constitutes a *res ipsa* claim may be unclear. Another issue is whether to create an exception or extension for plaintiffs in cases where the defendant has failed to produce the relevant medical records in a timely fashion, since this would hinder the plaintiff from obtaining expert review of the case.⁹⁸ An alternative mechanism for addressing this problem is to include in the statute a requirement that defendants promptly comply with plaintiff's requests for document production during the period between the filing of the complaint and the filing of the affidavit. This approach may help address conflicts between COM requirements and state constitutional provisions guaranteeing access to courts.⁹⁷
- Consequences of failure to comply: In some states, where a plaintiff has not met all of the requirements of the COM statute, the case is dismissed with prejudice (meaning that the plaintiff cannot re-file the complaint). Other states allow a plaintiff to correct technical

deficiencies in the affidavit of merit as long as the plaintiff is substantially in compliance with the COM requirement. Still others impose sanctions on the plaintiff's attorney for noncompliance.

3.3.2. Effects on Key Outcome Variables

Somewhat curiously, studies of state tort reforms have generally omitted COM statutes from their analyses.²⁵ Evidence concerning the effects of COM is extremely limited.

- Claims Frequency and Costs.

Only one study has isolated the effect of COM requirements on claim frequency or payouts. That well-designed study found that the reform was not associated with significant differences in the number of paid claims per 1000 physicians or payment amounts among "large" claims (those paid \$50,000 or more). This may be explained by the possibility that the law does not actually change existing practice. Some experts have made the observation that experienced plaintiff's attorneys routinely obtain an expert opinion before agreeing to invest in bringing a case, calling into question the marginal value of a COM requirement.²⁵

Because COM requirements are often implemented as part of a package of several tort reforms, single-state studies that have found large reductions in the number of claims filed after implementation of reforms^{99,100} do not permit inference about the specific effect of the COM law.

- Patient Compensation.

Aside from the studies of claims discussed above, research has not examined the effect of COM requirements on patients' timely access to compensation or the equity of payouts. In theory, obtaining a COM might lengthen the time plaintiffs must wait to receive compensation. Whether COM requirements serve as a barrier to bringing meritorious cases has not been empirically explored, but it seems unlikely. Finding an expert willing to vouch that such cases pass the low bar for proceeding should not be difficult. With regard to equity in payouts, there is no clear theoretical relationship between COM requirements and vertical or horizontal equity.

- Overhead Costs.

COM requirements increase litigation costs for plaintiffs. Obtaining the affidavits entails direct costs for plaintiff's attorneys that are estimated at \$1,000-\$5,000.¹⁰¹ In some states, COM requirements have led to additional legal expenses when the defendant has challenged whether the plaintiff's expert meets the statutory requirements.¹⁰¹ Such wrangling is more likely to occur when the statutory language concerning expert witness qualifications is vague or subject to interpretation.

- Providers' Liability Costs.

No information is available regarding the effect of COM requirements on malpractice insurance premiums. The effect would be determined by the effect on claims frequency and cost. The theoretical prospects for reductions in premiums are not strong.

- Healthcare Spending and Defensive Medicine.

No information is available regarding the effect of COM requirements on defensive medicine or healthcare spending. There is no theoretical reason to believe there would be a significant effect, since COM requirements do not appear to impose a substantial barrier to bringing malpractice claims. Reforms can affect defensive medicine if physicians perceive them as protective, even if they are in fact ineffective. However, there is no literature to suggest that physicians believe COM requirements provide strong protection. Physicians tend to believe that expert witnesses are widely available to provide whatever testimony plaintiff's attorneys seek.

- Physician Supply / Access to Care.

No information is available regarding the effect of COM requirements on physician supply. The connection would seem to be quite remote.

- Quality of Care.

No information is available regarding the effect of COM requirements on quality of care. There is no theoretical reason to believe there would be a significant effect. One study of birth outcomes found no significant association between COM requirements and infant mortality.⁷⁶

- Unintended Consequences.

Like screening panels, COM requirements might result in the "wrong" cases being shunted out of the civil justice system. Anecdotally, plaintiff's attorneys complain that COM statutes with heavy sanctions for noncompliance are used to defeat meritorious complaints. They assert that defendants allege some technical noncompliance with the requirement that results in the plaintiff's claim being dismissed.¹⁰² This assertion has not been substantiated, however.

- Differential Impact on Medicare Beneficiaries.

There is no reason, either empirical or theoretical, to believe that screening panels have a differential impact on the elderly.

3.3.3. Summary

Only one methodologically strong study has examined the effects of COM requirements and did not find an effect on the number of paid claims or payment amounts on large claims. On their face, COM requirements add a modest amount to the cost of litigation. Theoretically, the prospects for affecting the key outcome variables appear quite weak.

3.4. Attorney Fee Limits

Attorney fee limits cap the amount of a malpractice award that a plaintiff's attorney may take as a contingency fee. Nearly all medical malpractice cases are handled by plaintiff's attorneys on a contingent-fee basis, meaning that the attorney takes a percentage of any award the plaintiff receives

(legal expenses may be rolled into this percentage, or taken in addition to it), but the attorney receives nothing if no award is recovered. The rationale for attorney fee limits is to discourage plaintiff's attorneys from accepting cases of marginal or no merit by altering the attorney's expected return on investment in the case. Nineteen states currently have limits on attorney fees in medical malpractice cases.

The evidence base regarding the effects of attorney fee limits is fairly substantial. However, although there is a relatively large group of older studies examining the effects of the reform on claims frequency and costs, only 3 studies published in the past 6 years have included attorney fee limits explicitly in their regression models.^{41,42,73} Studies have not separated out fee limits of different types or at different levels.

3.4.1. Key Design Features and Decisions

Key design choices for attorney fee limits include the following:

- Nature of the limitation: Fee limits are typically expressed as a percentage of the award, but may also incorporate a maximum dollar value.
- Flat or sliding structure: A single limit may be applied, or some states have opted for a sliding structure that permits attorneys to take a larger share of smaller awards and a smaller share of bigger awards.
- Treatment of legal expenses: The fee limit may be specified to include all fees and expenses that a lawyer would charge, or may apply only to the attorney's fees. In the latter case, expenses such as expert witness payments, deposition expenses, and document filing fees could still be charged against a client's award.

3.4.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Theoretically, attorney fee limits should reduce the number of malpractice claims by dissuading plaintiff attorneys from accepting cases that have a low expected return on investment. This could affect both nonmeritorious and meritorious cases, because the expected value of a case to an attorney is a function of not only the probability of prevailing, but also the expected damages and the attorney's share of the damages.

Contrary to theory, there is considerable evidence that attorney fee limits do not affect claiming. Several multivariate studies have shown that attorney fee limits are not associated with either lower frequency of claims^{27,33} or differences in average payouts.^{27,33-37,42} Only one study found that attorney fee limits significantly *increase* average payout per paid claim, as well as the proportion of claims with a payment.⁴¹ The effect sizes identified in that study were rather implausibly large. The authors speculated that a reason for their counterintuitive finding could be that attorneys may be more selective about the cases they bring, resulting in a higher average award.

- Patient Compensation.

Studies have not explored other aspects of the effects of attorney fee limits on patient compensation, such as equity of awards or time to compensation. In theory, they could disproportionately affect access to justice for patients with low damages.

- Overhead Costs.

Theoretically, one may expect plaintiff attorneys to invest less time and resources in cases if their share of the proceeds is reduced. However, since lower investment also increases the risk of losing the case and recovering nothing, the theoretical relationship is unclear. Only one study has investigated this issue; it found that attorney fee limits were associated with a significant increase in average defense costs, possibly because attorneys were less inclined to bring small cases.⁴⁶

- Providers' Liability Costs.

There is strong evidence that attorney fee limits do not affect malpractice insurance premiums. Two well-designed studies^{33,48} and two methodologically weaker studies^{37,51} have reached this conclusion, while no studies have found a significant association. The theoretical relationship to malpractice premiums is quite remote, and is mediated by the effect on claim frequency and payouts.

- Healthcare Spending and Defensive Medicine.

The theoretical relationship between fee limits and defensive medicine or healthcare spending is tenuous at best, but has not been extensively investigated. The CBO's 2006 model found no significant effect on either general or Medicare healthcare spending.⁶⁷ One study found no relationship with rates of cesarean section or vaginal birth after cesarean section.⁵⁵ On the other hand, one study found limited evidence that implementation of one or more "indirect" reforms (attorney fee limits, periodic payment, joint-and-several liability reform, or patient compensation fund) reduced Medicare payments for patients hospitalized for myocardial infarction, breast cancer, diabetes, or stroke.⁶⁴ However, the study's authors expressed concern that the result might be spurious. Overall, the existing evidence does not support a relationship between fee limits and defensive medicine or healthcare spending.

- Physician Supply / Access to Care.

Four multivariate studies directly examined the relationship between attorney fee limits and physician supply;^{73,76,80,103} three of these found no relationship.^{76,80,103} The fourth found that the reform was *negatively* associated with physician supply, a finding the authors attributed to possible endogeneity (in other words, states that were already losing physicians may have been more likely to have adopted attorney fee reform, making the direction of causality difficult to discern).⁷³ Finally, one study examined whether states that adopted one or more of 5 "indirect" reforms (attorney fee limits, periodic payment, joint-and-several liability reform, statute of limitations reform, or patient compensation funds) experienced different levels of growth in physician supply over time and found that they did not.⁷⁰ There is no strong theoretical relationship between the two.

- Quality of Care.

No studies have directly examined the effects of attorney fee limits on quality of care. There is no clear theoretical relationship between the two. One study found no relationship between “indirect” reforms, including fee limits, and 1-year mortality among Medicare patients,⁶⁴ and two others found no association between attorney fee limits and birth outcomes.^{76,85} Overall, the limited evidence available does not support an inference that attorney fee limits affect quality of care or patient outcomes.

- Unintended Consequences.

Unintended consequences are not a particular concern for attorney fee limits. Their intended effect is to discourage the bringing of malpractice claims, so although this may result in particular forms of unfairness, it cannot be said that such effects are unanticipated.

- Differential Impact on Medicare Beneficiaries.

No study has documented disproportionate effects of attorney fee limits on Medicare beneficiaries. Theoretically, they may have a disproportionate effect on the ability of elderly claimants to file lawsuits because those claimants are likely to have lower expected damages awards than younger claimants.

3.4.3. Summary

Several well-designed studies have evaluated the effects of attorney fee limits and have fairly consistently found no effect on claim frequency, claims payouts, malpractice insurance premiums, or physician supply. The limited available evidence concerning defensive medicine and quality of care suggest that fee limits have no effect on these variables.

3.5. Joint-and-Severall Liability Reform

At common law, when an award was made against more than one defendant, each defendant would individually be fully liable (“jointly and severally liable”) for paying the amount of the award in the event that the others did not pay, even if the defendant bore only a small share of the causal responsibility for the plaintiff’s injury. For example, suppose two physicians were each found liable for malpractice damages totaling \$10 million. Dr. A was judged 90% responsible and Dr. B 10% responsible. However, Dr. A was insured for only \$1 million and had no assets that could be used to satisfy the judgment against him. At common law, the plaintiff could seek to collect the remaining \$9 million from Dr. B, even though B’s “fair share” was only \$1 million. Forty states have adopted statutes modifying this common law rule to limit the financial liability of each defendant to the percentage fault that the jury allocates to that defendant.¹⁰⁴ The rationale for this reform is to eliminate the unfairness involved in joint-and-severall liability for “deep pockets” defendants (e.g., hospitals).

The evidence base concerning the effects of joint-and-severall liability reform is fairly large. Because early studies often found this reform to achieve statistical significance in models, it has often been included as a separate variable in later studies. In the last 6 years, a dozen studies have examined the effect of this reform.

3.5.1. Key Design Features and Decisions

The key design decisions for joint-and-several liability reform include the following:

- Applicability to types of damages: Joint-and-several liability can be abolished for all components of a plaintiff's award, or only for the noneconomic damages portion of the award.
- Relationship to comparative negligence: Joint-and-several liability can be abolished in all instances, or it can be maintained when a defendant's percentage share of the responsibility for an injury exceeds a certain threshold (typically 50 percent).¹⁰⁵
- Relationship to private contractual arrangements: Two or more parties who reasonably anticipate that they may be named as joint defendants in malpractice litigation—for example, a hospital and a physician who has staff privileges at the hospital—may choose to specify in a contract how liability will be allocated between or among them. Joint-and-several liability reforms can be designed to respect these contracts or to supersede them.

3.5.2. Key Design Features and Decisions

- Claims Frequency and Costs.

The theoretical link between joint-and-several liability reform and claim frequency is highly tenuous. If many defendants were expected to default on their judgments, then the expected value of malpractice claims would be lower and plaintiff's attorneys would be discouraged from bringing them.⁶⁷ There would need to be a widespread belief that defendants commonly had insufficient resources to cover judgments in order for this to occur, however.

Three studies have examined whether joint-and-several liability reform results in fewer claims. One found a significant reduction in per-capita claims frequency,²⁶ while the others found no significant association.^{27,29} Overall, the evidence on this point is limited and inconclusive.

Joint-and-several liability reform theoretically should result in lower total claims payments, since "deep pocket" defendants are no longer required to pay the damages owed by insolvent co-defendants. Six multivariate studies have examined the relationship between joint-and-several liability reform and claims payouts.^{26,27,29,37,41,45} Five found no significant association^{26,27,29,37,45} while one identified a significant reduction in average payouts per paid claim.⁴¹ That study also found that the proportion of claims that received a payment was lower in states with joint-and-several liability reform, although it is not clear why this should be the case.

In a related vein, a well-designed study found that over both 5-year and 10-year analysis periods, insurer losses were higher in states with joint-and-several liability reform.⁴³

Overall, the evidence is weighted towards the conclusion that joint-and-several liability reform does not significantly affect claims costs in the aggregate.

- Patient Compensation.

Theoretically, joint-and-several liability reform could reduce patients' access to compensation by creating a situation in which plaintiffs cannot recover a portion of their award from an insolvent or underinsured defendant. However, the above-referenced studies point to the conclusion that total payouts do not significantly decrease, on average. Joint-and-several reform has no apparent implications for the timeliness of compensation or equity in awards.

- Overhead Costs.

There is no clear theoretical link between joint-and-several liability reform and litigation expenses. One study has examined this relationship and found no significant association between the reform and defense costs.⁴⁶

- Providers' Liability Costs.

The effect of joint-and-several liability reform on malpractice insurance premiums has been studied by several research teams, with mixed results. Two strong studies^{43,48} and one weaker study⁴⁹ found no relationship to insurance premiums, while 3 studies with somewhat weaker methodologies found a significant association with lower premiums.^{37,45,47}

Theoretically, the link between the reform and premiums is largely mediated by the reform's effect on claims costs, so the positive findings regarding premiums are difficult to explain. It has also been postulated that the reform could cause some physicians' insurance premiums to increase, if the effect of the reform was to decrease hospitals' share of liability in multi-defendant cases. However, there is no evidence to support or refute this thesis.⁶⁷ Overall, the weight of the evidence (particularly the evidence from more recent studies) slightly favors the conclusion that joint-and-several liability reform does not significantly affect insurance premiums.

- Healthcare Spending and Defensive Medicine.

The effects of joint-and-several liability reform on defensive medicine have been investigated in several studies. The strongest theoretical possibility is that elimination of joint-and-several liability would increase defensive practices by physicians, because the effect of the reform is to increase physicians' liability relative to that of hospitals. Hospitals typically serve as the "deep pockets" defendants in cases involving both physician and hospital defendants, and eliminating joint-and-several liability removes the possibility that physicians' share of the award could be picked up by hospitals.⁵⁶ A CBO analysis lends support to this thesis, finding that joint-and-several liability reform was associated with an increase in general and Medicare healthcare spending per capita, as well as hospital spending per capita.⁶⁷

However, other studies have not reached the same conclusion. Some have found no relationship to healthcare expenditures per capita⁶³ or hospitalization rates,⁶¹ while others found the reform to be associated with *lower* spending for 4 diagnoses in Medicare patients⁶⁴ and *reduced* outpatient visits and surgeries.⁶¹

In terms of utilization of particular medical procedures that indicate defensive practice, it is notable that two rigorous studies reached opposite conclusions as to whether joint-and-several liability reform led to decreased use of cesarean section.^{55,56} In summary, the evidence on the relationship to healthcare spending and defensive medicine is equivocal.

- Physician Supply / Access to Care.

Theoretically, there is no clear link between joint-and-several liability reform and physician supply. Consonant with theory, most of the 7 multivariate studies that have examined the effects of joint-and-several liability reform on physician supply have produced null findings. One found that states that adopted one or more of 5 “indirect” reforms, including joint-and-several liability reform, experienced levels of growth in physician supply over time no different from states that did not.⁷⁰ Four more recent studies that modeled joint-and-several liability separately from other reforms found no significant effect on physician supply.^{72,74,76,80} In contrast, 2 recent studies did find a statistically significant decrease in the probability that a physician moved out of state⁷⁵ and an increase in overall physician supply.⁷³ Overall, the evidence weighs in favor of a conclusion that there is no empirical relationship.

Results concerning the effect of joint-and-several liability reform on health insurance coverage and cost are limited and complex. Two studies have been conducted by the same group of well-regarded researchers. One examined employer-sponsored health insurance premiums and found that joint-and-several liability reform was associated with significantly (1.4 percent) lower premiums for self-insured plans, but no significant differences for fully insured plans.⁸³ The second examined health insurance coverage rates. It found that results were quite sensitive to model specification, but in arguably the best model, joint-and-several liability reform did not significantly predict coverage rates overall, but did significantly increase the coverage rate among a particularly price-sensitive group, the “young and single”.⁸¹ Overall, this evidence base is too limited to support a conclusion that joint-and-several liability reform improves access to health insurance.

- Quality of Care.

There is no strong theoretical link between joint-and-several liability reform and quality of care. The weight of the evidence finds no association, although study findings are not uniform.

The most useful studies examine direct quality measures. Two studies have found evidence linking joint-and-several liability reform to a lower rate of preventable complications of labor,^{56,86} but one found no significant relationship with complications of delivery or maternal trauma rates.⁸⁷ That study also found no relationship to rates of avoidable hospitalizations across a range of clinical areas or to cancer screening rates.⁸⁷

Studies of birth outcomes (such as infants’ Apgar score, likelihood of low birthweight, likelihood of preterm birth, likelihood of birth injury, or infant or maternal mortality) have not found any relationship to joint-and-several liability reform.^{56,76,85,86} Studies examining all-cause accidental mortality⁸⁹, 1-year mortality among hospitalized Medicare patients,⁶⁴ or mortality during non-obstetrical inpatient care⁸⁷ also have not identified significant associations.

- Unintended Consequences.

A potential unintended consequence of joint-and-several liability reform is to discourage attorneys from bringing meritorious claims. The scenario that raises such concerns is that the defendant with the largest apparent share of responsibility for the harm event is believed to be insolvent, underinsured, or protected by a statutory cap on damages. With joint-and-several liability, the attorney would anticipate recovering that defendant's share from co-defendant(s). Without it, the damages—and the attorney—will be underpaid. This is a highly foreseeable consequence of limiting joint-and-several liability, but because the motivation for the reform is to prevent the unfairness associated with sticking one defendant with a disproportionate share of the damages, not to reduce total payouts, it could be considered an unintended consequence.

- Differential Impact on Medicare Beneficiaries.

There is no theoretical or empirical basis for believing that joint-and-several liability reform has a differential effect on the elderly.

3.5.3. Summary

There is a large evidence base regarding the effects of joint-and-several liability reform. Although research findings are somewhat mixed, on balance, the evidence suggests that it has no significant effect on claims costs, providers' liability insurance premiums, physician supply/access to care, or quality of care. The evidence concerning the effects on defensive medicine/healthcare spending, litigation costs, and health insurance coverage is equivocal.

3.6. Collateral-Source Rule Reform

At common law, a jury is not permitted to consider evidence that a plaintiff received compensation for his injury from other sources, such as health or disability insurance, when making a decision about how much to award in damages. Thirty-four states have modified this "collateral-source rule" so that any amounts received from other sources are deducted from the amount that a defendant who is found liable for that injury must pay. The rationale for this reform is to eliminate the unfairness and expense of this perceived double recovery to the plaintiff.

Collateral-source rule reforms interact with provisions in insurance contracts (and rules of the Medicare program), known as subrogation clauses, that permit insurers to recoup money they pay in connection with an injury to an insured person if the insured collects damages from a liable third party.¹⁰⁶ In effect, such provisions already prevent double recoveries. However, subrogation rights are not always exercised (indeed, they may rarely be exercised) because of the associated administrative costs.

Like joint-and-several liability reform, collateral-source rule reform was found to have significant effects in some of the early studies of tort reforms. Consequently, it has often been retained as a separate variable in the more recent studies, creating a fairly large evidence base for gauging its effects. In the last 6 years, 13 studies have examined various impacts of collateral-source rule reform.

3.6.1. Key Design Features and Decisions

The key design decisions for collateral-source rule reforms include the following:

- Types of collateral sources covered: Modifications to collateral-source rules could apply to all collateral sources, or only to a specified set of sources. For example, the reform could apply offsets to health insurance but not life insurance.
- Relationship to subrogation rights: Some states have made their collateral-source rule reforms inapplicable to sources that are entitled to a subrogation right. Some courts have interpreted the subrogation rights in the federal statutes governing Medicare and Medicaid to override conflicting state law.¹⁰⁵
- Mandatory or discretionary: The reform can be implemented by automatically reducing a plaintiff's award or by allowing defendants to introduce evidence of collateral sources at trial, allowing the trier of fact discretion to decide whether and how to adjust the award.¹⁰⁵

3.6.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

The theoretical case for a link between collateral-source rule reform and claims frequency is hard to make. The most plausible argument would be that the lower expected award amounts when the offset is eliminated might discourage some plaintiff's attorneys from proceeding with the case.

Five multivariate studies have modeled the relationship between collateral-source offset rule reform and claims frequency.^{26,27,29,33,35} The mixed findings do not, overall, support a conclusion that a significant association exists. The oldest study found a significant, negative association, as theory might predict;³⁵ three found no significant association;^{26,27,33} and one found that the reform *increased* the number of claims per thousand physicians in some but not all models.²⁹

Theoretically, collateral-source offsets should substantially reduce average award size because the literal effect is to deduct money from the plaintiff's damages. However, somewhat curiously, most studies do not support this notion. Eight multivariate studies have examined the association between collateral-source offset rule reform and claims payments or insurer losses.^{26,27,29,34-36,41,43} Two studies found a significant, negative effect,^{34,35} while the other 6 found no association^{26,27,29,36,41,43} (in one,⁴³ that finding was limited to the first 5 years after the reform became effective; there were longer-term savings on insurer losses).

- Patient Compensation.

Apart from the potential effects described above, collateral-source rule reform should not affect patients' access to timely or equitable compensation. However, effects on time to disposition and vertical and horizontal equity have not been studied. One study found no significant association with the proportion of claims receiving a payment.⁴¹

- Overhead Costs.

One study has examined the effects of collateral-source rule reform on defense costs and concluded that there is no significant association between the two.⁴⁶ The only theoretical link is that defendants may incur extra expenses investigating collateral sources.

- Providers' Liability Costs.

Theoretically, to the extent that collateral-source offsets decrease claims payments, insurers should pass along their savings to their insureds in the form of lower premiums. Overall, the evidence suggests that this effect is weak or nonexistent. Seven multivariate studies have examined the association between collateral-source rule reform and malpractice insurance premiums.^{33,37,43,47-49,51} Five did not identify a statistical association on average.^{33,37,47,48,51} One found a significant, negative effect on premiums for some insurance companies but not others.⁴³ Another study with a notable methodological limitation found a significant effect for mandatory collateral-source offsets but not for laws that merely allow the jury to consider evidence of collateral sources.⁴⁹

- Healthcare Spending and Defensive Medicine.

There is no plausible theoretical link between collateral-source offsets and defensive medicine or healthcare spending. Three studies found no significant effect on healthcare spending,^{63,64,67} and another found no significant association with rates of hospitalization, surgeries, or outpatient visits.⁶¹ Other work found no relationship to rates of cesarean section, induction or stimulation of labor, vaginal birth after cesarean section, episiotomies, or inpatient days following delivery of a baby.^{55,56,58}

- Physician Supply / Access to Care.

Seven studies have directly measured whether collateral-source rule reform is associated with higher physician supply, and all found no association.^{72-75,80,82,83} Another study found that states that had adopted collateral-source offsets and/or 3 other "direct" reforms had 3 percent higher growth in physician supply over time,⁷⁰ but the individual effects of the various reforms cannot be ascertained on the basis of this analysis. The theoretical association is not apparent, because physicians are unlikely to perceive the protection of the offsets as substantial enough to justify a decision to practice in a particular state. Overall, the evidence suggests there is no relationship between collateral-source rule reform and physician supply.

Does collateral-source rule reform increase the affordability of health insurance? The theoretical relationship is tenuous. Subrogation rights allow health insurers to recoup from healthcare providers the amounts they paid in medical expenses for patients injured by malpractice, which could result in lower health insurance premiums. However, these rights may be exercisable whether or not the plaintiff's award was offset for the collateral source.

The limited available evidence does not provide much evidence that collateral-source reform boosts insurance coverage rates or prices. One unpublished study with important methodological limitations found no significant association with the prevalence of health insurance coverage among under-65-year-olds.⁸⁴ Another study with stronger methods found that collateral-source rule reforms were significantly associated with lower health insurance premiums for self-insured plans, but not for fully insured plans.⁸³

A third study conducted by those same researchers found that in what is arguably the best-specified model, collateral-source rule reform did not significantly predict health insurance coverage rates either in the entire population or among price-sensitive subpopulations (the “young and single” and the self-employed).⁸¹

- Quality of Care.

There is no plausible theoretical link between collateral-source rule reform and quality of care, because this is simply not a reform that physicians are likely to feel provides them with a strong deterrent signal. Eight studies, discussed below, have ventured into the quality-of-care arena, and a reasonable inference to draw from them as a group is that evidence of an association has not been established.

With regard to the more direct measures of quality of care, one well-done study found no significant associations with complications of labor and delivery, maternal trauma, avoidable hospitalizations across a range of clinical areas, or cancer screening rates.⁸⁷ The results of a second study of four Patient Safety Indicators (PSIs) related to labor and delivery are difficult to draw conclusions from, but the most reasonable interpretation is that no association was found. In that study, collateral-source rule reform significantly elevated rates of all 4 PSIs in *hospital*-level models, but not in *patient*-level models; and the coefficients were no longer statistically significant once corrections for multiple comparisons were made.⁸⁶ Finally, two other studies found no relationship to rates of preventable complications of labor or infant health or mortality.^{56,85}

Looking next at studies of more distal patient outcomes, findings are mixed and difficult to interpret. One study found no association between adoption of one or more “direct” reforms, including collateral-source offsets, and 1-year outcomes for Medicare patients hospitalized for myocardial infarction, breast cancer, diabetes, or stroke.⁶⁴ The specific effect of collateral-source rule reform cannot be disentangled from the effects of the other direct reforms, such as damages caps. Among studies of the relationship between collateral-source rule reform and mortality, one found a *reduction* in infant mortality,⁷⁶ two found *increases* in mortality for delivering mothers⁸⁶ and for accidental deaths other than vehicle crashes⁸⁹; and one found no relationship to inpatient mortality for selected non-obstetrical events such as myocardial infarction.⁸⁷ The notion that collateral-source rule reform could affect care so much that patients live or die in greater numbers strains plausibility; although most of these studies used solid methods, the associations between collateral-source rule reform and mortality could be spurious.

- Unintended Consequences.

Collateral-source rule reform does not raise theoretical concerns about unintended consequences, nor does existing research establish any such concerns.

- Differential Impact on Medicare Beneficiaries.

Medical expenses are likely to constitute a greater share of damages awards for Medicare beneficiaries than for younger plaintiffs, because elderly plaintiffs are much less likely to have substantial lost wages and may receive a lower amount in noneconomic damages due to their shorter lifespans. In this sense, a rule deducting already-paid medical expenses from plaintiffs’ awards can be expected to have a disproportionately large effect on Medicare beneficiaries.

3.6.3. Summary

The evidence base concerning collateral-source rule reform is fairly strong, though more so for some outcome measures than others. On balance, the evidence suggests that the reform does not significantly affect claims frequency, claims payouts, liability insurance premiums, defensive medicine/healthcare spending, physician supply, health insurance coverage rates, or quality of care. Evidence concerning effects on litigation costs is too limited to support a conclusion.

3.7. Periodic Payment

Periodic payment allows or requires insurers to pay out malpractice awards over an extended period of time, rather than in a lump sum. This enables insurers to purchase annuities (sometimes called “structured settlements”) from other insurance companies that cost less than paying the entire award up front. Insurers are also able to retain any amounts that the plaintiff does not actually collect during his or her lifespan. The rationale for this reform is to smooth out an insurer’s expenses over time and to permit the purchase of annuities. Thirty-one states currently permit or require periodic payment.

The evidence base regarding the effects of periodic payment is of moderate size. In the last 6 years, 4 studies have examined its effects, adding to a small group of older studies.

3.7.1. Key Design Features and Decisions

The key design decision for periodic payment is whether to make it mandatory in all cases, mandatory in cases involving damages over a certain amount, or simply available at the request of either of the parties.

3.7.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

There is no theoretical reason to believe that periodic payment would affect either the number of claims filed or the average amounts awarded. They do not affect the valuation of a case, only the means through which the award is paid out. Four studies have examined the effect on claim frequency; one found a significant reduction,²⁷ while the others found no effect.^{26,29,34} Six studies have examined the effects of periodic payment on claims payments; 5 found no significant effect,^{27,29,34,36,37} while one found a significant reduction.²⁶ Overall, the evidence base is small but suggests that periodic payment does not result in a significant reduction in the number or cost of claims.

- Patient Compensation.

Studies have not explored other aspects of the effects of periodic payment on patient compensation, such as equity of awards or access to justice. There is no obvious theoretical connection.

- Overhead Costs.

No information is available regarding the effects of periodic payment on overhead costs. In theory, periodic payment could increase insurers' administrative expenses (e.g., search and transaction costs for annuities; tracking periodic payments over time) or decrease these expenses (e.g., by smoothing out shocks due to large awards that may make reinsurance more expensive or difficult to find).

- Providers' Liability Costs.

Theoretically, periodic payment should result in modest savings to insurers due to the availability of annuities. Whether they pass along these savings in the form of lower liability insurance premiums is, however, another matter. Only 2 studies have examined this issue; one found no significant association between periodic payment and premiums³⁷ and in the other, the results varied across medical specialties.⁴⁹ Overall, the evidence concerning this effect is limited and equivocal.

- Healthcare Spending and Defensive Medicine.

Very limited information is available regarding the effects of periodic payment on defensive medicine. There is no plausible theoretical nexus between the two. One study found no significant relationship between periodic payment and rates of cesarean section or vaginal birth after cesarean section.⁵⁵ Another found that implementation of one or more "indirect" reforms, including periodic payment, was associated with lower spending for 4 diagnoses for Medicare patients, but the authors were skeptical of the finding.⁶⁴ Overall, the evidence is too limited and equivocal to support a firm conclusion about the effect on defensive medicine.

- Physician Supply / Access to Care.

The theoretical relationship between periodic payment and physician supply is tenuous at best. There is no reason to think physician location decisions would be influenced by a reform that affects only insurers directly and has no demonstrated effects on physician insurance premiums. This is borne out by the empirical literature. Five studies have examined periodic payment in isolation from other reforms, and all found no significant association with physician supply.^{73,75,76,80,103} Another study that lumped 5 indirect reforms, including periodic payment, together also found no significant effect on physician supply.⁷⁰

- Quality of Care.

No studies have directly measured the effects of periodic payment on quality of care. There is no plausible theoretical nexus between the two. One study examined the relationship to 1-year mortality among Medicare patients; in most models, the association was not significant.⁶⁴ A second study also found no effect on mortality, this time examining deaths due to all accidental causes except motor vehicles (a broad measure that is highly unlikely to be sensitive to malpractice reforms).⁸⁹ The only other pertinent study, an unpublished work, examined 6 birth outcomes and found no significant relationship to periodic payment reforms.⁸⁵

- Unintended Consequences.

Periodic payment does not raise major concerns about unintended consequences. It does disadvantage claimants who incur substantial debt due to their injuries and need an immediate, large influx of funds to pay off the debt. That problem has not, however, been empirically studied.

- Differential Impact on Medicare Beneficiaries.

Although no studies have examined particular effects of periodic payment on Medicare beneficiaries, it this reform may differentially affect the elderly. Elderly persons who perceive their remaining lifespan as short and/or have low savings may prefer to receive their entire award up front. On the other hand, it could be argued that younger plaintiffs would have an even stronger preference for receiving a lump sum payment because they can reap returns from investing that money over a longer period of time (i.e., a longer lifespan).

3.7.3. Summary

The effects of periodic payment have not been extensively studied. The limited evidence available suggests that it has no beneficial effects on claims frequency, claims payments, physician supply, or patient care outcomes. The evidence is too limited to draw conclusions about the effect on overhead costs, defensive medicine, or direct measures of quality of care. The evidence concerning liability insurance costs and defensive medicine is limited and/or equivocal.

3.8. Statutes of Limitations/Repose

This reform aims to restrict the amount of time a patient has to file a malpractice claim. Statutes of limitations bar suits unless they are filed within a specified time after the injury is discovered or should reasonably have been discovered by the patient. Statutes of repose are more stringent, specifying that the time limit runs from the date of injury regardless of when the injury is discovered or should reasonably have been discovered. All states have adopted statutes of limitation or repose for medical malpractice claims, though they vary in length and triggering event. Statutes of limitations typically are set at 2 or 3 years, and statutes of repose at 3 to 4 years.

The primary rationale for this reform in the context of malpractice claims is to shorten the long “tail” associated with such claims—that is, the long time between the incident date and the date the insurer learns what its liability for the incident will be. The tail problem is believed to be one of the factors driving insurer mistakes in pricing malpractice insurance. Many insurers are thought to have underestimated their liability in the 1990s, not realizing what lay in their tail, which led to price shocks in the early 2000s. A second rationale for statutes of limitation and repose is to avoid the difficulties of litigating claims when the evidence has grown stale (for example, when people’s recollections of an event have faded over time).

The group of studies examining the effects of reforms to statutes of limitation/repose is small, and has not grown in the past 6 years.

3.8.1. Key Design Features and Decisions

Key design decisions for this type of reform include the following:

- Discovery rule: Statutes of repose are quite stringent because the time period for filing the claim begins to run from the date of injury, regardless of when the patient discovered (or reasonably could have discovered) the injury. Some types of malpractice injuries, such as missed diagnoses of cancer, may not become known for several years. An alternative is to set the statute of limitations to run from the date of discovery (or the date that a reasonable person would have recognized the injury).
- Length of period: In setting the length of time to file, the competing considerations are, on the one hand, allowing a reasonable period of time for an injured plaintiff or grieving family to obtain legal representation and assemble the information needed to support a claim, and on the other, providing reasonable protection for healthcare providers against claims relating to incidents that have faded from the recollection of the involved parties.
- Applicability to minors: States typically apply a special rule to minors, allowing the statute to run only after they have reached the age of majority, but the alternative is to put the onus on the minor's parents to file within a specified period of time from the date of injury or discovery of the injury.

3.8.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

In theory, shorter statutes of limitation/repose should reduce the number of malpractice claims by barring suit by plaintiffs who wait too long to file. Multivariate studies that have examined the association between statutes of limitation/repose and claim frequency have returned mixed findings. Two well-designed studies found a significant effect,^{33,35} while two strong studies did not.^{27,34} Overall, the evidence concerning claim frequency is too equivocal to ground firm conclusions.

Statutes of limitation/repose should not affect average claim payments, and all studies of this issue but one³⁴ confirm this theoretical prediction.^{27,33,36,37}

- Patient Compensation.

From a patient compensation perspective, shorter statutes of limitation are concerning in that they limit access to the civil justice system. Statutes of repose raise even greater fairness concerns, since patients may not be aware they have an injury that may be due to malpractice for some time. The weak evidence that these reforms reduce the number of claims somewhat undercuts these concerns, but they have not been studied.

- Overhead Costs.

Theoretically, shorter statutes of limitation/repose could decrease liability insurers' operating expenses by improving their ability to predict their long-term losses, thereby facilitating accurate decisions about

reserving, investment, and reinsurance practices. However, the one study to examine this issue found no significant relationship between the reform and defense costs.⁴⁶

- Providers' Liability Costs.

Four studies have looked at the relationship between statutes of limitation/repose and malpractice insurance premiums.^{33,37,49,51} In theory, shorter statutes should decrease insurers' losses and the degree of unpredictability around their long-term liability, both of which could translate into lower premiums for physicians and hospitals. The study with the strongest methodology found a significant effect on premiums,³³ but 2 other studies did not.^{37,51} The remaining study found a significant association for some clinical specialties but not others.⁴⁹ Overall, study findings are mixed, but the evidence weighs slightly in favor of a conclusion that premiums are reduced.

- Healthcare Spending and Defensive Medicine.

Very limited information is available regarding the effects of shorter statutes of limitations/repose on defensive medicine or healthcare spending. The theoretical connection between the two is tenuous at best. One recent study found no effect on rates of cesarean section or vaginal birth after cesarean section.⁵⁵

- Physician Supply / Access to Care.

Only one study has examined the effect of shorter statutes of limitations/repose on physician supply, though it did not isolate that effect from the effects of other reforms. It found that the change in physician supply in a state over time was not significantly affected by the state having adopted one or more of the 5 "indirect" reforms.⁷⁰ There is no plausible theoretical nexus between statutes of limitations and physician supply.

- Quality of Care.

No information is available regarding the effects of shorter statutes of limitations/repose on quality of care. There is no plausible theoretical nexus between the two. The only relevant study is an unpublished study finding no relationship between this reform and any of 6 birth outcomes.⁸⁵

- Unintended Consequences.

This reform does not raise major concerns in terms of unintended consequences.

- Differential Impact on Medicare Beneficiaries.

Although it has not been studied, there is no theoretical reason to expect that shorter statutes of limitation/repose disproportionately burden the elderly.

3.8.3. Summary

The evidence base concerning statutes of limitation/repose is of fair size and strength. The weight of the evidence suggests that this reform does not significantly affect claims payouts, but (somewhat counterintuitively, given the null effect on claims costs) may be associated with lower liability insurance premiums. Very limited evidence hints at no effect on defensive medicine or physician supply. The evidence concerning the reform's effect on claim frequency is equivocal. The evidence concerning overhead costs and quality of care is too limited to ground firm conclusions.

4. Evaluation of Innovative Reforms

This section synthesizes the literature on the effects of innovative reforms—reforms that are relatively new in use, or have limited or no implementation, in the U.S. The reforms reviewed here include: health courts (both the medical court and administrative models), communication-and-resolution programs (sometimes termed disclosure, apology, and offer programs), safe harbors for adherence to evidence-based practice guidelines, mandatory pre-suit notification laws, apology laws, state-facilitated alternate dispute resolution, and judge-directed negotiation. Due to either limited implementation or limited time in use of these reforms, the literature assessing their effects is scant compared to that evaluating the traditional reforms. For the 2016 update to our original 2010 report, we incorporate information below on an additional 42 published papers and reports discussing the effects or potential effects of one or more of these innovative reforms.

4.1. Health Courts

The use of “health courts” for medical injury has been proposed frequently over the last 40 years.¹⁰⁷⁻¹²³ Proposals for such systems vary along several features, but most fit into one of two general models. In one model, often described as a *medical court*, a jury is replaced with a specially (in most proposals, medically) trained judge to adjudicate the negligence determination. Most of the other features of the present tort process are kept without much change. In the second, *administrative model*, an administrative body (such as a state agency) investigates and adjudicates claims for medical injury. Both models would replace the current jury system with a more efficient process, but variations in their approaches could translate to different effects.

Most health court proposals today adopt the administrative model. The two models are reviewed separately below, with a greater focus on the administrative model. Though there is a small amount of evidence on the adoption of administrative models handling a narrow set of injuries in the U.S., neither model has enjoyed broad implementation in the U.S. We confine our review to literature assessing health court models for injuries that would ordinarily be handled as medical malpractice claims.

4.1.1. Medical Court Model

The medical “health court” model is a much smaller departure from the present tort system than the administrative model. In the medical court model, the primary change is the replacement of the lay judge and fact finder (either a judge or jury) with a judge and fact finder with both medical and legal training. In some medical court models, the court could seek opinions from its own specialized neutral experts on a case-by-case basis. Other variations are possible, such as changing the compensation standard, but most medical court proposals keep the remainder of the tort process intact.

The medical court model is rooted in the notion that better equipped judges and fact finders would make quicker and more accurate decisions. The objective is not necessarily to improve patients' access to compensation, but rather to improve the efficiency and accuracy with which the claims are adjudicated. The medical court model differs from judge-directed negotiation in that it preserves the jury's and judge's roles as fact finders and adjudicators. But like judge-directed negotiation, it calls for judges to take a formal, activist role in encouraging dialogue and settlement.

4.1.1.1. Key Design Features and Decisions

Due to the relative small departure from the tort system, the key design decisions for medical courts are relatively limited, and include the following:

- Adjudicators and fact finders: The adjudicator will likely be a physician-judge. The design will need to include how these judges will be selected and assisted in using the best available evidence to yield accurate decisions.
- Compensation standard: Medical court proposals usually do not change the compensation standard from negligence. However, broader standards could be employed, including those that do not require proof of provider negligence or fault. The options and rationale for broader compensation standards—which are more frequently proposed with administrative models—are discussed below in the administrative model section.

4.1.1.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

Based on current evidence, it is difficult to determine what effect a medical court model would have on claims frequency. If the medical court model gives the impression that claims with less merit are less likely to be successful, there may be a reduction in the number of claims seen. However, if it appears that more accurate adjudication of claims will lead to greater claims success rates, more claims may result. As discussed above, screening panels and certificates of merit, which also strive to improve the accuracy of adjudication through application of expertise, have not been demonstrated to significantly affect claim frequency. On balance, though, a medical court model that retains a negligence standard and requires an attorney for filing is unlikely to affect claim frequency.

It is unclear what would happen to the average award in a medical court model, as it would depend on what type of guidance judges or juries were given on damages and the extent to which damages were limited by design. Overall, a medical court model's costs are hard to predict without making assumptions about its rules around damages.

In summary, total claims are likely to remain the same in a medical court model. The average award will depend upon what damage limits, if any, are set, but is otherwise likely to remain the same.

- Patient Compensation.

Based on one frequently-cited study of malpractice claims, the claims success rate may not change much.¹²⁴ This study found that approximately 60 percent of all claims contain medical error. Approximately equal proportions (about 25 percent) of claims containing medical error and claims not containing medical error are resolved discordantly with their merit (i.e., errors are unpaid and non-errors are paid).¹²⁴ A more accurate system of adjudication would theoretically reduce the number of claims incorrectly paid, but this may be more than offset by greater number of claims that would now receive payment.

- Overhead Costs.

Medical court models are designed to streamline the adjudication process through the use of neutral fact finders with medical expertise. This change can reduce the overhead costs currently used to educate juries and hire experts. However, no firm conclusions can be drawn from the available evidence.

- Providers' Liability Costs.

Providers' liability costs will depend upon the total claims paid, average award, overhead costs, and whether any savings in these variables are passed along by liability insurance companies to providers. As discussed above, the effects on claims frequency and compensation amounts are unclear, as they depend on the particular design features of the medical court. There is no particular reason to believe there would be savings in overhead costs.

- Healthcare Spending and Defensive Medicine.

To the extent that a medical health court creates a perception that claims will be adjudicated correctly and assuages fears that "non-defensive" medicine is legally risky, defensive medicine may decline.^{54,64,125,126} Many other model features such as financing of the system and provider reporting requirement can also be adjusted to reduce defensive behavior. However, it is unclear how a medical court model (using a negligence standard and not changing the current provider reporting requirements) would change perceptions unless it was able to disseminate information on the accuracy of its judgments. Physicians may, however, be reassured by the knowledge that claims will be evaluated by another physician.

- Physician Supply/Access to Care.

A medical court model, if it can help reduce liability insurance costs and non-meritorious claims, may decrease physicians' likelihood of leaving practice or restricting their scope of practice. As discussed above, some evidence concerning traditional tort reforms supports a link between reduced liability pressure and increased physician supply. However, with respect to medical courts, it is unclear what will happen to liability costs and how financing of the model would be undertaken. To the extent that a medical court model could be designed to reduce overhead and liability costs, a small increase in physician supply may occur.

- Quality of Care.

To the extent that medical courts would decrease defensive medicine or improve access to treatment (physician supply), quality of care may be improved, but there is not enough evidence to draw conclusions about whether that would happen.

- Unintended Consequences.

The primary unintended consequence that could result from the medical court model is that medically-trained adjudicators might exhibit bias in favor of physicians and healthcare facilities. For all the problems with adjudication by lay juries, many legal scholars favor them over expert adjudicators because the latter may be subject to conscious or unconscious bias and influence by industry.

- Differential Impact on Medicare Beneficiaries.

Because medical courts would still require plaintiffs to hire attorneys to bring claims, Medicare beneficiaries are not likely to experience any special benefits arising from improved access to justice—nor are other differential impacts on the elderly anticipated.

4.1.2. Administrative Model

In the administrative “health court” model, compensation decisions are no longer made in court, but rather by an administrative agency. This agency would act as a neutral fact finder and adjudicator so that the process would not be slowed down by an adversarial fact finding process. Decisions could theoretically be rendered more cost-effectively because neither attorneys nor experts to represent each point of view would be required. Because filing a claim should be easier, administrative models could have the additional benefit of increasing the number of patients with access to the compensation system. To further boost access to compensation, most administrative models call for the use of a compensation standard broader than negligence, such as “avoidability” (explained below).

Because no comprehensive administrative systems for medical injury have been launched in the United States, little direct evidence exists regarding the effects of administrative compensation system models on the key outcome variables evaluated in this report. However, some analysis regarding key design features and outcomes is possible based on the limited administrative systems operating in the U.S., foreign experience with administrative models, and research on the effects of other tort reforms.^{110,111,123,127-130} Administrative systems in the United States include Florida’s Birth-Related Neurological Injury Compensation Plan and Virginia’s Birth-Related Neurological Injury Compensation Program, both of which aim to provide compensation for birth-related injuries.^{127,129,130} In addition, the U.S. National Vaccine Injury Compensation Program has been operating since 1998 to compensate for vaccine-related injuries.^{110,128} Scandinavian nations (notably Denmark and Sweden) and New Zealand have also operated administrative compensation models since the 1970s when their nations began to abandon their negligence-based system for medical injury driven in part by a desire to improve compensation for patients while allaying physician dissatisfaction with system.^{111,123}

4.1.2.1. Key Design Features and Decisions

The key design decisions for the administrative model include the following:

- Exclusivity of remedy: In the design of any administrative compensation system, one of the first questions that must be answered is whether the system will be patients' only legal remedy for malpractice, or whether claimants can opt to pursue their claims through the administrative system or the courts. Although the administrative system should be attractive to claimants due to the ease with which a claim can be filed, some claimants may prefer the tort system—for example, because it is more likely to lead to a larger award or because juries are perceived as fairer or more sympathetic than judges.^{114,116}

Any exclusive system must be designed to pass constitutional muster. The United States Constitution and state constitutions guarantee several rights that bear on the constitutionality of health courts, including due process, the right of access to courts, and the right to a jury trial.^{110,115,129-131} A detailed constitutional analysis is beyond the scope of this report, but has been conducted elsewhere.^{115,129,130} Other exclusive administrative systems, such as workers' compensation systems, the National Vaccine Injury Compensation Program, and the state birth-injury compensation funds, have been successfully designed and implemented while withstanding constitutional challenges.^{115,132-134}

A voluntary design avoids these constitutional difficulties for the most part, but has other disadvantages. Due process rights would still require a mechanism for informing patients about their options and eliciting informed consent for participation, ideally before they are ill and in need of care. Laws in some states may prohibit such pre-injury agreements.^{118,130} A significant loss of cost-control potential arises from possible selection effects if claimants are permitted to choose the system (administrative vs. tort) that best serves their needs. Claimants with higher-value claims may disproportionately select into the tort system, resulting in lost opportunities to curb very high-cost awards through an administrative process. Such an approach perpetuates the current inefficiencies of the tort system and essentially creates two tracks for compensation, leading to greater complexity.^{114,116,122}

- Appeals rights: Whether or not use of the administrative system is mandatory, the system will need to address parties' rights to appeal unfavorable decisions.^{115,130} Claimants may wish to appeal findings that no compensation is warranted or findings as to the appropriate amount of compensation. Providers may also wish to appeal the adjudicator's findings, particularly if an adverse decision results in an unwelcome consequence for the provider, such as a report to the National Practitioner Data Bank. Appeal rights may be structured to provide direct appeal to judicial courts or judicial appeal only after an intermediate, administrative appeal. The standard of appellate review can be specified at various levels ranging from *de novo* review (a fresh look at the evidence, with no deference given to the initial tribunal's decision) to an "arbitrary and capricious" standard (the initial adjudicator's decision will only be overturned if it appears to be totally arbitrary).
- Types of claims: An administrative system will also need to specify what types of claims it will handle. A system may opt to process all claims for medical injury. It may also just hear a subset of them, for example: injuries representing certain types of harm (e.g., neurological injuries to newborns); injuries resulting from specific causes (e.g. medication-related injuries); or injuries of a certain severity level (e.g., only injuries that have resulted in 5 days or more of lost work time). Examples of medical injury compensation systems that cover specific injuries include Florida's Birth Related Neurological Injury Compensation Plan and Virginia's Birth-Related Neurological

Injury Compensation Program.^{114,129,130} A compensation system that covers harm based on the cause of injury is the National Vaccine Injury Compensation Program.¹²⁸ The Swedish and Danish administrative systems provide an example of systems that apply severity thresholds; in Sweden, claims must be valued above approximately USD\$275 to be eligible for compensation, and in Denmark, approximately USD\$1500.^{111,135,136}

One potential benefit of defining a subset of claims for administrative system jurisdiction is the creation of a more predictable set of claims to adjudicate. However, the potential impact on system-wide costs, access to compensation, and other variables is obviously smaller the narrower the set of included claims is. Additionally, legal wrangling may arise over whether a particular claim meets the defined categories for jurisdiction.

- Filing method: In the current tort system, plaintiffs may file suits without an attorney, but navigating the litigation process is daunting enough that most claimants need an attorney. Administrative systems can be designed to be navigable without an attorney.^{111,112} The complexity of the model—whether administrative or medical court model—and the particular claim will determine the likelihood that an attorney will be needed.

Removing the need for an attorney carries the potential to make filing easier, particularly for claimants whose claims may be too small to interest attorneys working on a contingent-fee basis. On the other hand, it would be expected to result in the filing of more claims, possibly including a greater number of noncompensable claims.

- Compensation standard: Administrative models generally propose to replace the negligence standard with broader standards that do not require proof of provider negligence or fault. Among the options are an *avoidability* standard (compensating all injuries that ordinarily should not occur in the hands of the best practitioner or an optimal system of care) or a *no-fault* or strict liability standard (compensating all injuries attributable to medical management, except for some known, frequent, or unavoidable complications). For example, an injury to a ureter during an uncomplicated hysterectomy (without any evidence of error the chart) may not be deemed negligent because it can sometimes happen in the hands of a reasonable provider, but under a “best practitioner” standard, it would be deemed to be avoidable because it would generally not occur in the hands of the best practitioner.¹¹¹ A *no-fault* standard is broader than an *avoidability* standard in that it would provide compensation in cases of unexpected or rare complications that may not meet an *avoidability* standard. For example, a *no-fault* standard would compensate a patient who suffers a severe and unexpected adverse reaction to a properly prescribed and administered medication; under an *avoidability* standard, this injury would not be compensable because it would have happened in the hands of the best specialist.

Relevant considerations in selecting a compensation standard include patient access to compensation, operational feasibility, alignment with principles and practices in patient safety, and administrative and liability costs. A broader standard (e.g., avoidability) may not only bring compensation to a greater number of patients, but also improve system efficiency because it is more easily adjudicated than negligence.^{111,113,137} In addition, an avoidability standard may also better match the concept of preventable harm that dominates the patient safety movement (i.e., provide compensation for injuries which, although not the result of unreasonable actions, are still avoidable or preventable).^{111,113,137} An even broader standard, such as no-fault, would be even easier to administer.¹¹¹ A no-fault standard would not compensate all injuries caused by

medical care, only those that are not “necessary and ordinary to” medical care (e.g., the loss of hair due to chemotherapy would not be compensable but a post-surgical infection would be).¹¹¹ A no-fault standard would, however, be more expensive, because a greater proportion of claims would be paid. It also would not align as well with patient safety principles that focus on preventability of harm.

To bring further efficiency, accuracy, and consistency around application of a compensation standard, some commentators have recommended that consideration be given to creating “accelerated-compensation events” (ACEs) which are automatically or presumptively eligible for compensation on a “fast track” because a group of experts has judged them to be almost always negligent or avoidable.¹³⁸⁻¹⁴⁰ Retained foreign bodies from surgical operations are an example of a potential ACE.

- Adjudicators: For the medical court model, the adjudicator will likely be a physician-judge. In the administrative model, the options include a judge who specializes in malpractice cases, a physician-judge, and (at lower levels of decision making) an administrative claims manager (with or without a background in law or healthcare) with expert physician support. Administrative models, such as those in New Zealand and Scandinavia, tend to rely heavily on administrative claims managers with only limited review by other adjudicators.¹¹¹ The design of both models will need to include how adjudicators will be assisted in using the best available evidence to yield accurate decisions and how precedent will be recorded, consulted, and followed to promote consistency in decision-making. Some proposals suggest that adjudicators be assisted by both neutral experts and decision guidelines developed in advance by a group of experts covering considerations relevant to commonly seen injuries.¹¹²
- Award types and amounts: Except in states that have adopted statutory limits, the tort system does not set limits on the damages (economic, noneconomic, and punitive) that juries and judges may award. The design of an administrative compensation system will need to include whether or not limits on damages (economic, noneconomic, or punitive) will be applied. One option is to adhere to any existing damages caps but impose no other restrictions. Another is to strike the existing caps and allow the adjudicator full discretion, but this may pose cost-control problems. A third option is to create a schedule of noneconomic damages and award full or close to full economic damages.
- Financing: If a new paradigm for compensation will be used, financing options will need to be considered. Virginia’s Birth-Related Neurological Injury Compensation Program is funded by physician and hospital fees as well as assessments on liability insurance companies and non-participating physicians.¹⁴¹ Florida’s Birth-Related Neurological Injury Compensation Plan is funded by a combination of state funds, participating physician fees, hospital assessments.¹⁴² Maintaining the status quo (liability insurance or self-insurance model) is an option, but may encounter some resistance from the insurance community if a broader compensation standard is used or filing made easier (due to uncertainty of total compensation payouts). Other financing options include a tax on medical care, a tax on providers, or a general financing mechanism. A combination is also possible. Private insurers could continue to provide primary-layer insurance but the government could step in to provide reinsurance or other stop-loss protection.

- Potential links to quality and patient safety improvement: The current tort system is not designed to systematically capture and catalog the adverse events represented in claims.^{112,137,143} If such data were collected, a database to promote patient safety could be developed. An administrative compensation system could be designed to do so.^{112,137,143,144} The more claims that flow through the system, the more useful the database would become. In this sense, a more liberal compensation process and simple filing procedure would, by encouraging claims filings, support greater learning about medical errors and how to prevent them. A linkage to patient safety would directly foster achievement of one of the laudable goals of our current tort system: to help reduce future injury.
- Relationships to provider reporting and discipline: Currently, if a plaintiff files a claim against a physician, the physician must report these claims on state licensing applications and renewals and to credentialing committees and insurance companies. In addition, if a claim is paid on behalf of a physician, the payment must be reported to the NPDB. Separate Board of Medicine disciplinary investigations may be requested or launched on a claim-by-claim basis. A new administrative system would need to determine how to comply with existing reporting requirements or how they should be modified. This would be of particular importance if a compensation standard broader than negligence is selected because many reporting mechanisms are predicated on the notion that malpractice payments are indicative of negligence.
- Level of jurisdiction: The current tort system operates primarily at the state level. Whether or not the administrative system will operate at the state or federal level would need to be determined. A federal system would create greater uniformity and a greater potential pool of claims for patient safety analysis, but likely would be challenging to win support for, as it would disrupt long-settled presumptions about the primacy of state law for medical malpractice disputes.

4.1.2.2. Effects on Key Outcome Variables

- Claims Frequency and Costs.

One of the main goals of an administrative model is to make the process of filing and adjudicating claims easier. More claims are the logical result of a system that involves decreased transaction costs for claimants. Altering the compensation standard to be more favorable to claimants should also increase the number of claims filed by increasing the expected value of the claim, relative to the difficult-to-prove standard of negligence. Foreign systems that have adopted administrative models (with broader standards than negligence) see higher claiming rates per population.¹¹¹ Estimates of claims per million persons per year are 200 in the U.S.; 1000 in Sweden and Denmark; and 750 in New Zealand.¹¹¹

The average award will depend on the whether and how compensation award limits are set. However, because of attorney representation is not necessary, many smaller claims can be anticipated. Thus, it is very likely that claim frequency will rise and the average award will shrink. One study utilized malpractice claims in Utah and Colorado (for the year 1992) to model costs based on an avoidability standard (and also applied some disability thresholds, caps to pain and suffering, and some reasonable limits on allowable benefits, as the administrative compensation systems in Sweden and Denmark do).^{113,122} The authors found that the number of compensated events would rise, but that total costs

would remain approximately the same in Utah (approximately \$55 million) and drop in Colorado (from \$100 million to \$82). The savings were due to lower average awards and overhead costs. Overall, weighing the changes in all three factors—a larger number of claims, a greater proportion of successful claims, and smaller average awards—the total liability costs are somewhat uncertain, but could be neutral if design choices similar to those made in the Nordic countries were made.

In summary, total claims are likely to rise in the administrative model. The average award will depend upon what damage limits, if any, are set, but is likely to decline.

- Patient Compensation.

The claims success rate is likely not to change much if the standard is maintained at negligence (similar to medical courts), but will increase if a broader standard (such as avoidability or no-fault) is used. Claim success rates in administrative models are greater in Scandinavia (approximately 40%) which use an avoidability standard and New Zealand (as high as 60%) which uses a no fault standard. In one analysis, Florida's Birth Related Neurological Injury Compensation Plan was reported to have a claim success rate of approximately 36% and Virginia's Birth-Related Neurological Injury Compensation Program of approximately 70%, but both had relatively small caseloads of 636 and 192, respectively.¹²⁷

Ease and access to compensation can be expected to improve with administrative systems that do not require an attorney and have a broader compensation standard; time to compensation in Sweden and Denmark (avoidability standard) is approximately 7-8 months for most claims and on average 16 days in New Zealand (no fault standard).¹¹¹

- Overhead Costs.

Administrative models are designed to help lower overhead costs by reducing the adversarial nature of the adjudication, making use of neutral experts and decision guidelines, and reducing the need for attorney involvement. These alterations result in streamlined compensation determinations. Data from the Florida, Virginia, and foreign systems have shown a lower administrative cost structure compared to tort.^{111,114,116,123,124,127,128,145,146} Current overhead cost estimates are as follows: U.S. tort system, 40%; Florida and Virginia's birth-related injury systems, about 8-10%; Sweden and Denmark, 15-20%, New Zealand, 10%.^{123,124,128,146}

For both models though, the overall effect on overhead costs can depend on how often the courts are utilized for appeal.¹⁴⁷ With proper system design, contribution of appeals to overhead costs could be minimized. Appeals rates in the foreign administrative systems (Sweden, Denmark, and New Zealand) have been about 18-20%.¹¹¹

- Providers' Liability Costs.

The liability costs that a provider will experience will depend on the choice of system financing. If the present financing system is retained (liability insurance), provider insurance costs will be a function of total claims costs, but as noted above, these are unclear. However, if a different method of financing, such as a general tax on medical care or on providers or a general public levy, the liability costs providers experience could drop substantially.

- Healthcare Spending and Defensive Medicine.

To the extent that the administrative model, like the medical court model, creates a perception that claims will be adjudicated correctly and assuages fears that “non-defensive” medicine is legally risky, defensive medicine may decline.^{54,64,125,126} Many other model features such as financing of the system and provider-reporting requirements (e.g., whether claims must be reported to the NPDB) can also be adjusted to reduce defensive behavior.

The increased number of claims and claims success rate (if using a broader standard) could lead to increased defensive medicine. However, the use of an alternative compensation standard that does not carry the stigma of negligence could reduce the reputational and psychological costs of being sued, potentially enervating the propensity to practice defensively. Additionally, the use of decision guidelines could reduce defensive medicine by sending a clearer signal to providers about the legal standard of care. A recent analysis of OECD countries concluded that countries that had patient compensation systems that delinked the patient compensation and deterrence functions (i.e., a finding of compensability does not lead to disciplinary action or investigation against a physician) experienced a reduction in per-capita healthcare expenditures of 0.11%.¹⁴⁸

- Physician Supply/Access to Care.

As with the medical court model, to the extent that an administrative compensation model decreases physicians’ liability insurance premiums or liability risk, it could decrease their propensity to leave practice or restrict their scope of practice. However, if financing of liability costs is kept as is, and liability costs increase, physician supply could be adversely affected. Overall, changes in supply with an administrative model are not possible to predict.

- Quality of Care.

To the extent that administrative compensation systems would decrease defensive medicine or improve access to treatment (physician supply), quality of care may be improved. However, as noted above, the likely effects of administrative systems on defensive medicine and physician supply are hard to predict. Nevertheless, administrative compensation models hold promise for improving quality of care by providing the infrastructure for patient safety improvement (e.g., a database of medical injuries and their contributing factors). Precedent for the systematic use of claims to improve safety exists, as seen in the Anesthesia Closed Claims Project in the United States and the foreign administrative compensation systems.^{111,144,149} For example, the foreign systems have started cataloging claims into electronic databases so that they can analyze them for patient safety related issues.^{111,144,149,150} They have also created feedback mechanisms to healthcare institutions.

- Unintended Consequences.

Concerns about bias have also been raised in relation to administrative models; critics worry that the agency that adjudicates claims will become unduly influenced by the healthcare and insurance industries. Another concern sometimes raised in discussions of the model in the U.S. is that adopting a compensation standard that is less stringent than negligence will result in a ballooning of the number of claims, and thus, costs.

The experiences of foreign systems have not borne out these concerns. However, it is possible that claiming rates would be higher in the U.S., given its more meager social insurance programs. Whether this qualifies as an *unintended* consequence is arguable, however; one of the objectives of the system is to improve access to compensation for patients. It is only the ballooning of costs that is truly unintended, but that can be controlled by adjusting the amount of compensation that claimants may recover (for example, limiting noneconomic damages).

- Differential Impact on Medicare Beneficiaries.

Medicare beneficiaries may experience particular benefit from administrative compensation systems because such systems are more accessible to claimants who have been unable to find attorney representation. Finding an attorney can be especially difficult for Medicare beneficiaries because of their relatively low expected damages awards.

4.1.3. Summary

Proposals for “health courts” come in two general varieties: a medical court model in which specially trained judges fact find and adjudicate claims, and an administrative model that replaces the courts with an administrative agency. Both models seek to reduce the high overhead costs associated with the tort system and generate more accurate, consistent decisions. Both can also be designed to improve access to compensation by using a broader compensation standard, but most recent proposals for broader standards relate to the administrative model. An administrative model also offers the added advantage of easing the claiming process for patients, and the resultant disadvantage (from a cost-control perspective) of increasing claim frequency.

Very little actual experience on either type of health court model for medical injury in the United States exists, making it impossible to draw any firm conclusions on outcomes. However, for the administrative model, it is possible to learn from administrative compensation systems for vaccine injuries, birth injuries, and workplace injuries, as well as from other nations that have switched from negligence-based tort to administrative systems. Collectively, these systems demonstrate that an administrative model can reduce overhead cost and may boost quality and safety improvement efforts. The number of new claims remains unknown, but is likely to grow under an administrative model that uses a standard broader than negligence. Some modeling has predicted that total costs in an administrative compensation system may remain unchanged or slightly decline as compared to the negligence based tort system. Total costs, nevertheless, will vary based on the compensation standard and award limits (if any). Effects on defensive medicine, healthcare spending, and quality of care are likely to be positive, while effects on insurance premiums and physician supply are difficult to predict. Unanticipated consequences are not expected to be significant. Medicare beneficiaries may benefit from administrative systems more than the average claimant because any system that is accessible without attorney representation is useful for claimants, such as the elderly, with low expected damages awards.

4.2. Communication and Resolution Programs (CRPs)

CRPs support and guide clinicians in discussing unanticipated outcomes of care (and how they happened) with patients and families and in taking quick steps toward resolving the matter, including making offers of compensation when warranted. CRPs were initially termed “disclosure and offer” or “disclosure, apology, and offer” programs based on the most prominent features of these programs,

disclosing errors to patients and families and offering financial compensation for negligent injuries. As these programs and our knowledge of them has evolved, the preferred terms to describe these programs has moved from “disclosure” to “communication” because these programs promote communication in all unanticipated outcomes (not just errors) and from to “offer” to “resolution” due to the recognition that most cases will not involve an offer of compensation as part of the resolution process because they do not involve harm caused by error.

Presently, CRPs are operated by only a limited number of hospitals, health systems, and liability insurers.¹⁵¹⁻¹⁵⁴ The goals of CRPs are to encourage transparency around unanticipated care outcomes in order to expedite compensation to patients injured by negligence, reduce malpractice claims and payouts, reduce overhead costs for claims processing, and foster institutional safety improvement efforts.

CRP programs vary in their structures and processes, but contain some common elements:

1. When an unanticipated adverse outcome occurs, clinicians are asked to promptly report it to the institutional risk management or patient safety office. This will lead to an institutional investigation to determine how it happened.
2. Conversations regarding the adverse outcome and its causes are conducted with the patients and families, even where the outcome is not due to a medical error or the cause of the harm is unclear. Although communication about the harm event may take place in a one-time conversation, more commonly, there are multiple communications over time. As the investigation into the cause of the adverse outcome is conducted, ongoing updates are provided.
3. Typically, the healthcare institution or insurer offers support and coaching to the clinicians. This may include formal training and/or “just-in-time” coaching on how to have discussions with patients, as well as “care for the caregiver” services to address the psychological well-being of providers involved in harm events.
4. Conversations with patients and families should include an appropriate apology. Depending on the results of the institution’s investigation into the cause of the injury, this may be a statement of sympathy (“We’re sorry this happened”) or may also include a statement of responsibility (“We’re sorry that our error injured you during the operation”).
5. Based on the program’s compensation standard (usually negligence), the institution makes an expedited decision on how best to resolve the matter. If a violation of the standard of care caused the harm, discussions with the patients and families are initiated to explore and try to meet the family’s needs. Typically, but not always, this includes an offer of compensation that is comparable to the value of the case in the tort system. On the other hand, if the standard of care was met, or there was no causal relationship between the adverse outcome and the medical care, this is explained to the family, and the institution indicates that it will vigorously defend the provider if a malpractice suit is brought.
6. Patients who accept a compensation offer usually must sign a release of claims, converting that offer into a final settlement. Incidents not resolved through settlement can go on to become malpractice suits in the tort system.
7. Patient safety lessons learned through the investigation process are disseminated and case information is used in ongoing safety analyses.

As these elements make clear, CRPs are different from programs or policies of full disclosure that have become widespread in healthcare institutions. CRPs and disclosure policies both seek to bring about prompt and candid communication from providers to patients when an error occurs, but CRPs do not stop there—they also include a proactive resolution component. Aside from financial compensation,

resolution elements may include “service recovery” (waiver of medical bills and/or provision of small financial benefits, such as hotel stays for family members), an explanation of what will be done to prevent recurrences of the event, symbolic gestures (e.g., putting up a plaque with a deceased patient’s name to memorialize the decedent and remind staff of the event), and including the patient or family in ongoing safety improvement efforts. For harms determined not to be due to error, the key elements of resolution are providing an explanation of what occurred, answering the family’s questions, and expressing sympathy.

We focus on the most commonly discussed and widely adopted CRP model, the Michigan Model. Pioneered and developed at the University of Michigan Health System (UMHS),^{154,155} this model has all of the elements discussed above. A second model, sometimes called the reimbursement model, has also been adopted by a limited number of insurers—most prominently, COPIC Insurance Co.¹⁵¹ In that model, the institution reimburses out-of-pocket expenses up to a dollar cap (typically \$5,000) without regard to whether or not the harm event was due to negligence. No investigation of fault is conducted. The patient need not waive their right to sue in order to accept the payment. Both models have merit, but the COPIC model has attracted less interest because it does not provide a final remedy and is not appropriate for addressing serious-harm events.

CRPs differ from the varying types of statutory “Early Offer” programs that have been historically proposed.¹⁵⁶⁻¹⁶⁵ In those proposed programs (including one proposed in a federal bill in 1984), providers are given a defined period of time (e.g., 120 or 180 days) to make an offer of compensation for claims asserted against them.^{159-161,163,165} The offer need only include a promise to make periodic payments for economic damages. With the offer, the provider would ideally also disclose any error in care. In many Early Offer proposals, claimants do not receive noneconomic damages, but do receive reasonable attorneys fees. The patient may refuse the offer and sue for all damages, including noneconomic damages. However, the claimant either must prove a more culpable breach than negligence (e.g., gross misconduct) or face a higher burden of proof (e.g., clear and convincing evidence). Statutory amendments may also allow for modified NPDB reporting requirements to mitigate reporting effects.

Early Offer programs seek to improve upon the tort system by creating administrative efficiencies (less litigation), quicker compensation for patients (less litigation with an offer deadline for providers), awards that better reflect the “real” losses patients suffer (by eliminating or limiting “pain and suffering” payments), and improved quality of care (by sending clinicians clearer signals). However, there are no real-world examples of Early Offer programs to test the extent to which they achieve their aims. In 2003, the Institute of Medicine (now called the National Academy of Medicine) called for system demonstrations of Early Offer programs with limits on noneconomic damages coupled with government-provided reinsurance.¹⁶³

Early Offer programs are different from CRPs in the sense that their primary driver is remedying the ails of the tort system, whereas CRPs are primarily driven by ethical and patient safety principles. That is, Early Offer provides a means of better managing asserted claims; CRPs reach farther and promote communication about cases of harm that may not otherwise be known to the patient and reconciliation after harmful events in the absence of a formal claim.

CRPs appeal to many clinicians because they are consonant with principles of medical ethics, including fulfilling fiduciary duties (e.g., placing a patient’s interest in knowing about the injury ahead of any reputational or financial harm that may result to the provider), furthering patient autonomy (e.g., supporting the patient’s right to make informed decisions about his/her future care), and advancing

equity (e.g., duly compensating patients for the injury).^{166,167} Leading organizations such as the National Academy of Medicine, The Joint Commission, and the National Quality Forum have also called for disclosure as part of greater patient safety agendas.^{149,168-170} Several states also require that disclosure alone be made to patients and families in certain circumstances in which a harmful error occurs.¹⁷¹ In 2010, the AHRQ funded four demonstration projects seeking to evaluate the effects of CRPs.¹⁷²

On the other hand, there are significant barriers to greater transparency around medical errors. Liability risk is widely cited to be among the chief barriers, and the number of institutions with formal CRPs remains limited.¹⁷³⁻¹⁷⁶ Other barriers to disclosure and early settlement include the emotional difficulty of the conversation, shame and guilt, the stress of a possible lawsuit, potential consequences in credentialing processes and insurance underwriting, and reputational harm.^{173,177-179}

In the remainder of this section, we discuss design features, decisions, and outcomes related to Michigan-Model CRPs.

4.2.1. Key Design Features and Decisions

- **Eligibility:** CRPs could be available for all injuries, or only a subset, such as significant injuries. Most CRPs that have been implemented are available for all types of injuries, but the workload involved in investigating every reported harm has led some institutions to exclude minor harms.^{151-153,155}
- **Compensation standard:** CRPs could award compensation only in cases in which the legal standard of care appears not to have been met, in all cases in which the institution “could have done things better,” or in all cases involving an injury due to medical management, regardless of its avoidability. The more stringent the compensation standard, the more extensive the required investigation, but the lower the program’s total compensation costs. Most CRPs today use a negligence standard.
- **Types of damages:** A determination of what types of damages will be compensated should be made.¹⁵¹ Most programs make some offers that include only a waiving of medical charges and courtesy items such as complimentary hotel stays for family members during the patient’s hospitalization. The next step up is to provide only reimbursement for out-of-pocket expenses. Alternatively, some or all of the patient’s economic losses (including lost income) could be compensated. Finally, programs could also offer some amount representing noneconomic loss, whether characterized as “pain and suffering” or “loss of time.” The more generous the offer, the less likely a patient or family may be to file a lawsuit. On the other hand, program costs will likely be higher with more generous settlements. The Michigan Model provides compensation for medical, economic, and non-economic damages.¹⁸⁰
- **Timing of compensation assessment:** Some CRPs specify target timelines for investigation and compensation decisions, while others do not. Timelines could vary from a few days to a few months. Programs also must determine how they will make offers to patients with injuries that are permanent, uncertain in duration, or uncertain in extent. This issue is most acute for severe neurological injuries to newborns, as the developmental implications for the child may not become apparent until testing can be conducted at 2 years of age. Programs could opt for periodic payments based on regular assessments of the severity of injury or for a lump sum

payment. The former improves accuracy in compensation, while the latter achieves a rapid disposition of the case and enables the insurer to better understand its extent of liability.

- Amount of damages: Programs will also need to decide if there is a maximum amount that will be offered for economic and noneconomic damages. Setting maximums may help speed negotiations, but may also result in more patients rejecting the offer. A further issue, particularly for programs with no preset maximums, is the basis for valuation of the case. Offers could be determined based on what the insurer believes the case would be worth if it went to trial, or based on its own assessment of what is required to make the patient whole.
- Assignment of responsibility: It will be important to determine on whose behalf monetary settlements will be made. For self-insured institutions or insurers that are covering all involved parties, the financial consequences of who accepts responsibility can be of minimal consequence for the insurer. However, there can be federal and state reporting ramifications for the involved physicians. If the error is a system-level error, a healthcare institution (such as a hospital) may opt to accept responsibility and have individual clinicians dropped from the financial settlement. This may obviate the need for provider reporting to NPDB, but may also run afoul of the intent of the NPDB statute.¹⁸¹
- Attorney involvement: For cases in which compensation is being considered, CRPs may suggest that the patient or family get attorney representation. This may occur only in certain cases—for example, high-severity cases or cases in which the institution feels that the patient or family has inflated expectations of the value of the case—or in all cases. Attorney representation can help ensure that amounts paid to patients are adequate; that the program is perceived to treat patients fairly and protect their interests; that patients do not have inflated expectations about what their injury is worth; and that settlement agreements are not vulnerable to later challenge in court on fairness grounds. One design decision institutions need to make is whether to simply notify patients of their right to be represented, refer patients to an organization (such as the state Bar Association) that can connect them with an attorney, or refer patients to a set of attorneys with whom the institution is familiar. The last strategy can maximize the chance that a patient can find an attorney experienced in medical malpractice and familiar with the CRP approach with minimal search costs, but raises questions about whether the institution can recommend attorneys in an unbiased fashion.
- Release of claims: Programs must decide whether acceptance of an early compensation offer will constitute a release of further liability claims for the event or whether patients will not be asked to sign a release of claims. The advantages of releases are clarity and finality for the involved providers and insurer. The advantage of not requesting a release is that it may help preserve goodwill, increasing the likelihood that a compensation offer is perceived by the patient as a gesture of caring. For minor injuries, at least, the risk that a family would go on to sue is probably low. The Michigan Model usually requires a release of claims.¹⁸⁰
- Duty-to-cooperate provisions in insurance contracts: Institutions that are not self-insured will need to ensure that the CRP is compatible with duty-to-cooperate clauses so that their insurers will not attempt to deny coverage.¹⁸² These clauses are frequently found in malpractice insurance policies and require insured providers to cooperate with the insurance company in its defense of the claim. Cooperation clauses commonly forbid insureds from admitting liability without the consent of the insurance company.

4.2.2. Effects on Key Outcome Variables

Though the imperative to disclose adverse events and the CRP concept continue to garner significant interest, there remains limited evidence in the public domain concerning the effect of CRPs on key outcome variables.¹⁷¹ The AHRQ demonstration projects included four that tested CRP approaches, but published reports are only beginning to emerge from those projects, and few of them included evaluations of impacts on overall liability costs. Presently, only two institutions have published in the scientific literature the effect of their CRPs on malpractice-related compensation costs.^{154,183} Other published reports focus on implementation experiences but provide some information about the probable effects on claims costs.¹⁵¹

- Claims Frequency and Costs.

There remains a fair amount of uncertainty about the effects of CRPs on claims volume and costs. Commentators and a simulation analysis of injury and claims data have suggested that full disclosure policies, without accompanying compensation programs, may increase healthcare providers' claims and costs by alerting patients to the fact and cause of a medical error.^{171,173-175,184} Although survey research suggests that disclosure improves trust in providers, that patients often sue out of a sense of "cover up",¹⁸⁵⁻¹⁸⁸ and that patients are more likely to sue if they learn of an error on their own as opposed to having a provider disclose it,^{189,190} at least one survey study suggests that disclosure and apology alone are unlikely to dissuade most patients from seeking legal advice.¹⁹¹ Rather, some surveys reported that a substantial number of patients will expect compensation if informed of a harmful error in their care.^{189,190}

However, CRPs go beyond full disclosure to provide a remedy. They also offer early resolution—which can include offers to settle—that may avoid the consequences that may otherwise flow from disclosure alone. This result seems particularly likely if patients perceive the apologies and disclosures in these programs to be sincere and carried out well and the compensation offers to be both fair and part and parcel of the provider's acceptance of responsibility for the error.^{154,155}

Accordingly, there are strong theoretical reasons for optimism in the ability of CRPs to constrain claims costs. Logically, average payouts should be lower in a CRP because (1) many patients would willingly trade off the possibility of a larger award for a quicker resolution; (2) the reduced involvement of attorneys should alter the existing incentives in the contingent-fee system to seek a large award (although attorney involvement could also help manage the expectations of some patients who seek large awards); and (3) a greater number of low-severity incidents should receive a payment under CRPs than in the tort system. The last effect arises from the fact that some CRP programs help resolve low-severity injuries, whereas in the tort system, claims with low expected value may not be brought due to lack of interest on the part of plaintiff's attorneys.^{154,155}

The available empirical evidence suggests that this may occur, where CRP processes are consistently followed. A Veterans Affairs Medical Center (VAMC) in Lexington, Kentucky, after adopting a CRP, saw its total liability compensation costs drop from the top to the bottom quartile in comparison to its peers.¹⁸³ The authors did not report effects on the number of claims or average settlement amount, only total costs. The generalizability of the VAMC experience has often been questioned. Liability in that setting is limited by the Federal Tort Claims Act and the VAMC provides care to a specific patient

population—veterans—that many malpractice scholars believe may be less inclined to sue or expect high compensation for injuries than other patients.

In a peer-reviewed article, UMHS reported that the number of claims (including any proactive offers of compensation by the institution) dropped by 36% in a pre/post analysis that evaluated its CRP 7 years after implementation.¹⁵⁴ The total amount spent on compensation dropped by 59%, with most of the savings being driven by lower compensation amounts in claims that became lawsuits. Drops in claim frequency with CRPs have also been reported by Stanford University in an unpublished analysis.¹⁵³

The New York demonstration project implemented CRPs in 5 New York City hospitals and published results on its implementation experiences in 2014.¹⁹² The hospitals chose to implement the program only in one clinical department, general surgery. Because the baseline number of claims in general surgery was low and the project lasted only 3 years (meaning that many patients still had time to file a lawsuit when the project's observation finished), the project team could not assess the effect of the CRP on total liability costs or claims volume. However, its report on implementation experiences suggests that the impact would have been minimal. One reason is that the program was limited to a single department; another is that the hospitals did not consistently adhere to CRP protocol. Specifically, compensation offers were not made in many cases in which they were deemed appropriate. Among the reasons were that families did not ask for compensation and seemed satisfied with an explanation and that physicians feared that a compensation offer could lead to escalating demands. The conclusion to be drawn from this project report is that not all institutions will be able to consistently deliver on the commitment to proactively offer compensation whenever negligent care causes harm; and when implementation fidelity is low, CRPs cannot be expected to generate large effects on claims and compensation amounts.

In summary, the limited observational evidence concerning the effects of CRPs indicates that claims frequency and costs per claim can drop markedly when the CRP process is consistently followed, but that some institutions may struggle with implementation fidelity. Further reports from the AHRQ demonstration projects and an ongoing project in several Massachusetts hospitals should be available within the next several months and may shed further light on both implementation experiences and CRP outcomes.

- Patient Compensation.

In theory, CRPs should provide easier and quicker access to compensation for patients. Available data from UMHS showed that after implementation of its CRP, the median time to resolution dropped by about 30%.¹⁵⁴ UMHS also made a payment in a higher proportion of claims than other institutions in Michigan (43% vs. 24 to 32%).¹⁵⁴ No data are available regarding the effects of CRPs on equity of awards.

- Overhead Costs.

Nearly all hospitals that have implemented CRPs have found that they require additional administrative FTEs to run—for example, to administer communication training and support services and to enable risk management to more quickly investigate incidents. The exception is UMHS, which has long maintained that the workload can be managed by existing staff by reallocating effort away from defense of indefensible cases.¹⁵⁴

While hospitals are likely to need to augment their risk management FTEs, it is likely that the CRP approach reduces *insurers'* overhead costs substantially overall. Earlier settlement of incidents, in most cases without recourse to litigation, avoids costs relating to protracted investigation and discovery, consultation with external expert witnesses, involvement of outside counsel, and preparation for trial.¹⁵⁷ The UMHS program found a 61% drop in defense costs paid to attorneys.¹⁵⁴

- Providers' Liability Costs.

Whether providers will see lower insurance premium costs will depend upon whether insurers pass along any savings that results from reduced claims frequency, compensation costs paid to patients, or overhead costs (e.g. litigation costs). In its pre/post analysis 7 years after CRP implementation, UMHS found that its total compensation costs (amounts paid to attorneys and patients) as a proportion of operating revenue dropped by 59%.¹⁵⁴

- Healthcare Spending and Defensive Medicine.

It remains unclear what effect a CRP will have on defensive medicine. In theory, CRPs should reduce defensive behaviors by creating a climate in which clinicians know that the institution will stand behind them if an adverse event occurs—meaning, it will be there to support them in disclosing the event and in handling the aftermath. A key component of CRPs is sending patients the message that where the institution finds the harmful event was not due to negligence, it will vigorously defend the provider against a subsequent malpractice claim. In contrast, traditional practice for many insurers is to settle wherever settlement is economically expedient, regardless of the degree to which the provider's conduct was actually culpable. Providers object to this approach because settlements trigger a report to the NPDB and state regulatory bodies. If providers feel they will get relief from such practices and that they and their patients will be psychologically and financially supported when error does occur, they may feel comfortable relinquishing some defensive practices.

However, the reverse effect may occur if providers perceive CRPs as programs that hand out money to patients in the interest of "resolution" even where no negligence occurred. Anecdotal reports from one early adopter suggest that some physicians may form this perception unless the institution seeks to educate them about the program's philosophy.¹⁵¹

- Physician Supply/Access to Care.

It is unclear whether and to what extent widespread use of CRPs would affect physician supply. At least two key factors could be affected by CRP use: liability costs and the quality of physician-patient relationships. Of these, liability costs will likely have the largest influence on supply. There is no evidence available to indicate whether individual institutions that have implemented CRPs have seen an effect on physician recruitment or retention.

- Quality of Care.

Efforts to improve the prevalence of disclosure are on the agendas of several organizations that seek to improve quality and safety.^{152,168,169,171,179,180,193} Routine, meaningful disclosure is itself a measure of high-quality care because of the greater transparency and honesty delivered to patients and the improved trust and decision making that can result. In addition, disclosure may also have a secondary,

downstream benefit for quality improvement efforts. If providers disclose their errors to patients, many subsequent and critical steps to improve patient safety will be made easier: promotion of a culture of transparency and safety, facilitation of reporting of errors (because the error is now known to the patient), and open discussion of errors so that efforts to improve can be initiated. While the concept that disclosure is a component of high-quality, patient-centered care is well accepted, the tangible, downstream benefits for quality and safety improvement efforts have not yet been proven.

CRPs can also have direct effects on patient safety by generating a greater number of adverse event reports and investigations. Early adopters emphasize this benefit. CRPs aim to track and investigate a broader number of adverse events than would traditionally be the case. Outreach to clinical staff stresses the benefits of timely reporting of adverse events. Further, while ordinarily risk managers would prioritize for investigation primarily serious-harm events involving a patient or family member who is complaining about the care, CRPs call for at least a cursory review of each adverse event that exceeds whatever severity threshold the institution has adopted for its CRP. The New York demonstration project hospitals reported that their programs resulted in greater communication across risk and quality offices about how to respond to adverse events, as well as more systematic tracking and review of events.¹⁹² Those hospitals were less active in disseminating patient safety lessons learned, but that is another potential way in which CRP investigations can contribute to healthcare quality.

- Unintended Consequences.

Institutions that have been operating CRPs have not reported any significant unintended consequences. One issue that has arisen, however, is how to handle NPDB reporting requirements in the context of CRPs. Some (but not all) academic medical centers that have implemented CRPs have adopted a practice of making reports to the NPDB only where the settlement reflects culpable conduct by an individual clinician. Where systems errors are heavily in play, the hospital may choose to settle the claim entirely in the name of the hospital, not individual clinicians, thereby avoiding the need to report to the NPDB. Concerns have been raised that this constitutes an end run around NPDB reporting requirements that are meant to help identify “bad apple” doctors and that it may lead to less physician accountability for care. On the other hand, it can be argued that sending the liability signal to the institution may actually lead to increased and more effective safety efforts.

- Differential Impact on Medicare Beneficiaries.

Easier and quicker access to compensation should benefit all patients, but may be especially valuable for Medicare patients for the reasons discussed earlier regarding the difficulty of finding attorney representation to pursue traditional litigation.

4.2.3. Summary

Full CRPs (as opposed to just disclosure policies) have only been implemented by a limited number of institutions, and only 2 have published information about the effects of the programs on liability costs and claims volume. Consequently, the evidence base for evaluating the effects of such programs on the key outcome variables remains small, though it is poised to grow in the next year as more demonstration projects publish their results. The available reports suggest that CRPs are a highly promising approach which can return substantial benefits in terms of reductions in claim frequency, payouts, and overhead costs and at the same time improve patient access to compensation and patient

safety. However, these benefits will only be achieved where CRPs are fully and consistently implemented, which is not easy to accomplish. The recent availability of an AHRQ-sponsored CRP implementation toolkit¹⁹⁴ should help new adopters follow best practices, but cultural challenges and leadership gaps may prove to be enduring barriers to full implementation at some institutions.

4.3. Safe Harbors for Adherence to Evidence-Based Practice Guidelines

“Safe harbors” for physician adherence to evidence-based clinical practice guidelines have been proposed as a means to protect healthcare providers from malpractice liability risk when they practice evidence-based care.¹⁹⁵⁻¹⁹⁷ Three primary rationales for this reform have been offered. First, it is intended to help prevent or quickly dispose of claims that lack merit, addressing liability fears related to the filing of “frivolous” suits when injury occurred even though the physician was not negligent. Nonmeritorious claims would be more easily defended because defendants could offer evidence of the applicable guideline to obtain a rapid disposition of the claim and perhaps avoid the “battle of the experts” that typically dominates malpractice trials. Second, safe harbors are intended to reduce defensive medicine. If healthcare providers know that it will be hard to successfully sue them for failing to provide tests and services that are not indicated according to the accepted medical standard of care, they will have less incentive to provide such services. Third, and relatedly, safe harbors can encourage physicians to adhere to evidence-based guidelines, thereby improving the quality and cost-effectiveness of care.^{196,197}

Several states experimented with safe harbors in the early 1990s under short-term demonstration projects:

- **Maine:** In 1990 and 1991, the Maine legislature passed legislation creating a 5-year demonstration project known as the Maine Medical Liability Demonstration Project (MLDP).¹⁹⁸ The MDLP created an affirmative defense for physicians in 4 selected specialties (obstetrics and gynecology, anesthesiology, radiology, and emergency medicine) who adhered to designated clinical practice guidelines.¹⁹⁹ In total, about 100 physicians practiced in the state of Maine in these specialties. Physicians were permitted to opt in to the system, and rates of participation varied from 58% (in anesthesiology) to 90% (in obstetrics and gynecology).²⁰⁰ The applicable guidelines were selected by a committee composed mostly of physicians, which chose guidelines issued by the national medical associations for the relevant specialties, with some modifications to reflect local practice in Maine.²⁰¹ The affirmative defense was (through legislation introduced in 1991) permitted to be raised before Maine’s pretrial screening panel. The MLDP authorizing legislation did not include funds for an evaluation, but did require insurers to report data on malpractice claims in the 5 years prior to the project and during the project period. In addition to an interim evaluation by the Maine Bureau of Insurance,²⁰² the project attracted external evaluators, including the General Accounting Office²⁰¹ and the Agency for Health Care Policy and Research.²⁰³
- **Florida:** For a 4-year period beginning in 1994, Florida operated the Cesarean Demonstration Project (CDP), which allowed physicians to introduce evidence of compliance with practice guidelines for cesarean section as a defense to a malpractice claim.²⁰⁴ A limited evaluation of the CDP’s effect on cesarean section rates was conducted.²⁰⁵ The project was not renewed in 1998, although the evaluator’s report recommended further experimentation with practice guideline safe harbors.^{205,206}
- **Minnesota:** In 1992, Minnesota passed legislation allowing the state’s Health Care Commissioner to approve practice guidelines for use as an absolute defense to malpractice

claims.²⁰¹ No information is available concerning any formal program evaluation. The program was not renewed and Minnesota law now expressly forbids the admission of guidelines issued by a “review organization” (i.e., a professional committee formed to evaluate and improve care provided in the local area or institution) into evidence in malpractice litigation.²⁰⁷

- **Vermont:** Vermont passed legislation very similar to Minnesota’s in 1992,²⁰¹ but no information on the program is available.

In addition to these demonstration projects, current Kentucky law states that healthcare providers who adhere to practice guidelines approved by the executive director of the state worker’s compensation program will be presumed to have met the standard of care in malpractice litigation.²⁰⁸ The safe harbor is, however, limited to providers who are rendering services in connection with injuries eligible for worker’s compensation (i.e., workplace injuries). The executive director is given latitude to develop the guidelines or to adopt any guidelines issued by “qualified bodies, as determined by the executive director.”

Safe harbor proposals were considered during the 1990 Clinton health reform initiative by the Physician Payment Review Commission, and again during the most recent round of health reform.^{209,210} In 2010, the AHRQ funded one planning grant to evaluate the potential for the reform to improve safety as well as liability outcomes.^{197,211} As recently as 2014, safe harbor legislation was introduced in Congress, but not enacted.²¹² Aside from Kentucky’s limited program, no state currently has a formal safe harbor. However, courts in all states allow experts testifying in malpractice cases to discuss clinical practice guidelines and their relevance to the standard of care and allow litigants to introduce documents containing the guidelines into evidence.²¹³ Thus, the primary effects of safe harbors reforms are to increase the weight given to clinical practice guidelines, give litigants the ability to introduce them into evidence without the accompanying testimony of a medical expert, and permit their introduction at an early stage in the litigation in support of a motion to dismiss or motion for summary judgment.

4.3.1. Key Design Features and Decisions

Key design decisions for safe harbors reforms include the following:

- **Nature of the safe harbor:** Although safe harbors for practice guideline compliance are sometimes described as creating “immunity” from suit, applying blanket immunity is not feasible because it will often be unclear whether a covered guideline applies to the particular clinical situation before the court.²¹⁴ Instead, safe harbors need to be designed to allow consideration by some qualified decision maker of whether the guideline is relevant to the physician, patient, and clinical situation in the case. Thus, a judge could consider whether to dismiss or enter summary judgment in the case on the basis of the defendant’s proffer of the guidelines. The weight given to the guidelines can vary: the strongest protection would come from establishing an *irrebuttable presumption* that a healthcare provider’s compliance with a specified guideline in an applicable situation constitutes adherence to the legal standard of care. The plaintiff could dispute the applicability of the guideline, but if it was clearly relevant to the plaintiff’s clinical situation, the defendant would have a very strong defense. A lesser form of protection would be to create a *rebuttable presumption*; this would open the door for the plaintiff to contest that the guideline indeed reflects reasonable and customary medical practice.^{215,216}

- Mechanism of invoking the defense: Safe harbors are typically described in terms of an *affirmative defense* that a defendant can assert in pleadings at an early stage of the litigation (indeed, state law often requires affirmative defenses to be plead in the defendant’s initial answer to the complaint). In states with pretrial screening panels, the defendant can present the guidelines as evidence for consideration by the panel. An alternative would be to require defendants to wait until trial to introduce the guidelines into evidence, but this approach has less potential to reduce litigation costs.¹⁹⁹ The timing issue is critical not merely because it affects litigation expenses, but also because it determines who (judge or jury) will decide the applicability and weight given to the proffered guidelines and what information the judge or jury will have at hand. Having judges make this decision on the basis of motions and briefs alone, without benefit of input by medical experts, carries some risk of error in decision making.
- Selection of covered guidelines: The selection of which practice guidelines, among the thousands in existence, will constitute the basis for a safe harbor is likely to be contentious.^{196,197,213} In the process of choosing guidelines, disputes are likely to arise over the validity of guidelines—focusing, for example, on the sufficiency of the underlying evidence or whether guidelines created by specialty societies are biased (i.e., too “physician-friendly”). The selection decision may be reposed with an expert committee, but the composition of the committee itself, particularly the balance between medical experts and other stakeholders, is likely to be controversial.²¹⁷ Although Maine relied heavily on physicians to select the guidelines, such an approach carries the risk that the public will perceive the process as biased. An alternative would be to allow trial judges the discretion to determine whether a guideline offered by the defendant is authoritative and applicable,²¹⁴ although this removes the decision from individuals with relevant medical expertise.
- Continuing review process: A process must be established for ongoing review of selected guidelines to ensure that they remain current and appropriate, and for considering how local variations in medical practice can or should be accommodated in a safe harbors system. The obsolescence of the covered guidelines in the Maine demonstration project has been cited as one reason the project was not more successful.²⁰⁶
- Universal vs. opt-in program: A safe harbor could be made available to any healthcare provider or only to those who choose to enroll in a safe harbor demonstration project. A universal program has greater potential to impact practice patterns and cost.
- Covered providers: The safe harbor program should specify which types of medical providers are eligible to invoke the safe harbor. Options include: all institutional and individual healthcare providers; all individual providers; physicians only; and physicians or providers in particular specialties only. The inclusion of providers in a particular specialty only makes sense if the safe harbor includes guidelines that are relevant to that specialty.
- Inculpatory use of guidelines: Some states that have experimented with safe harbors have allowed plaintiffs to use the defendant’s noncompliance with the specified guidelines to show that the defendant was negligent (i.e., to use the guidelines for inculpatory purposes or as a “sword”). Others have only permitted the use of guidelines by defendants to show that they were in compliance with the standard of care (i.e., using the guidelines as a “shield”). The appeal of the “sword” approach is its evenhandedness by making the standards available to patients as well and the possibility of reinforcing legal incentives for guideline adherence,^{218,219}

while the latter (“sword”-only approach) is more narrowly tailored to the goal of reducing nonmeritorious litigation.^{213,218,219}

4.3.2. Effects on Key Outcome Variables

The evidence base for safe harbors is very small, consisting primarily of the limited evaluations of the Maine and Florida demonstration projects and one study that estimated the potential effect of safe harbors in Oregon using simulation methods.

- Claims Frequency and Costs.

In theory, safe harbors should discourage plaintiff’s attorneys from bringing claims that clearly lack merit if the facts suggest that a practice guideline was followed. A small empirical literature shows that adherence to practice guidelines in obstetrical practice is associated with reduced medicolegal risk.^{220,221} However, there is no evidence from the state demonstration projects to support or rebut the notion that safe harbors decrease the frequency or cost of claims.

It was difficult to evaluate the effect of Maine’s demonstration project on claims because the project was so limited in scope. The 22 guidelines selected in Maine covered only select areas of practice within 4 specialties, estimated to constitute 3-4% of all medical practice in the state. Moreover, because claims are a rare event for any given physician, an experiment involving such a small number of physicians could not support quantitative evaluation of changes in claiming and claim disposition over time.^{200,222} Five years into the demonstration, only one claim in which a participating physician invoked a covered guideline as a defense had been reported.²⁰²

Florida’s project was even more limited in clinical scope than Maine’s. Moreover, the CDP evaluators were unable to obtain data on the frequency of malpractice claims.²⁰⁶ At the time of evaluation (January 1998), there was no known case of a participating physician invoking a CDP-covered guideline as a defense in a malpractice claim.²⁰⁶

Recently, an AHRQ-funded simulation study analyzed a sample of over 900 closed malpractice claims from Oregon to determine how frequently a safe harbor would have changed claim outcomes had it been available.^{153,197} It found that safe harbors would have impacted payments in defendants’ favor in less than 1% of the claims. The main reason was that applicable guidelines only existed for about 15% of the clinical situations at issue; a second reason was that where physicians had followed an applicable guideline, they had tended to prevail in the litigation even absent a formal safe harbor. This work suggests that the effects of safe harbors on liability outcomes may be quite modest unless and until the bank of guidelines grows substantially.

- Patient Compensation.

Safe harbors, if used only as a shield, are designed to reduce the number of claims in which patients would be successful. However, as discussed above, while the availability of practice guidelines *in general* may have this effect, adopting a formal safe harbor may add little marginal value.¹⁹⁷ In other words, guidelines may already be providing liability protection for physicians.

The Oregon study also examined what might happen if safe harbors were also available for plaintiffs to use to try to inculcate physicians. It found that just 1.6% of claims that were not compensated might have been paid in that scenario. Thus, the analysis concluded that safe harbor legislation, whether made available as a shield alone or as a sword and shield, would have minimal impact on the proportion of claimants who receive compensation.

Effects of safe harbors on the timeliness of compensation or equity in awards have not been examined. In theory, safe harbors could reduce time to resolution of claims by providing more determinative evidence about what constitutes the standard of care.

- Overhead Costs.

No information is available regarding the effect of safe harbors on overhead costs. Theoretically, because of the early resolution safe harbors can bring, litigation costs should decrease substantially in cases in which guidelines are applicable. However, such cases could represent a small proportion of all claims and these savings may not be realized if plaintiff attorneys spend money on expert reports in an attempt to contest the applicability of the guidelines to the facts of the case.¹⁹⁷

- Providers' Liability Costs.

No information is available regarding the effect of safe harbors on liability insurance premiums. The Maine Superintendent of Insurance estimated that the MLDP would result in a 0.5% savings in medical malpractice premiums, but the Bureau of Insurance subsequently reported that it was unable to determine the effects of the MLDP on premiums.^{202,217} The Florida evaluators also were unable to obtain data to permit an evaluation of the CDP's effect on malpractice premiums.²⁰⁶

The theoretical connection between safe harbors and insurance premiums is remote; it is mediated by the extent to which quality of care improves as a result of better guidelines adherence and the extent to which attorneys are discouraged from bringing claims. The simulation study in Oregon suggested that very little would change directly in the way of liability costs, unless the legislation was successful in driving better adherence to guidelines.¹⁹⁷ In that case, there could be liability savings (resulting from fewer adverse outcomes) which insurers might pass along to providers.

- Healthcare Spending and Defensive Medicine.

Even if safe harbors have no effect on claims frequency and cost, they may nonetheless have a reassuring effect on physicians that leads to reductions in defensive medical practice.^{196,197} The reassurance may spring from a perception that frivolous claims will be brought less frequently or will be easier to defend, or simply from greater clarity about what standard of care the law requires. The appeal of safe harbors is that they target defensive medical practices for which there is little or no evidence of a salutary effect on patient care.⁹⁶ Theoretically, the effect of safe harbors on defensive medicine should vary according to the strength of the safe harbor, the clarity and comprehensiveness of the selected guidelines, the level of physician awareness of the safe harbor, and the extent to which physicians are already practicing in compliance with the guidelines.⁹⁶

The most relevant available evidence concerning these effects is the AHCPR evaluation of the Maine demonstration project.²⁰³ Using medical record reviews and physician and hospital surveys, the

evaluation compared obstetrical practice in Maine in the four years following implementation of the project to (1) practice in Maine in the 5 years prior and (2) practice in Vermont and New Hampshire during the project period. Among the key findings of the evaluation were the following:

- The MLDP did not affect rates of diagnosis of failure to progress and prolonged pregnancy (which are associated with cesarean section) or rates of cesarean section. All of these rates declined among MLDP-participating physicians during the intervention, but similar or greater decreases were seen in the comparison groups.
- The MLDP did improve adherence to guidelines for management of fetal distress. Adherence increased among all groups, but the increase was significantly larger among MLDP-participating physicians. The effects of guideline adherence on birth outcomes were not evaluated.
- Documentation of adherence to the guidelines was higher among MLDP-participating physicians than among others.
- Low proportions of Maine physicians perceived the MLDP to have reduced malpractice risk (38%), defensive medicine (25%), or cesarean section (10%). Only 1 in 5 physicians reported that the MLDP had led them to make changes to their practice; many reported in this and an earlier survey²⁰¹ that they were already in compliance with the guidelines.

An earlier evaluation of the Maine project by the General Accounting Office was unable to draw conclusions about the effect of the MLDP on defensive medicine because of the unavailability of baseline data on utilization of sentinel procedures and inability to control for confounding effects of regulatory changes, changes in insurance coverage, and changes in insurance reimbursement in Maine during the study period.²²³

The results of the Florida evaluation are not publicly available at this time. However, the Florida CDP had very limited uptake among eligible physicians: only 20% of obstetricians chose to participate. This limits the prospects for affecting any of the key outcome variables.

- Physician Supply/Access to Care.

No information is available regarding the effect of safe harbors on physician supply. Theoretically, a safe harbor program with demonstrated success in reducing malpractice risk could serve as a magnet for physicians who experience liability pressure in other states.

- Quality of Care.

Safe harbors programs have considerable theoretical promise for improving the quality of care by providing incentives for adherence to evidence-based practice guidelines (assuming that the guidelines selected for coverage by the safe harbor reflect high-quality, evidence-based care).^{196,197} However, little is known about how this plays out in practice.

The effects of the MLDP on outcomes of care were not evaluated, nor were its effects on adherence to practice guidelines in specialties other than obstetrics. The MLDP resulted in higher adherence to guidelines for management of fetal distress among participating physicians than among comparators, but was not associated with higher rates of adherence to other practice guidelines. Survey evidence suggests that obstetrical practice may have been relatively static under the MLDP because most physicians believed they were already following the selected guidelines at the time of project implementation.²⁰³

The Oregon analysis does shed some light on the potential safety-enhancing effects of safe harbors. It revealed that in the sample of 907 closed claims, physicians had adhered to guidelines in only half the cases in which a guideline was applicable. Further, adverse outcomes in about 4.5% of the claims reviewed might have been avoided had physicians adhered to guidelines in those cases (for example, had a physician properly prescribed prophylactic medication against blood clots in a patient at high risk for developing the complication).¹⁹⁷ This study demonstrates that there is substantial room for improvement in compliance with guidelines and that higher compliance can enhance safety—but does not show what effect the legal protection of a safe harbor would have on compliance.

- Unintended Consequences.

Due to the limited experience with safe harbors, unintended consequences are not well understood. However, one predicted consequence includes the “watering down” of guidelines to better protect physicians, if medical professional societies promulgating guides know they could be used in safe harbor programs. Another concern is the additional litigation expense associated with contesting whether the guidelines apply to the care in question. Finally, the costs associated with administering a safe harbors program (e.g., choosing the guidelines and keeping them updated) may outweigh the litigation costs they save. In the Oregon analysis, even assuming every guideline in the National Guideline Clearinghouse was available as a safe harbor, guidelines were applicable in only about 15% of the claims.

- Differential Impact on Medicare Beneficiaries.

No major differential impact of safe harbors on Medicare beneficiaries is predicted. To the extent that some guidelines apply only to younger patients, safe harbors may have a slightly greater effect on younger patients’ ability to prevail in claims than on Medicare beneficiaries.

4.3.3. Summary

Safe harbors have considerable appeal as a mechanism for discouraging frivolous malpractice claims, reducing defensive medicine, and providing incentives to move toward evidence-based care. However, existing experimentation with safe harbors is too limited and too incompletely evaluated to provide reliable evidence for or against the concept. One recent simulation study suggests that the greater benefit of safe harbors may be in improving patient safety rather than liability outcomes. If there is more experimentation on that basis, such testing should be coupled with evaluations to shed more light on the effects on liability outcomes.

4.4. Mandatory Pre-suit Notification Laws

Mandatory pre-suit notification laws require malpractice plaintiffs to give defendants advance written notice (typically 1 to 6 months) that they intend to file suit.¹⁵³ The rationale behind these statutes is that advance notice of the impending lawsuit can give physicians, healthcare organizations, and their liability insurers time to investigate and possibly resolve the matter before it goes to court—for example, by making an early settlement offer or meeting with the patient to explain the provider’s view of the case. Pre-suit notification periods are also known as “cooling off periods” because they require the plaintiff to wait, take stock, move beyond initial reactions to the traumatic event, and potentially engage more with the provider and/or legal counsel before filing.²⁷

By creating, if not forcing, time for pre-suit settlement, these laws theoretically can lead to quicker resolution of claims, lower indemnity payments (if claimants are willing to settle for less in return for obtaining compensation without recourse to a lawsuit), and lower overhead costs (if less time is spent in litigation). By creating the opportunity for institutions to “do the right thing,” pre-suit notification laws are also seen as a mechanism that can help facilitate the growth and successful operation of institutional communication-and-resolution programs (CRPs) (described above).¹⁸¹

4.4.1. Key Design Features and Decisions

- Length of time for the notice: Although 6 months is a common choice, the amount of time required by statute varies across states that have adopted pre-suit notification requirements. Setting the time period requires balancing of how much time is needed for a good-faith investigation and attempt at settlement with how long it is acceptable to delay a plaintiffs’ access to the civil justice system. The impact of the delay in cases that are not resolved before the end of the cooling-off period may be minimal given that lawsuits require time for investigation once filed; the notice requirement may simply shift the timing of this investigation to before the formal filing of the suit.
- Interaction with statutes of limitations and repose: Statutes are designed so as not to compromise access to the legal system for patients who are approaching the end of the applicable statute of limitation or repose. Otherwise, the mandatory waiting period may cause a plaintiff to miss the filing deadline (for example, if a state has a 3-month notice requirement but the statute of limitations is due to expire in 1 month). In Tennessee, which has a 60-day notice requirement, statutes of limitations and repose are automatically extended by 120 days upon filing of the notice.²²⁴ Massachusetts waives its 182-day notice requirement for cases initiated within 6 months of the expiration of the statute of limitations.²²⁵
- Duty to respond: To encourage settlement negotiations, pre-suit notification laws can require the defendant to respond within a reasonable period of time. Specific design considerations include what timeframe the defendant is given for responding, the form of the response, and any potential penalties for not responding.

4.4.2. Effects on Key Outcome Variables

Only one published analysis has evaluated the effect of pre-suit notification laws on the resolution of medical malpractice claim.²⁷ Due the limited evidence on the effects of these statutes, the potential effects of these statutes are also described below.

- Claims Frequency and Costs.

If successful in achieving their goal of improving early resolution of malpractice disputes, pre-suit notification laws should not affect the number of claims for compensation (where “claims” are defined as written demands for compensation), but would reduce the number of lawsuits. They may reduce compensation costs if earlier settlement leads to reduced settlement amounts (because the attorney has not invested as much money in the case and the plaintiff is willing to grant a “discount” for early payment). However, in one multivariate analysis using NPDB data from 1990-2003 to evaluate the

effect of several tort reforms on malpractice claims and payments, the authors reported no significant difference in average payment amounts among paid claims in states with and without pre-suit notification requirements.²⁷ The same analysis reported no significant difference in the number of claims receiving compensation. Because there is only one study, the evidence is insufficient to support the drawing of firm conclusions about the effect of pre-suit notification periods on claims frequency and costs.

- Patient Compensation.

Pre-suit notification laws may be expected to reduce the time to compensation, if pre-suit settlements actually occur more frequently and/or earlier. Stakeholders in Massachusetts have reported that the state's 2012 pre-suit notification law has been helpful in encouraging hospital systems and liability insurers to implement CRPs, which may expedite access to compensation. However, no data exist to substantiate the notion that pre-suit notification expedites settlement. There is no reason to think that pre-suit notification laws should affect the vertical or horizontal equity of awards.

- Overhead Costs.

To the extent that pre-suit notification laws lead to earlier settlements, they have the potential to lower overhead costs (less attorney time and court costs). They could lead to increased investigation costs by defendants, particularly if the laws require defendants to file a timely response to a plaintiff's pre-suit notification. However, the investigation costs likely would have occurred anyway—just later in the litigation process.

- Providers' Liability Costs.

No evidence indicates what effect pre-suit notification laws have on providers' liability costs. The hope is that pre-suit settlement amounts (as well as associated overhead costs) would be smaller, and that insurers would pass these savings along to providers in the form of lower premiums.

- Healthcare Spending and Defensive Medicine.

No conclusions can be drawn on the effect of pre-suit notice laws on healthcare spending and defensive medicine. To the extent that these laws and the CRPs they foster can reduce the fear of litigation for physicians, defensive medicine may decline. However, that remains speculative.

- Physician Supply/Access to Care.

No conclusions can be drawn on the effect of pre-suit notice laws on physician supply and access to care. As with defensive medicine, if these laws and the CRPs they foster reduce physicians' fear of litigation, physician supply may increase.

- Quality of Care.

No conclusions can be drawn on the effect of pre-suit notice laws on the quality of care. Theoretically, patient safety may improve if providers and insurers receive earlier notification of harmful events that

patients intend to litigate. These events should already have been reported to the healthcare facility, but that does not always occur, and some harms are not known until a patient brings it to the institution's attention. Earlier reporting creates an opportunity for rapid intervention to prevent recurrences.

- Unintended Consequences.

There is no evidence regarding unintended consequences of pre-suit notice laws. One potential concern is that patients will experience a longer time to compensation. However, it is already the case that lawsuits are often filed only after the patient has first given notice of his/her grievance by sending a claim letter to the healthcare facility. Thus, many if not most lawsuits already result from a failure to reach a resolution during the pre-suit claim period. The additional waiting time imposed by a pre-suit notification law may not be substantial. Moreover, if providers indeed use the notice time to resolve claims, the time to resolution may be shorter for patients on average.

- Differential Impact on Medicare beneficiaries.

There is no reason to suspect that Medicare beneficiaries would be differentially affected by pre-suit notification requirements, relative to younger patients. Exceptions may occur for elderly patients with very short life expectancies, for whom a several-month waiting period may be burdensome.

4.4.3. Summary

Pre-suit notification laws are designed to encourage early resolution negotiations, but there has been only one analysis that has evaluated their effect and it found no changes in the number of paid claims or claim payment amounts. Insufficient data exist to support any firm conclusion. If successful in achieving their goals, pre-suit notification laws could result in quicker access to compensation and lower overhead costs. Another potential benefit to pre-suit notification laws is that they can be deployed by legislatures to foster the growth of CRPs. However, how well they do this also remains unclear.

4.5. Apology Laws

Apology laws, sometimes called "I'm Sorry" laws, aim to encourage apologies for harmful acts, and therefore reconciliation, by eliminating worries that statements of apology will be used against the person who apologizes in a subsequent lawsuit. A typical apology law stipulates that certain classes of statements by healthcare providers to patients or families, which may include statements of remorse or regret, statements of sympathy or benevolence, and explanations for what happened, are inadmissible as evidence in civil lawsuits.²²⁶ Apology laws are based on the premise that most providers would like to apologize when an error occurs (or even when there is an unanticipated outcome in the absence of an error), but don't, for fear of elevating their liability risk. That chilling effect prevents the type of open dialogue and reconciliation that could prevent patients from filing lawsuits.^{173,227}

In protecting apologies and expressions of sympathy, legislatures hope that humane communication at the time of the event will (1) reduce claims for compensation by meeting the need that injured patients and their loved ones have for a sincere expression of remorse and accountability, as well as information about what occurred;¹⁷³ and/or (2) expedite compensation of harmful events due to errors by starting

the resolution conversation earlier.^{226,228,229} These laws may also improve patient satisfaction with the reconciliation process, and in the longer term, enhance trust in the patient-provider relationship.²³⁰

The earliest apology law in the U.S., adopted in Massachusetts in 1986, covered all types of accidents, not just medical injuries.²²⁶ It had its genesis in a car accident that killed a cyclist. Other states have followed with laws protecting apologies that could result in civil claims.²²⁶ Today, apology laws that cover either accidents in general or only medical injuries are now in effect in at least 36 states in the U.S.^{226,231,232} These statutes are, however, quite heterogeneous in what they protect and how they work. Features that vary include the triggers for the evidentiary privilege, the length of time after the event the protection is available, the types of expressions protected, the types of content protected, and the consequences if the provider later makes a statement that contradicts the earlier statement of apology.

Some commentators worry that these laws' complicated wording, and the heterogeneity across states in the specific statements covered, may be confusing to providers. There are also concerns that the laws distort providers' incentives to give an authentic apology. Apology laws could harm providers who mistakenly believe that their state's apology law provides broader protection than it does, and could promote insincere apologies that are too carefully "crafted," coming off as disingenuous or not fully open and harming the patient-physician relationship.²²⁹

4.5.1. Key Design Features and Decisions

- What activates the evidentiary protection: The types of adverse events that trigger this protection should be clear to providers. Depending on the state, they may include all types of accidental events (as is the case in states that originally adopted their laws with auto accidents or other, non-medical injuries in mind), unanticipated outcomes of medical care, medical errors, or alleged negligence. Most statutes cover all types of accidental events or unanticipated outcomes.²³³
- Types of statements and expressions protected: Apology laws may protect oral statements, written statements, conduct, or some combination of these types of expressions. The greater the range of types of expressions protected, the greater the certainty providers should have that they can safely apologize in the way they would like.
- Content of statements protected: Apology laws can be written to protect a combination of expressions of benevolence and sympathy (e.g., "I'm sorry you were harmed by the medication"), explanations of what happened (e.g., "You lost consciousness because you received too much medication"), and admissions of fault (e.g., "We mistakenly gave you the wrong medication that harmed you."). Again, the broader the protection afforded, the easier it should be for a provider to freely communicate after the adverse event.
- Time period after event: Some states specify that the protection is only available for statements and expressions made within a short amount of time after the adverse event (e.g., 72 hours in Illinois; 30 days in Vermont and Washington). However, the majority do not place a time limit.²³³⁻²³⁵ Imposing a time limit may encourage rapid apologies, but discourage communications outside the window. The latter may be an important disadvantage because full information about the adverse event often is not available until an investigation has been

completed, which may take days, weeks, or even longer, depending on the complexity of the event.

- Subsequent contradictory statements: In some states, if a provider (or defense expert witness) makes subsequent statements that contradicts an initial apology, that apology can then be introduced into evidence.²²⁵

4.5.2. Effects on Key Outcome Variables

Very limited evidence exists on the effect of apology laws on liability and clinical outcomes. The lack of evidence may be in part due to the recency of these laws: 34 states' apology laws were enacted after 2000 and 24 were adopted since 2005.²³⁶

- Claims Frequency and Costs.

Although the impetus for these statutes is the intuition that apology promotes reconciliation and deters tort litigation—a supposition buttressed by a substantial literature in the field of restorative justice^{228,237}—there are actually 2 possible effects of apology laws on malpractice claiming. One possibility is that patients will be less likely to sue when their psychological need for a sincere apology and explanation are met. The other is that patients armed with information about and acknowledgment of an error may be more likely to sue. Even though the statements themselves are inadmissible, an apology may put a patient on notice that an error has occurred and provide key facts that facilitate a plaintiff attorneys' investigation of the event. These strategic advantages could make it more likely that a patient will seek out and successfully obtain representation from an attorney, leading to a greater number of claims.

A number of surveys report that patients are often driven to sue because of a lack of apology, but these findings are merely suggestive that providing apologies could deter lawsuits.^{189,237-241} Moreover, these surveys speak to the potential effects of apologies, not whether apology *laws* actually increase the number of apologies that occur or whether the apologies produced are perceived by patients as authentic.²³⁰

More informative about the effects of the laws themselves are two analyses by Ho and Liu.^{231,242} These studies used difference-in-difference analysis (which compares the change in the outcome variables over time in states that passed apology laws to states without the laws) to evaluate the effect of apology laws on the number of lawsuits and size of malpractice payments. The researchers reported that apology laws were associated with 12.8% lower average payment among paid claims, a statistically significant difference.²⁴² The drop in compensation amounts was largest in cases involving obstetrics and anesthesia, cases involving infants, and cases involving improper management by the physician or failure to diagnose. The other paper by the same authors, using similar data and methods, found apology laws to be significantly associated with lower average payments in cases of major permanent injury or death, but not for more minor injuries.²³¹

The picture with regard to effects on claims frequency was more complex. Overall, having an apology law was associated with a statistically significant, 15% increase in the number of paid claims, according to Ho and Liu.²³¹ This increase was driven entirely by claims involving severe injuries and deaths; the number of paid claims involving minor injuries decreased 17-18%. The authors reported their suspicion that the increase in frequency, which controverted the prevailing theory about the effect of apology

laws, was an “artifact of data limitations”. No other study exists against which that conclusion might be tested. Further muddying the waters is that the Ho and Liu analysis was based on the number of *paid* claims and cannot generate information about whether total claim filings changed with the adoption of apology laws.

In summary, although there are good theoretical reasons to believe the number and average payment per paid claim may drop in the presence of apology laws, there are also theoretical reasons that claim frequency may increase. The available evidence is too limited to draw a conclusion about these matters; a reasonable summary at this point is that the liability-reducing effects of apology laws have not yet been demonstrated.

- Patient Compensation.

As would be theoretically expected, Ho and Liu also found that apology laws speed the resolution of at least some types of malpractice claims.²³¹ In light of the study limitations, though, from this single analysis it not possible to draw firm conclusions on what happens to time to compensation for patients with the passage of apology laws. No published studies have evaluated the proportion of claims that receive compensation or the vertical or horizontal equity of payments.

- Overhead Costs.

Apology laws theoretically could lower overhead costs by leading to quicker settlements after injury, but there is insufficient evidence as to their effect on this outcome.

- Providers’ Liability Costs.

If successful in promoting quicker settlements that result in lower compensation amounts, apology laws could theoretically reduce providers’ liability costs, assuming that insurers pass along the savings. However, there is no evidence as to whether or not this occurs.

- Healthcare Spending and Defensive Medicine.

No conclusions can be drawn regarding the effect of apology laws on healthcare spending and defensive medicine. To the extent that these laws may reduce fear of litigation among physicians, defensive medicine may decline.

- Physician Supply/Access to Care.

No conclusions can be drawn about the effect of apology laws on physician supply and access to care. To the extent that the laws reduce physicians’ fear of litigation, physicians may gravitate towards, or remain in, states with apology laws.

- Quality of Care.

No conclusions can be drawn on the effect of apology laws on the quality of care. To the extent that these laws themselves and the CRPs they foster promote physician and institutional accountability for patient safety, quality of care may improve.

- Unintended Consequences.

One concern is that apology laws may lead to inauthentic apologies that may further upset patients in the wake of an adverse event. This could lead to more claims for compensation or reduce trust in the patient-provider relationship. It remains unknown as to whether the detrimental effects of insincere apologies would be offset by the positive effects of a potentially greater number of well-executed apologies.

- Differential Impact on Medicare Beneficiaries.

Apology laws are likely to have a similar effect across all patients. To the extent that they reduce patients' need to file a claim in order to get information about what happened to them, and to the extent that getting attorney representation is especially difficult for elderly patients, the laws' effect may be slightly greater on Medicare beneficiaries than younger patients.

4.5.3. Summary

Overall, the evidence base on the effects of apology laws is very small, though a larger literature supports the notion that authentic apologies and providing information about why an injury occurred may diffuse anger and deter tort claims. Limited observational evidence suggests that apology laws may speed the resolution of claims and reduce average compensation amounts, and increase the overall number of claims, but more evidence is needed to support firm inferences on these issues.

4.6. State-Facilitated Alternative Dispute Resolution (ADR)

State-facilitated alternative dispute resolution is a legal mechanism through which patients or healthcare organizations can voluntarily file for ADR with a state agency if they are concerned that an error or adverse event may have occurred in medical care. Neither party needs legal representation. The state agency will then assist the parties in mediating a communication-and-resolution process. To facilitate greater openness, the conversations that occur during the process are protected from discovery and use in trial.

State-facilitated ADR is a new model that is being tested in Oregon, where it is termed "Early Discussion and Resolution".²⁴³ The stated goals of the Oregon program include providing confidentiality to encourage open communication, creating a path to resolution without lawsuits, preventing bad situations from getting worse, and fostering learning and improvement across the state (the state agency plans to disseminate deidentified patient safety findings).

Oregon's ADR process is not available for all adverse events, only those that meet the following criterion: an "unanticipated consequence of patient care that is usually preventable and results in the death of or serious physical injury to a patient." "Serious physical injury" is defined an injury that "is life

threatening, results in significant damage to the body, or requires medical care to prevent or correct significant damage to the body.”²⁴³

It is too early to tell how well Oregon’s program, which was implemented in July 2014, will work and what effect it will have. A first-year report on the program found that a total of 29 notices were filed by patients and healthcare professionals²⁴³—a small number for a statewide program. Patients filed 21 of those notices (72%) and healthcare professionals, 8 (28%). Whether other states will adopt the state-facilitated ADR approach is not clear.

4.6.1. Key Design Features and Decisions

- Protections for conversations: The legal discoverability and admissibility into evidence of the conversations and negotiations that occur as a result of filing should be clearly stated in program materials. The issues raised mirror in many respect those raised by apology laws.
- Mediator: A state could decide to provide its own mediators or could help the parties locate a qualified private mediator. The former may carry the benefit of providing a neutral mediator that both the parties to the suit may readily trust, while the latter may appeal more to healthcare facilities which, as “repeat players” in the medical liability system, have had positive experiences with particular mediators in the past.
- Reporting to NPDB: By declaring that all settlements from Early Dispute Resolution not to be a result of a written demand for payment, Oregon’s program founders attempted to avoid the federal requirement that all settlements made on behalf of a healthcare practitioner must be reported to the NPDB. The goal was to encourage providers to reach resolution during this process by removing the NPDB reporting concerns that they may have had. However, the federal Department of Health and Human Services has opined that a state may not make such a determination where it would conflict with the requirements of a federal statute.²⁴⁴ Thus, broad language suggesting that settlements are protected from NPDB reporting requirements if reached under the auspices of state-facilitated ADR may provide false reassurance to clinicians. Narrower language which clarifies that payments made in response to a written request for compensation are reportable and advising how the ADR process may be carried out orally is preferable.
- Deidentification of cases: Agencies that plan to share patient safety lessons across the state need to ensure that information about ADR cases is sufficiently deidentified that patients and providers will feel that their privacy has been protected. Insufficient assurance and protections around privacy could prevent patients and providers from bringing cases to the state agency.
- Voluntariness: Although Oregon’s ADR program is voluntary for both parties, other options exist. The state could require all parties to a malpractice dispute to undergo mandatory mediation or could require ADR where at least one party desires it. Because ADR is a cooperative process, however, it may fail where the parties are forced into it—particularly if one or both attorneys in charge of the case would prefer not to use it.
- Financing: The administrative costs of state-facilitated ADR could be paid out of a state’s general revenues, or could be financed through a surcharge on professional liability insurers or

healthcare providers. A user-fee-based system may discourage participation if the fee is levied on a per-case basis, but encourage participation if the fee is annual (because users may wish to “get their money’s worth” out of the system).

4.6.2. Effects on Key Outcome Variables

Due to the limited time Oregon’s model has been in operation, it is not possible to draw conclusions about its effects. Some theoretical effects are discussed below. We do not summarize below the extensive literature on the outcomes of voluntary and mandatory mediation, but mediation is generally perceived to be a useful process and is often incorporated into the process of resolving claims and lawsuits even in the absence of state-facilitated ADR or CRPs.

- Claims Frequency and Costs.

Although state-facilitated ADR is intended to reduce liability costs, in theory it could either increase or decrease total costs. If early resolution is successful, the number of claims or requests for mediation that proceed to the lawsuit stage could drop substantially. On the other hand, state-facilitated ADR enhances the ability of a patient who has not been able to retain legal counsel to access a resolution process. Consequently, individual and institutional providers may find that it increases the number of claims (demands for payment).

The effects of state-facilitated ADR on average payouts are unknown, but the expected effect would be to reduce payments by expediting settlement. Attorneys and patients may be willing to settle for less money if they can receive payment faster.

- Patient Compensation.

As suggested above, state-facilitated ADR opens a pathway to communication and resolution—possibly including compensation—for many patients who otherwise would see their claims founder because of their inability to find an attorney willing to take the case. Patients retain full rights to sue up until the time they execute a settlement agreement and release of claims, so there is no tradeoff in utilizing the new pathway other than a possible delay in filing suit.

The program may also speed time to compensation, at least in cases where liability is relatively clear. Although neither voluntary nor state-facilitated, a mandatory mediation program at the University of Florida Health System that was evaluated 5 years after launch effected an 81% reduction in time to resolution.²⁴⁵

- Overhead Costs.

The state-facilitated ADR model is designed to reduce the administrative costs associated with resolving claims by avoiding costly litigation. But whether it will achieve this goal is unknown. Encouraging anecdotal evidence comes from the University of Florida Health System, which found that its mandatory mediation program resulted in a 90% drop in provider legal expenses per claim.²⁴⁵ These savings might be partially offset by the costs of administering the program, but those expenses might be borne by the state, not insurers.

- Providers' Liability Costs.

The effect of state-facilitated ADR on providers' liability costs has not been measured. It will largely depend on three factors: whether the number of paid claims rises or falls, what happens to the average payment among paid claims, and the extent to which insurers pass along any savings they experience to providers in the form of lower insurance premiums.

- Healthcare Spending and Defensive Medicine.

No conclusions can be drawn on the effect of state-facilitated ADR on healthcare spending and defensive medicine. To the extent that the program is successful in reducing physicians' fears about unwarranted lawsuits, defensive medicine may be reduced, leading to lower spending. In addition, to the extent that the state is able to spread patient safety improvement lessons, a reduction in medical errors could lead to lower healthcare spending.

- Physician Supply and Access to Care.

No conclusions can be drawn about the effect of state-facilitated ADR on physician supply or access to care. If successful in reducing physicians' liability fear, such programs may help attract and retain physicians in the state.

- Quality of Care.

If the patient safety lessons learned from ADR cases are actionable, generalizable, and broadly disseminated, a state-facilitated ADR program could lead to a reduction in medical errors. Whether these effects occur is unknown and would be difficult to measure because of the many concurrent influences on error rates and difficulties standardizing detection and reporting across institutions and over time.

- Unintended Consequences.

One intended consequence that could arise from state-facilitated ADR is an increase in overhead expenses if patients "double dip"—that is, if the first seek resolution first through the ADR process and then, if unsuccessful, turn to the courts. It is unclear as to how often this would happen or to what extent the marginal costs in double-dipping cases would be offset by faster and lower-cost resolutions in other cases.

- Differential Impact on Medicare Beneficiaries.

State-facilitated ADR could prove especially beneficial for Medicare beneficiaries because it provides a resolution process that is more accessible than litigation to patients who are not represented by attorneys. As discussed earlier, elderly patients may have special difficulty finding attorney representation because their expected damages awards tend to be lower than those of younger patients. To be sure, the assistance of an attorney is a powerful benefit in resolution discussions of all kinds, including state-facilitated ADR. But ADR is open to and practicable for patients without attorneys, and

would increase elderly patients' ability to obtain information about their injuries and, possibly, compensation.

4.6.3. Summary

Although related literatures on mediation and CRPs are relevant for understanding the likely effects of state-facilitated ADRs, there is no direct evidence about how programs like Oregon's will affect liability or clinical outcomes. Oregon's experience bears watching and further evaluation, but the low volume of requests for ADR in the program's first year makes rigorous evaluation difficult. While it is reasonable to posit that a similar program that enjoyed wider uptake would have positive effects on all of the outcomes considered, such conclusions cannot be substantiated at this time.

4.7. Judge-Directed Negotiation

Judge-directed negotiation is a process in which medical malpractice lawsuits are routed to a small number of judges who have special expertise and experience adjudicating healthcare cases. Judges volunteer to participate and receive training in mediation skills and clinical medicine ("Medicine For Judges" short courses). The judges are assisted by a Court Attorney, an attorney with medical training who is employed by the court system to help them with the clinical subject matter. The judges take an unusually active role in settlement negotiations by requiring the parties to appear at conferences early and often; offering their own assessment of each party's case (including what they might expect from a jury); and engaging in mediation and "shuttle diplomacy" to attempt to bring the parties closer together in their bargaining positions.²⁴⁶ Attorneys are required to appear with a strong command of the issues in the case and full authority to settle on the spot. In contrast, outside judge-directed negotiation programs, senior attorneys may appear before the judge with little familiarity with the case their junior colleagues have been working up, with the expectation that nothing substantive will be negotiated during early conferences.

The same judge retains responsibility for the case from initiation through trial. This enables the judge to develop and implement a tailored case management plan, develop deep knowledge of the case and, it is hoped, develop a trusting relationship with the attorneys. The attorneys also have greater incentive to cooperate in the process so as not to alienate the judge who will preside at trial. As described by one participating judge, "it's not ADR-type mediation" but more a "judge sitting down and trying to settle a case early on, earlier than they would other cases. It's a mediation technique."²⁴⁷ The goal is to create "an environment in which lawyers view the court as credible, fair, and willing to be involved in the settlement process."²⁴⁸

The primary aim of judge-directed negotiation is to reduce time to disposition, which means lower litigation expenses; quicker access to compensation for patients; quicker resolution of nonmeritorious claims for providers; and, possibly, lower settlement amounts.²⁴⁹ A secondary aim is to reduce the frequency with which cases go to trial, but this proportion is already quite low, generally around 5%.

Judge-directed negotiation in the medical malpractice realm is a new form of "managerial judging," a bundle of techniques through which judges have, over the last 35 years or so, taken a more active role in pretrial case management.^{250,251} The first systematic application of the model to malpractice occurred in New York City beginning in 2010, when AHRQ funded a demonstration project that aimed to expand pilot work by one New York judge.^{172,246} In the demonstration project, which recently concluded,

medical malpractice cases filed in New York against one of the 5 participating hospitals were automatically directed to the program. Participation in the program was mandatory for the parties, although of course individual attorneys could choose not to be very engaged during the conferences they were required to attend.²⁴⁷

4.7.1. Key Design Features and Decisions

- Selection of judges: The success of the judge-directed negotiation program turns on the skill and commitment of the involved judges. Although the judges receive training and support from the Court Attorney, these aids are no substitute for judicial talent and enthusiasm for the program. Thus, judges need to be selected carefully. The New York program recruited judges with a reputation for being skilled mediators; participants also had a strong interest in achieving the objectives of the project. There may be a limited pool of judges with the necessary expertise, skills, and openness to the approach,²⁴⁶ which may limit the size of the program. Hard decisions may need to be made between constraining the size of the program and expanding it to include judges who may be less suited to the role than the “first-round draft picks.”
- Court Attorney: In the New York project, the RN/JD Court Attorney was considered a crucial part of the program architecture, assisting with data collection for purposes of evaluating the program, in addition to supporting the judges. But funding this position adds cost to the program,¹⁵³ and in theory, judge-directed negotiation programs could function without a Court Attorney. Eliminating the position could improve the financial accessibility of the program to cash-strapped jurisdictions, and the administrative aspects of the program could be handled by the court system’s regular administrative personnel.
- Mandatory vs. voluntary participation: New York’s program is mandatory in all cases for the hospitals that committed to participate in it and anyone who sues them in the State of New York. Alternatively, judge-directed negotiation programs could be run on an opt-in basis, like state-facilitated ADR. Anecdotally, New York judges reported that relationships between judges and attorneys, and among attorneys, were strengthened by the “repeat player” aspect of the program that arose from that fact that *every* case involving the hospitals went through the program. Participants came to know and trust one another and develop mutual understandings about how to work together. On the other hand, mandatory participation may produce poor outcomes when participants object to the coercion and are resistant to the judge-directed negotiation approach.
- Training for judges: The amount of formal training in clinical medicine and negotiation skills could range from single-day workshops to in-depth courses, depending on financial and time constraints. Training together may build connections among judges that lead to communication and sharing of experiences later on, reinforcing practices that have been found to promote positive outcomes. However, training takes busy judges away from already-overloaded dockets.

4.7.2. Effects on Key Outcome Variables

The newness of this model for medical malpractice means that there is limited evidence on the effects of judge-directed negotiation. Analysis of final outcomes data from the New York project is underway

and not yet available for public release. However, some interim data from New York, provided in a mid-project report to AHRQ, are available.²⁵²

- Claims Frequency and Costs.

Unless judge-directed negotiation programs come to acquire an unfavorable reputation (e.g., for unfairness or delay) among plaintiff's attorneys, their availability should not discourage the filing of claims. Indeed, it may encourage claims, if plaintiffs and their attorneys know that there is mechanism to facilitate relatively rapid settlement. No data are available on whether lawsuits increased or decreased in New York because of the program.

It was expected that judge-directed negotiation would reduce average payouts. Plaintiffs may be willing to trade off the potential for a larger settlement on the courthouse steps or the chance of a large jury verdict for a reasonable settlement that is reached more quickly. In an early application of the concept in New York City involving one hospital system, the hospital reported that its average payments declined from \$567,000 in 2003 to \$428,000 in 2010,²⁵³ but these are descriptive data that do not account for potentially confounding influences on payment amounts. Subsequent descriptive data provided in the New York demonstration project's report to AHRQ indicated that median settlements were comparable to historical benchmarks in the same borough.²⁵²

- Patient Compensation.

Early results suggest that New York's program has been successful in substantially shortening the median time to resolution relative to historical benchmarks in the same boroughs.²⁵³⁻²⁵⁵ For example, the interim report from the demonstration project reported that among settled cases, the median time to settlement was 370 days, compared to historical medians of 718 days, 952 days, and 1,266 days in the 3 boroughs.²⁵²

Although the reductions reported in the interim analysis are dramatic, the final results will likely show more modest differences. The analyses are (for obvious reasons) based on closed cases only, and the cases that closed early in the project may have shorter settlement times than those that were disposed of later and were not included in the interim analysis. For example, a very complex case with uncertain causation would be expected to require longer to settle than a straightforward case involving clear causation; the latter may have been included in the interim analysis while the former was excluded. Additionally, the final analysis will include multivariate modeling, while the interim analysis was a simple pre/post comparison of descriptive data. The multivariate model controlling for other factors that may explain differences in times to disposition may lead to the conclusion that only a partial share of the difference can be attributed to the judge-directed negotiation program.

In contrast to time to disposition, there is no reason to think that judge-directed negotiation should change other patient compensation outcomes, including the proportion of claims that result in a payment or the vertical or horizontal equity of awards. Nor should it improve access to the civil justice system, because—unlike state-facilitated ADR—it does not reduce the need for attorney representation.

- Overhead Costs.

If the program indeed results in reduced time to resolution, there should be concomitant savings on

overhead costs.²⁵⁵ Even if it does not, litigation costs may decrease because the program causes judges to think carefully about how extensive discovery really needs to be in each case. The individual case management plans specify either full discovery or reduced/expedited discovery (or in some cases, no further discovery). Reducing the scope or length of time for discovery may reduce the amount attorneys spend investigating the case.

- Providers' Liability Costs.

It is much too early to gauge the effects of judge-directed negotiation on insurance premiums. If a sustained drop in insurer losses results from lower settlements and/or litigation expenses, insurers might choose to pass the savings along to providers.

- Healthcare Spending and Defensive Medicine.

If successes from judge-directed negotiation programs are publicized, it might address physician fears about incorrect jury verdicts, leading physicians to conclude that non-meritorious claims are less likely to result in compensation and more likely to be dismissed or abandoned at an early stage. This, in turn, could lead to less defensive medicine and lower healthcare expenditures. However, current evidence does not allow any conclusions to be drawn on these matters.

- Physician Supply/Access to Care.

Following the above logic, if physicians perceive that judge-directed negotiation reduces their risk of incurring a sizeable or unwarranted malpractice payment, they could gravitate towards, or remain in, jurisdictions that offer this program. But again, this is speculative at this point.

- Quality of Care.

No major effect of judge-directed negotiation programs on quality of care is anticipated. The program focuses on speeding resolution of filed lawsuits, not sharpening the deterrent signal sent by tort litigation (for example, by encouraging more filings).

- Unintended Consequences.

Legal scholarship has raised concerns that managerial judging techniques such as judge-directed negotiation may compromise the procedural fairness of the civil justice system.²⁴⁶ Such programs transform the judicial role from one of a detached arbiter of disputes, largely in open court, to one of an activist promoting rapid resolution of disputes, largely in closed chambers. Although judges participating in New York's program stress that they perceive their role as facilitating *resolution* rather than settlement per se, in practice much of the focus of judge-led conferences is on reaching a settlement agreement. While this is a desirable outcome for most plaintiffs, some may prefer to have their proverbial day in court. Yet their attorney may feel pressured to settle the case; and the defense, too, may perceive pressure to agree to a settlement that they feel is unfair.^{246,256} They may worry, for example, that refusing to cooperate may put them out of the judge's good graces when it comes time for trial. Finally, there is always the danger a judge may have biases that unfairly affect the outcome of

negotiations.²⁴⁶ For instance, the same trusting relationships with attorneys that facilitate cooperative resolution of claims might operate to the disadvantage of a newcomer attorney.

Although these concerns should be considered seriously, interim findings from the New York project provide reassurance that both plaintiff and defense attorneys perceive judge-directed negotiation as a fair and valuable process. In survey data collected from attorneys who participated in one of more cases in the program, the overwhelming majority of attorneys on both sides of the litigation expressed high satisfaction with the program and with the fairness with which they and their client were treated.

- Differential Impact on Medicare Beneficiaries.

There is no reason to suspect that Medicare beneficiaries would be differentially affected by judge-directed negotiation programs, but the elderly may be especially appreciative of programs such as this that can expedite time to compensation, particularly if they have low savings or are approaching the end of their life expectancy.

4.7.3. Summary

Judge-directed negotiation has only recently been submitted to empirical study in the medical malpractice context. The current level of evidence available does not allow any firm conclusions to be drawn, although forthcoming final results from the New York demonstration project should be helpful. Interim, descriptive data from New York suggest that the program may reduce time to settlement but not significantly affect average payments. Theoretically, if resolutions are expedited, overhead costs should be reduced, although this has not been measured. How judge-directed negotiation affects the number of claims filed, defensive medicine and healthcare costs, physician supply, and quality of care is unknown. In terms of unintended consequences, procedural fairness concerns merit further study, although preliminary indications are that in New York, perceptions of unfairness were not a problem.

5. Conclusions

The findings of our analysis of the effects of traditional and innovative tort reforms are detailed in Exhibit 1. In brief, we find that the evidence base for evaluating many traditional state tort reforms is large and mature, allowing some reasonable conclusions to be drawn regarding effects on liability system performance as well as clinical outcomes. The evidence base is sufficient to support the following conclusions:

- Noneconomic damage caps are associated with reduced claims frequency, lower compensation award amounts, lower liability premium costs for physicians, reductions in some types of defensive medicine, higher physician supply, and shorter time to settlement—but may have disproportionately large effects on claiming by the elderly.
- Pretrial screening panels have no significant effect on claims frequency or compensation amounts.
- Attorney fee limits have no significant effect on claims frequency, compensation amounts, liability insurance premiums, or physician supply.
- Joint-and-several liability reform has no significant effect on compensation amounts, liability insurance premiums, physician supply, or quality of care.

- Collateral-source rule reform has no significant effect on claims frequency, compensation amounts, liability insurance premiums, defensive medicine, physician supply, or health insurance coverage rates.
- Periodic payment has no significant effect on claims frequency, compensation amounts, physician supply, or patient care outcomes.
- Shorter statutes of limitation/repose have no significant effect on compensation amounts, but are associated with lower liability insurance premiums.

The evidence base is too small, or study findings are too mixed, to support inferences regarding the relationship of the traditional reforms to other outcomes.

The evidence base for evaluating the innovative tort reforms is much smaller than the literature regarding traditional reform. Most of these reforms have not been tested in the U.S., and where experimentation has taken place, few data from systematic evaluations are publicly available. Analogous systems in the U.S. and abroad provide some insight, but are likely not clearly predictive of how these systems would function in the American medical liability setting, and much depends on the key choices in system design. Of the innovative reform methods, there is some evidence in the U.S. concerning one reform: CRPs. Early data suggest that CRPs may reduce claims frequency, compensation amounts, time to resolution, overhead costs, and liability premiums. In general, though, the limited evidence on the evaluated innovative reforms demonstrates the need for further experimentation and evaluation. Although few hard data are available concerning the innovative reforms we evaluated, based on theoretical predictions and the limited evidence available, all of these reforms likely merit further experimentation in the U.S.

Using paid claims data in the NPDB PUF, we also examined paid claims counts, compensation amounts, and trends over time and explored whether there are differences in these characteristics between elderly Medicare patients (aged ≥ 70) and younger patients (aged < 60). The analysis found that over the last decade, the number of claims reported to the NPDB has declined markedly, but that decline has been driven almost entirely by paid claims for younger individuals; paid claims counts for the elderly have remained stable. Paid claims for elderly Medicare patients were more likely than claims involving younger patients to involve severe injuries, and to be related to medication, anesthesia, treatment, or monitoring; they were less likely to be diagnosis-related. Finally, payments for the elderly were significantly lower than those for younger individuals.

The NPDB PUF claims analysis did not provide direct data bearing on how traditional or innovative reforms might differentially affect Medicare beneficiaries, but some insights can be gleaned from considering the NPDB results alongside the tort reform literature review and theoretical considerations. For example, the NPDB claims analysis found that the mean award for elderly Medicare patients is about \$230,000 (compared to about \$420,000 for younger patients), which puts a large proportion of settlements and awards to Medicare beneficiaries beneath the threshold for the damage caps in most states. This suggests that caps may affect elderly claimants less often than they affect younger claimants—although when they do apply, they tend to take a disproportionately large share of the award for elderly patients. Further, the tort reform literature suggests that caps have a disproportionate effect on of claims being filed by the elderly. Attorney fee limits, which may reduce incentives for lawyers to take smaller cases, may also disproportionately impair the ability of Medicare beneficiaries to access the legal system. Finally, collateral-source rule reforms may disproportionately burden Medicare beneficiaries, because they tend to have more significant injuries that likely require more medical care, yet they also tend to receive smaller awards.

With regard to the innovative reforms, it is difficult to draw any conclusions on which of these reforms may differentially impact Medicare beneficiaries. However, several such reforms make it easier to access legal redress without the aid of an attorney. To the extent the elderly face particular problems finding attorneys willing to take their malpractice cases, these reforms could disproportionately benefit the elderly (along with other claimants whose damages are relatively low). The reforms in question include the administrative model of health courts, CRPs, mandatory pre-suit notification laws, apology laws, and state-facilitated ADR. Finally, safe harbors may have less of claim-reducing effect for the elderly than for younger patients because clinical guidelines (which would operate to protect physicians) often are targeted at younger patients.

In closing, two important limits on the scope of our analysis should be noted. First, this report has not considered how the various reforms could be implemented through the Medicare program. However, other scholarship provides some insights.^{119,257-259} Second, constitutional and other legal barriers to implementing these reforms have been noted only selectively and in passing. They merit much more serious consideration in any process of further experimentation or implementation.

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