

FROM INFORMED CONSENT TO SHARED DECISION MAKING: HOW PATIENT DECISION AIDS CAN IMPROVE PATIENT SAFETY AND REDUCE MEDICAL LIABILITY RISK

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ABSTRACT

In April 2017, I published “Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law” in the *Journal of Law, Medicine and Ethics*. In that Article I defended both a negative thesis and a positive thesis. My negative thesis was that tort-based doctrines of informed consent have utterly failed to assure that patients understand material risks and benefits of the healthcare they are receiving. Fifty years of experience with the doctrine of informed consent have shown it to be an abject failure. My positive thesis was that patient decision aids (PDAs) and shared decision making offer a more promising path to empowering patients and to bridging the wide gap between the theory and practice of informed consent.

This Article is more practical. It concentrates on implementing solutions rather than on merely identifying them. This is an important objective, because despite robust evidence of substantial effectiveness, few U.S. clinicians are using PDAs when they deliver healthcare services. This must change. We should move PDAs from research to practice, from the lab to the clinic. In light of the prior article, I take this as a starting axiom. Accordingly, this Article does not focus on whether clinicians should be using PDAs. Instead, it focuses on how to provide clinicians with sufficient incentives, so that they will employ PDAs with their patients.

It is important to place these objectives in context. A shift from traditional models of physician-patient communication represents a paradigmatic change in the delivery of healthcare. This Article cannot possibly address the whole waterfront of challenges required to accomplish such a huge transition.

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[^] This is a relatively early draft. It is developed sufficiently for workshopping purposes. But it should be read in conjunction with my 2017 *JLME* article. The author warmly welcomes reader comments.

Instead, it has a narrower mission. It offers one key tool for the broader toolbox. Specifically, this Article makes the case for designing and offering clinicians the incentive of a professional liability insurance premium reduction. I direct my argument to medical malpractice insurance companies, because they are able to offer this incentive. To reach this intended audience most effectively, I plan to publish this Article in the *Journal of Healthcare Risk Management* or a similar journal.

My message for the healthcare risk management community is straightforward. I argue that medical malpractice insurance companies can and should encourage clinicians to use PDAs by offering premium discounts. These premium incentives will spur PDA use. In turn, PDA use will improve patient safety. Obviously, that benefits patients. But it also benefits malpractice insurers. Because discounting premiums necessarily reduces revenue, this argument needs justification. Accordingly, the bulk of this Article establishes the value proposition. I demonstrate several distinct ways in which using PDAs lowers liability risk.

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I. INTRODUCTION

Each year, the United States spends more than \$3 trillion on healthcare.¹ Over 60% of that amount is for only three services and products: (1) hospital care, (2) physician and clinical services, and (3) prescription drugs. Most of the healthcare in these three categories is “preference sensitive.”²

As the term “preference sensitive” suggests, the patient’s personal values determine the optimal choice at decision junctures. There is no clear objective evidence to support one intervention over another. Clinicians cannot determine the “correct” or “best” treatment option solely as a matter of medical science. Instead, there are usually legitimate alternative options that involve significant tradeoffs. For example, some people will prefer to accept a small risk of death to improve their function. Others will not make that tradeoff. Which option is best for any particular patient is heavily value-laden. Consequently, decisions about these interventions should reflect the patient’s

¹ Anne B. Martin et al., *National Health Spending: Faster Growth In 2015 As Coverage Expands and Utilization Increases*, HEALTH AFFAIRS (2017).

² Dartmouth Atlas Project, *Preference Sensitive Care*, http://www.dartmouthatlas.org/downloads/reports/preference_sensitive.pdf

own values and preferences.³

Unfortunately, clinicians rarely effectively assess whether a treatment they recommend matches the values and preferences of the patient who is getting that treatment. In other words, clinicians fail to determine whether patients “want” the treatments that they are getting. U.S. clinicians elevate clinical diagnosis over preference diagnosis.⁴ While clinicians are skilled at diagnosing the patient’s body, they devote far less effort to diagnosing the patient’s preferences. The result is a tsunami of unwanted medical treatment.⁵

The purpose of this Article is to pave a path toward better patient engagement and informed consent by paving a path toward greater use of patient decision aids (PDAs). We already know that these evidence-based educational tools result in more educated and engaged patients.⁶ But PDAs remain largely ignored. Uptake remains sparse and the promise of PDAs remains elusive. I argue that medical malpractice insurance companies can and should encourage clinicians to use PDAs by offering premium discounts. These premium incentives will spur PDA use. In turn, PDA use will improve patient safety.

I unfold this argument in five stages. In Section Two, I summarize the now enormous data demonstrating the effectiveness of PDAs to achieve value-congruent care. Unfortunately, despite this robust data, very few clinicians use PDAs. To address this dearth, in Section Three, I describe and defend one element of a broader strategy to promote wider uptake. Medical liability insurers should incentivize PDA use by offering premium discounts. Because clinicians will want to obtain this cost savings, premium reductions will spur more clinicians to use PDAs with their patients.

In the remainder of the Article, I show how this approach makes good economic sense for malpractice carriers. I explain that offering these premium incentives reduces liability risk, because they increase PDA use. In turn, PDAs reduce risk in two fundamental ways. In Section Four, I show how PDAs reduce the risk from negligent nondisclosure claims. In Section Five, I show how PDAs reduce the risk from medical malpractice claims. In Section Six, I concede that using PDAs introduces some new liability risks. But I argue these are minimal relative to their risk reducing benefits. Finally, in Section Seven, I

³ 42 U.S.C. § 299b-36(b)(2).

⁴ A. MULLEY, C. TRIMBLE, & G. ELWYN, *PATIENTS’ PREFERENCES MATTER: STOP THE SILENT MISDIAGNOSIS* (London: King’s Fund 2012).

⁵ Thaddeus M. Pope, *Legal Briefing: New Penalties for Ignoring Advance Directives and Do-Not-Resuscitate Orders*, 28(1) J. CLINICAL ETHICS 74 (2017).

⁶ Dawn Stacey et al., *Patient Decision Aids to Engage Adults in Treatment or Screening Decisions*, 318(7) JAMA 657 (2017).

conclude that the cost-saving incentive from lower malpractice insurance premiums is one key measure that can push PDAs from research to practice.

II. UNREALIZED PROMISE OF PATIENT DECISION AIDS

Already, over 130 randomized controlled studies show that PDAs help patients gain significant knowledge and understanding of their treatment choices. The evidence on PDA effectiveness is substantial. But their use still remains mostly limited to investigational trials.

A. What Are Patient Decision Aids?

PDAs are evidence-based educational tools. They take various forms. They include educational literature with graphics, photographs, and diagrams. They also take the form of decision grids, videos, and website-based interactive programs such as sequential questions with feedback. PDAs might even include “structured personal coaching.”

PDAs help patients do three things.⁷ First, PDAs help patients understand the various treatment options available to them, including the risks and benefits of each choice. Second, they help patients communicate their beliefs and preferences related to their treatment options. Third, PDAs help patients decide with their clinicians what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.⁸

No matter what form they take, the best PDAs provide an appropriate presentation of the condition and treatment options, benefits, and harms. They have three key advantages over the traditional informed consent process. First, the information in the PDA is accurate, complete, and up-to-date. Second, the PDA presents the information in a balanced manner.⁹ Third, the PDA conveys the information in a way (often graphically) that helps patients understand and use it. PDAs are truly patient-centered.

B. Patient Decision Aids Are Effective.

Robust evidence shows that shared decision making with PDAs meaningfully empowers patients. In contrast to traditional informed consent, shared

⁷ Thaddeus M. Pope, *Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law*, 45(1) J. L. MED. & ETHICS 12 (2017).

⁸ Dawn Stacey et al., *Decision Aids for People Facing Health Treatment or Screening Decisions*, COCHRANE LIBRARY, 10.1002/14651858.CD001431.pub5 (April 2017).

⁹ PDAs do not advise people to choose one option over another, nor do they replace clinician consultation.

decision making deliberately takes into account both the best scientific evidence available, as well as the patient's values and preferences.

PDA's meaningfully inform and guide both of these elements. First, PDA's provide relevant information on healthcare options, helping patients gain significant knowledge and understanding of their choices. Second, PDA's give patients control over the pace and timing of their education. And they permit patients to share that information with family.

Finally, PDA's prompt reflection, helping patients to form and clarify their values and preferences. PDA's thereby enhance deliberation by helping patients discover and associate their values and preferences with their healthcare options, and then communicate those associations to their provider. Together, the provider and patient make a treatment choice that aligns with the patient's values. PDA's help make the patient engaged, equipped, empowered, and enabled.

Randomized controlled trials are considered the most reliable form of scientific evidence in the hierarchy of evidence that influences healthcare policy and practice. Over 130 RCT's demonstrate that PDA's significantly enhance patients' knowledge of treatment options, risks, and benefits. Summarizing the benefits identified in these RCT's, a recent Cochrane review concluded that using PDA's can lead to patients:

- (1) Gaining significant knowledge
- (2) Having a more accurate understanding of risks, harms and benefits
- (3) Feeling less conflicted about decisions
- (4) Rating themselves as less passive and less often undecided¹⁰

In short, once patients understand their choices, they are better able to align their care with their preferences and values.

For these reasons, influential healthcare organizations from the Institute of Medicine to the Joint Commission have recognized these benefits.¹¹ And they have encouraged the widespread adoption of PDA's. For example, in its influential 2001 *Crossing the Quality Chasm* report, the Institute of Medicine recommended greater use of decision aids to ensure that patients' treatment

¹⁰ Stacey et al., *supra* note XX.

¹¹ The Joint Commission, *Informed Consent: More Than Getting a Signature*, QUICK SAFETY ISSUE 21 (February 2016),
<https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf>.

decisions are consistent with their preferences and values.¹² In 2014, the Institute of Medicine again reviewed the literature on shared decision making in clinical practice and reaffirmed the value of PDAs. It found that PDAs “trigger the robust communication that is necessary for shared decision making to occur.”¹³

C. Too Few Clinicians Are Using PDAs.

Despite robust evidence of effectiveness and despite influential recommendations to expand PDA use, widespread adoption has not happened. The use of PDAs has “not become the norm.”¹⁴ They remain “seldom adopted”¹⁵ and “rare in everyday practice.”¹⁶ The research is here. But implementation remains sparse and incomplete. “Practice lags behind” the evidence.¹⁷

The Institute of Medicine recently lamented that “the promise of shared decision making remains elusive.” Others agonize that the potential of PDAs remains “unrealized.”¹⁸ In short, a key challenge is to move PDAs from

¹² INSTITUTE OF MEDICINE, CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001).

¹³ See Alston et al., *supra* note XX.

¹⁴ *Id.*

¹⁵ See Gillick, *supra* note XX.

¹⁶ L. Hole-Curry, *State Legislation Promotes Use of Shared Decisionmaking through Demonstration Project, Learning Collaborative and Recognition of Decision Aids as Informed Consent*, AHRQ Health Care Innovations Exchange (August 28, 2013), *available at* <https://innovations.ahrq.gov/profiles/state-legislation-promotes-use-shared-decisionmaking-through-demonstration-project-learning>.

¹⁷ See Durand et al., *supra* note XX (“The well-documented implementation challenge has led to significant interest in developing incentives . . .”); Trenamon, *supra* note XX; O’Connor, *Health Affairs* (2007); A. Engelen et al., *Patients’ Views on Using Decision Support Tools: A Systematic Review*, 4(1) EUROPEAN JOURNAL FOR PERSON CENTERED HEALTHCARE (2016); C.A. Austin, *Tools to Promote Shared Decision Making in Serious Illness: A Systematic Review*, 175(7) JAMA INTERNAL MED. 1213 (2015); J.A. Tulsky, *Decision Aids in Serious Illness: Moving What Works into Practice*, 175(7) JAMA INTERNAL MED. 1221 (2015); C.L. Lewis et al., *Developing and Evaluating a Clinic-Based Decision Aid Delivery System*, MMD POLICY & PRACTICE 1 (2016); M.J. Barry, *Resolving the Decision Aid Paradox*, 175(5) JAMA INTERNAL MED. 799 (2015). See also C. E. Cox et al., *Development and Pilot Testing of a Decision Aid for Surrogates of Patients with Prolonged Mechanical Ventilation*, 40(8) CRITICAL CARE MED. 2327, 2327 (2012) (“Although the use of shared decision making is endorsed by many major critical care professional societies, its implementation in the intensive care unit is incomplete and infrequent.”); G. Sinha, *Decision Aids Help Patients but Still Are Not Widely Used*, 106(7) J. NAT’L CANCER INST. 6 (2014); Cf. M. L. Schwarze and M. J. Nabozny, *How People Die in 2014*, 260(6) ANNALS SURGERY 958 (2014) (“In contrast to the pace and complexity of technological innovation, innovation in communication has been nearly stagnant.”).

¹⁸ See Alston et al., *supra* note XX, at 2. See also Hole-Curry, *supra* note XX; “[T]he road to fully integrating SDM into clinical practice likely will be long and winding.” Alston et al., *supra*

research to use, from the laboratory to the clinic.

III. MEDICAL LIABILITY INSURERS SHOULD INCENTIVIZE PDAs BY OFFERING PREMIUM DISCOUNTS.

A variety of tools might incentivize greater use of PDAs.¹⁹ For example, some health insurers are conditioning payment on the use of a PDA. One of the nation's biggest payers, Medicare, will not reimburse clinicians for two procedures unless the billing clinician uses a PDA.²⁰ Yet, while not totally unheard of, reimbursement incentives remain sparse. Consequently, medical malpractice premium reductions are an important complementary incentive.

A. Medical Malpractice Insurers Already Use Premium Discounts to Incentivize Other Safe Conduct.

Most of us are familiar with insurance incentives for safe conduct. Our auto, home, and life insurance companies all use past claims experience to determine rates. An insured with prior car accidents, house fires, or robberies is going to pay higher premiums than someone with a clean record. This is known as 'experience rating.'²¹ Your claims "experience" determines your "rate."

In contrast to most other types of insurance, commentators have traditionally understood medical malpractice insurance to eschew experience rating.²²

note XX, at 25. While overall use remains low, PDAs are used in some facilities and systems, like the Massachusetts General Hospital and Seattle-based Group Health. *See, e.g.,* K. R. Sepucha, *Ten Years, Forty Decision Aids, And Thousands of Patient Uses: Shared Decision Making at Massachusetts General Hospital*, 35(4) HEALTH AFFAIRS 630 (2016); M. Hostetter & S. Klein, *Quality Matters: Helping Patients Make Better Treatment Choices with Decision Aids*, THE COMMONWEALTH FUND (2012).

¹⁹ Angela Coulter, *Shared Decision Making: Everyone Wants It, So Why Isn't It Happening?* 16(2) WORLD PSYCH. 117 (2017) ("A comprehensive strategy is required to promote wider uptake of SDM."). For example, state mandates disclosures might be fulfilled through PDAs rather than through dense text heavy documents. *See, e.g.,* http://www.mbc.ca.gov/Publications/publication_matrix.pdf

²⁰ Centers for Medicare & Medicaid Services (CMS), *Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)* (CAG-00439N), available at <<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274>>; Centers for Medicare and Medicaid Services, *Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy* (CAG-00445N), available at <<https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281>>.

²¹ Frank A. Sloan, *Experience Rating: Does It Make Sense for Medical Malpractice Insurance?* 80(2) AM. ECON. REV. 128 (1990).

²² Gary M. Fournier & Melayne Morgan McInnes, *The Case for Experience Rating in Medical Malpractice Insurance: An Empirical Evaluation*, 68(2) J. RISK & INS. 255 (2001); William M. Sage, *Medical Malpractice Insurance and the Emperor's Clothes*, 54 DEPAUL L. REV. 463 (2005).

Instead, a clinicians' rates have generally determined more by geographical location and specialty. For example, because of legislative tort reform, premiums are generally lower in California and Texas and higher in Florida. Similarly, premiums are cheaper for low-risk specialties like dermatology and more expensive for high-risk specialties like obstetrics and surgery.

But this standard story oversimplifies things. First, medical malpractice insurers may not look at claims experience to set rates among their existing policyholders. But they do look at claims experience to determine whom to accept as a policyholder in the first place.²³ Second, many carriers consider claims experience in an additional way. They discount premiums by up to 20% for favorable claims history.²⁴ Third, and most relevant to PDA incentives, most carriers adjust rates downward when the policyholder takes action that reduce liability risk.²⁵ Here are just three examples.

Example One. Consolidated Risk Insurance Company (CRICO), is the medical malpractice company owned by, and serving, the Harvard medical community. In 2001, CRICO introduced a 6% incentive for anesthesiologists who received training in Crisis Resource Management at the Center for Medical Simulation. A few years later, after examining the claims experience of anesthesiologists who participated in the program compared to those did not, CRICO concluded that the program was effective and increased the discount to 19%.²⁶ Today, premium rates for anesthesiologists with simulation training are 43% lower than for physicians without training.²⁷

Based on the favorable track record for the anesthesiologists, CRICO started offered a 10% incentive for OB/GYN physicians who participated in a similar simulation-based training program. Today, premium rates for OB/GYN physicians with simulation training are 26% lower than for physicians without training.²⁸ In short, clinicians with the training have fewer claims. So, the premium discount more than pays for itself.

²³ Shirley Svorny, *Could Mandatory Caps on Medical Malpractice Damages Harm Consumers?* CATO POLICY ANALYSIS No. 685 (Oct. 20, 2011).

²⁴ [CITE]

²⁵ Sage, *supra* note XX at 479 n.66 (advocating for expanding “premium discounts using process-based quality indicators”).

²⁶ Jack McCarthy and Jeffrey B. Cooper, *Malpractice Insurance Carrier Provides Premium Incentive for Simulation-Based Training and Believes It Has Made a Difference*, ANESTHESIA PATIENT SAFETY FOUNDATION NEWSLETTER (Spring 2007).

²⁷ Denise W. Gee, *Using Simulation to Decrease Medical Liability Risk*, CRICO PPT at 34 (Mar. 14, 2015).

²⁸ *Id.*

Example Two. NORCAL is the eighth largest medical professional liability insurance carrier in the United States.²⁹ It covers more than 27,000 policyholders in 35 states. NORCAL encourages its policyholders to take risk management courses. These often take the form of 45-minute webcast videos. Successfully completing several courses sends a notification to NORCAL, who credits the policyholder with a discount of around 5% in the next policy renewal cycle. This results in savings of hundreds or sometimes thousands of dollars in comparison to a non-discounted premium.

Example Three. Malpractice insurance carriers are increasingly offering discounts to physicians for using an Electronic Medical Records (EMR) system. The theory is that the EMR system reduces risk by helping to eliminate some of the most common reasons for claims. These often have to do with oversights on patient record reviews (e.g. reading x-rays) or notifying patients of prescription refills. The EMR discounts generally range from 2½ to 5% of the premium.³⁰

These three examples illustrate that medical malpractice carriers are already discounting premiums both to incentivize and to reward risk-reducing behavior.³¹ They recognize that policyholders who engage in risk reducing behavior are safer, cheaper customers to service.³²

B. Offering Discounts Will Spur Wider PDA Uptake.

Like the training and education programs that medical malpractice insurers have already linked to premium incentives, PDAs will also reduce liability risk. Therefore, medical malpractice insurers should extend these premium discounts to clinicians who use PDAs with their patients. “The time has come for the actuarial profession to join the patient safety battle, to focus energy on preventing injuries rather than just dealing with their aftermath.”³³ With PDAs, medical malpractice insurers can obtain the same objectives and benefits they now achieve from existing incentives.

The evidence suggests that premium discounts for PDAs would successfully spur wider uptake. First, medical malpractice carriers have already proven that offering premium reductions for risk reducing behaviors like training and

²⁹ <https://www.norcal-group.com/about>

³⁰ <http://www.covermd.com/Resources/Medical-Malpractice-Insurance-Rates.aspx>

³¹ Similarly, automobile insurance companies typically offer discounts when policyholders take accident prevention courses or driver training, install anti-theft devices, or take other risk reducing actions. [CITE]

³² <https://www.norcal-group.com/hello>

³³ Kevin M. Bingham & John Lucker, *It's the Right Time for Right Pricing in Medical Malpractice Insurance*, CONTINGENCIES (July/Aug. 2005) at 74-75.

education prompts policyholder clinicians to adopt that behavior. After all, everyone wants to save money.³⁴ Second, there is some closely related experience with incentives for consent-enhancing measures.

Take for example, the Barrow Neurological Institute in Phoenix, Arizona.³⁵ This elite specialty center routinely offers patients video recordings of their visits. This helps patients, because being able to listen again helps them improve their recall and understanding of medical information, and share the information with family members.³⁶ Because this program has been successful, participating clinicians get a “10% reduction in the cost of their medical defense and \$1 million extra liability coverage.”³⁷

IV. PDAS REDUCE LIABILITY RISK FROM NEGLIGENT NONDISCLOSURE CLAIMS.

It is necessary but not sufficient to establish that offering premium discounts will drive clinicians to use PDAs. Medical malpractice insurers will not offer the discounts unless they are confident that the increased use of PDAs will benefit not only the patient but also themselves. Premium discounting must make economic sense for the companies offering the discount.

This is the thesis that I will now defend. In this section I show how PDAs reduce liability risk from negligent nondisclosure claims. In the next section, I show how PDAs reduce liability risk from medical malpractice claims.

There are three ways in which PDAs reduce liability risk from negligent nondisclosure. First, using PDAs often earns clinicians a “shield” from liability. Second, failing to use PDAs will increasingly be used as a “sword” to find clinicians liable. Third, using PDAs save significant claims processing resources.³⁸

³⁴ Because risk management education is inexpensive, it is easy to find that premium discounts are worth the required investment. Whether this is similarly true for PDAs will depend on the cost of the PDAs.

³⁵ <https://www.barrowneuro.org>

³⁶ M. Tsulukidze et al., *Providing Recording of Clinical Consultation to Patients—A Highly Valued but Underutilized Intervention: A Scoping Review*, 95(3) PATIENT EDUC. & COUNSELING 297 (2014).

³⁷ Glyn Elwyn et al., *Can Patients Make Recordings of Medical Encounters? What Does the Law Say?* 318(6) JAMA 513 (2017).

³⁸ A fourth way in which PDAs can lower risk is through better documentation. Documenting informed consent using paper forms exposes the hospital to the risk of missing forms, improper documentation and the associated liabilities. One study found missing consent forms in 66% of procedures. Jacqueline M. Garonzik-Wang et al., *A Single-Center Assessment of the Scope of the Problem and Its Downstream Effects*, 148(9) JAMA SURGERY 886 (2013). PDAs facilitate better documentation which will help defend a negligent nondisclosure claim. Cf. Amber M. Klimczak, *Medicolegal Review: Essure Lawsuits and Legal Strategies Adverse to*

A. Medical Liability Insurers Face Significant Risk Exposure for Negligent Nondisclosure Claims.

Negligent nondisclosure is one of the top reasons that patients sue clinicians.³⁹ For example, in a review of its cases from 2008 to 2010, CRICO found that 484 of its 1160 cases involved communication factors such as inadequate informed consent, inadequate discharge instructions, or inadequate follow-up instructions.⁴⁰ The insurer incurred \$264 million in these cases.

B. Carrots and Shields: Using PDAs Enhances Liability Protection.

Liability law can guide conduct by serving as a shield or as a sword.⁴¹ A shield serves as a carrot by offering protection for specified conduct. Two examples of how PDAs serve as carrots and shields are de jure safe harbor legal immunity and de facto safe harbor legal immunity. First, some states expressly provide statutory protection to clinicians using PDAs. Second, PDAs serve a “protective” function even without express statutory terms. Jurors typically conclude that clinicians who use PDAs have satisfied their disclosure duties.

1. De Jure Safe Harbor Legal Immunity

The most concrete example of how using PDAs can reduce liability risk from negligent nondisclosure is in Washington State. In 2007, the state enacted legislation establishing what is practically safe harbor legal immunity. The statute affords materially increased legal protection to physicians who use PDAs during informed consent discussions.⁴²

Specifically, the Washington statute provides that “if a patient . . . signs an acknowledgment of shared decision making [with] patient decision aids . . . such acknowledgment shall constitute prima facie evidence that the patient gave his or her informed consent to the treatment administered.”⁴³ Moreover, the statute requires patients to overcome this presumption with “clear and convincing evidence.”⁴⁴

Gynecologists, 24(5) J. MINIMALLY INVASIVE GYNECOLOGY 727 (2017).

³⁹ [CITE]

⁴⁰ Jock Hoffman & Supriya Raman, *Communication Factors in Malpractice Cases*, CRICO INSIGHTS NEWSL. <https://www.rmhf.harvard.edu/Clinician-Resources/Newsletter-and-Publication/2012/Insight-Communication-Factors-in-Mal-Cases>.

⁴¹ See Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645 (2001).

⁴² REV. CODE WASH. § 7.70.060.

⁴³ REV. CODE WASH. § 7.70.060(2).

⁴⁴ *Id.*

This is significantly more demanding than the typical burden, “preponderance of the evidence.” Under Washington law, a “regular” signed consent form constitutes prima facie evidence that the patient gave her informed consent to the treatment administered. The patient has the burden of rebutting this by a preponderance of the evidence (showing it >50% likely that her consent was not informed). In contrast, a patient’s signed “acknowledgment” of shared decision making also constitutes prima facie evidence that the patient gave his or her informed consent to the treatment administered. But the patient has the heavier burden of rebutting this presumption by “clear and convincing evidence.”

In short, the use of a certified PDA offers clinicians added legal protection by materially changing the patient’s burden of proof. In contrast to the usual preponderance of the evidence standard under which a patient would have to show that her consent was probably (>50%) not informed, a patient must instead more confidently establish (>75%) that her consent was not informed.⁴⁵

While only Washington State has a statute that provides enhanced liability protection for using a PDA, other states are likely to follow. Washington enacted its safe harbor statute in 2007. But the state linked statutory protection to only “certified” PDAs.⁴⁶ Washington did not certify its first PDAs (relating to obstetrics and maternity care) until 2016.⁴⁷ Consequently, it may be a few years before there is a track record showing that the incentive works.

2. De Facto Safe Harbor Legal Immunity

Even in those states without a statutory safe harbor, clinicians may earn de facto liability protection by using a PDA. In an instructive study, prospective mock jurors found that clinicians followed the standard of care when care decisions emerged from the use of PDAs.⁴⁸ The study suggested that a PDA provides greater protection against a determination of malpractice than the clinician’s word or a medical record note about provision of information.

⁴⁵ This is my own ballpark estimate. The law does not assign specific percentage values to various burdens of persuasion. J.P. McBaine, *Burden of Proof Degrees of Belief*, 32 CAL. L. REV. 242 (1944). But in one survey of judges, most selected 75% as the appropriate percentage value for “clear and convincing evidence.” M.B. Steinberg, *Burdens of Persuasion: Burdened by Too Many Burdens*, 23 BALTIMORE L. FORUM 3 (1992).

⁴⁶ Pope, *supra* note XX.

⁴⁷ <https://www.hca.wa.gov/about-hca/healthier-washington/patient-decision-aids-pdas>

⁴⁸ Michael J. Barry et al., *Reactions of Potential Jurors to a Hypothetical Malpractice Suit Alleging Failure to Perform a Prostate-specific Antigen Test*, 36 J. L. MED. & ETHICS 296 (2008).

Presenting a PDA to mock jurors educated them about the complexity of the situation, documented content that had been presented to the “patient,” and demonstrated that the “physician” had taken great care to support the patient's knowledge and decision-making.⁴⁹ Use of the PDA seemed to prevent the situation when jurors might feel that a test or procedure should have been undertaken as a precaution, despite evidence or patient preferences to the contrary.⁵⁰

C. Sticks and Swords: Failing to Use PDAs Increases Risk of Liability for Negligent Nondisclosure.

While Washington State uses the law as a “shield” or “carrot” to motivate clinicians to use of PDAs, other states may instead use the law as a “sword” or “stick.” First, states with detailed disclosure mandates are likely to require PDAs to fulfill those mandates. Second, PDA use is likely to become a duty in the 20+ states that follow the reasonable patient material risk standard.

1. Disclosure Mandates and Presumptions of Negligence

In 1977, the Texas legislature created the Texas Medical Disclosure Panel. The TMDP is a panel appointed by the Commissioner of Health that consists of six physicians and three attorneys. Its purpose is to determine which risks health care providers must disclose to their patients (or persons authorized to consent for their patients). The TMDP is also charged with establishing the general form and substance of such disclosure.⁵¹

If the provider complies with the procedures established by the TMDP, the statute provides a “rebuttable presumption” that the provider was not negligent in obtaining informed consent. If a provider wants to be able to assert the rebuttable presumption that he or she has complied with the duty of disclosure, the provider must make the disclosure “in the form and to the degree required by” the TMDP.⁵² Therefore, in obtaining consent for a specified procedure, the provider should disclose the risks identified by the TMDP for that procedure and use the TMDP’s consent form.

⁴⁹ *Id.*

⁵⁰ *Cf.* Neil H. Ekblom, *Limit Lawsuits by Mitigating Risk*, OPTHALMOLOGY MGMT. (April 2017) (noting that clear documentation deters claims).

⁵¹ TEX. CIV. PRACTICES & REM. CODE §§ 74.101-74.107; 25 TEX. ADMIN. CODE §§ 601.1-601.8.

⁵² TEX. CIV. PRACTICES & REM. CODE § 74.105.

In a health care liability claim by a patient against a provider alleging negligent failure to disclose the risks of a medical treatment, if the provider disclosed the risks identified by the TMDP, there is a rebuttable presumption that the provider was not negligent. The patient must then present evidence to overcome or rebut the presumption that the provider fulfilled his or her duty to disclose risks and hazards to recover on the claim.⁵³

This rule looks like the Washington State presumption. But there is an important difference. The Washington statute provides a shield but no sword. “Failure to use a form or to engage in shared decision making, with or without the use of a patient decision aid, shall not be admissible as evidence of failure to obtain informed consent.”⁵⁴ In contrast, Texas adds a sword.

If a Texas provider fails to disclose the specific risks and hazards identified by the TMDP or to use the TMDP’s form, in the event of a health care liability claim on the issue of informed consent there will be a rebuttable presumption that the provider was negligent and failed to fulfill the duty of disclosure. The provider must then present evidence to rebut the presumption of negligence.⁵⁵

While the TMDP disclosure forms are now text documents, the TMDP is likely to replace these requirements with PDAs. At that point, failure to use a PDA will increase the clinician’s risk of liability for negligent nondisclosure.

2. Growing Risk of Liability under the Reasonable Patient Disclosure Standard.

The way courts measure the scope and extent of informed consent duties varies from state to state. Most states follow either of two dominant disclosure standards. Around 25 states follow the malpractice (aka “physician-based,” “professional” or “custom-based”) standard. The other 25 states follow the material risk (aka “patient-based” or “lay”) standard. There is probably now a duty to discuss costs under the material risk standard.

Malpractice Standard. The malpractice standard requires physicians to provide only the information that a hypothetical reasonably prudent physician would disclose in the same circumstances. The custom and practice of the medical profession set the standard. While a minority of states set geographical limitations, in most states a physician must disclose the same information that a reasonable physician in the United States would disclose under the circumstances. Because most physicians typically do not use PDAs with their

⁵³ TEX. CIV. PRACTICES & REM. CODE § 74.106.

⁵⁴ WASH. REV. CODE § 7.70.060(5).

⁵⁵ TEX. CIV. PRACTICES & REM. CODE § 74.106.

patients, there is no duty to do so.

Material Risk Standard. While the malpractice standard is physician-defined, the material risk standard is patient-defined. It requires physicians to provide all the information that a hypothetical reasonable patient would consider important or significant in making a treatment decision. This disclosure duty is broader than the malpractice standard and increases the burden on physicians.⁵⁶ After all, a reasonable patient may deem information material even if the medical profession does not customarily discuss that information. In light of the compelling evidence on PDA effectiveness, it is likely that a reasonable patient would want to know about that tool. Consequently, there may be a duty to use it.

D. Using PDAs Saves Significant Claims Processing Resources.

The most obvious way in which PDAs can reduce risk management costs from negligent nondisclosure claims is by reducing the risk of liability. But it is not the only way. Resource consumption for the resolution of such complaints far exceeds their proportional representation of complaints. While they represent only one-half of all complaints, they disproportionately absorb two-thirds of staff time devoted to complaint resolution.⁵⁷

Researchers measured the resources used during internal resolution of complaints by document complexity and length, plus document counts and staff involvement. For example, physician and non-physician staff time involved in producing required documents includes:

- Electronic file notes (non-physician staff): 15 minutes per short note, 30 minutes per intermediate note, 1 hour per extensive note.
- Response letter to patient (non-physician staff): 30 minutes per short letter, 1 hour per long letter, 2 hours per very long and complex letter.
- Clinical review (physician): 1 hour per short e-mail, 2 hours per lengthy e-mail and/or telephone note, 4 hours per substantive review with written review document.⁵⁸

⁵⁶ *Canterbury v. Spence*, 464 F.2d. 772 (D.C. Cir. 1972); Wisconsin Medical Examining Board, Clearinghouse Rule 14-040, Admin. Reg. (April 26, 2015).

⁵⁷ Karen L. Posner et al., *The Role of Informed Consent in Patient Complaints: Reducing Hidden Health System Costs and Improving Patient Engagement through Shared Decision Making*, 35(2) J. HEALTHCARE RISK MANAGEMENT 38 (2015).

⁵⁸ *Id.*

Greater PDA use not only serves a protective function once a claim is brought but also helps reduce the volume of negligent nondisclosure claims brought in the first place. Consequently, PDAs can save significant pre-claim dispute resolution resources.

V. PDAs REDUCE LIABILITY RISK FROM MEDICAL MALPRACTICE CLAIMS.

With respect to negligent nondisclosure claims, using PDAs can help clinicians avoid a breach of duty in the first place. PDAs cannot do that with respect to other malpractice claims like negligent diagnosis. But even if PDAs cannot affect the legal or factual validity of medical malpractice claims, they can have a substantial impact on whether such claims are filed.⁵⁹

Only a very small percentage of negligent medical errors result in claims even when those errors cause injuries. In just one of the many studies confirming this statistic, Harvard researchers used a sample of hospitalizations in New York State to compare medical records to claims files. They found that only one in six hospital-based medical errors results in a malpractice claim.⁶⁰ Researchers made similar findings in Colorado and Utah.⁶¹

Most patients who are injured from medical care do not make a claim. Not even most injured patients who can prove negligence make a claim. PDAs can mitigate key factors that motivate claims.⁶² First, PDAs result in more satisfied patients, and satisfied patients bring fewer claims. Second, PDAs result in better outcomes, and patients with better outcomes bring fewer claims.

⁵⁹ H.H. Hiatt et al. *A Study of Medical Injury and Medical Malpractice*, 321(7) NEW ENG. J. MED. 480; Hickson et al. *supra* note XX; W. Levinson et al. *Physician-Patient Communication: The Relationship with Malpractice Claims among Primary Care Physicians and Surgeons*, 277(7) JAMA 553 (1997); T. Relis, *It's Not About the Money!': A Theory on Misconceptions of Plaintiffs' Litigation Aims*, 68(2) U. PITT. L. REV. 341; C. Vincent et al., *Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action*, 343(8913) THE LANCET 1609 (1994).

⁶⁰ HARVARD MEDICAL PRACTICE STUDY GROUP, PATIENTS, DOCTORS AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990).

⁶¹ Studdert et al, *Beyond Dead Reckoning: Measures of Medical Injury Burden, Malpractice Litigation, and Alternative Compensation Models from Utah and Colorado*, 33 IND. L. REV. 1643 (2000).

⁶² R.A. Lindor et al., *Liability and Informed Consent in the Context of Shared Decision Making*, 23(12) ACAD. EMERGENCY MED. 1428 (2016); Marie-Anne Durand et al., *Can Shared Decision-making Reduce Medical Malpractice Litigation? A Systematic Review*, 15 BMC HEALTH SERVICES RES. 167 (2015).

A. Medical Liability Insurers Face Significant Liability Risk from Medical Malpractice Claims.

The best available estimate is that the national cost of the medical liability system is \$56 billion.⁶³ Much of this is borne by medical malpractice insurers, including \$6 billion in indemnity payments, \$1.2 billion in defense costs, and \$1 billion in risk management.⁶⁴ These costs have been dropping over the past few years.⁶⁵ But they are still significant. There is still plenty of room for improvement.

B. PDAs Result in More Satisfied Patients Who Bring Fewer Claims.

Significant evidence indicates that patients do not typically bring malpractice suits simply because they have bad outcomes. They bring lawsuits when those bad outcomes are accompanied by bad feelings.⁶⁶ Commentators and insurers have long recognized communication failures as an important source of malpractice litigation.⁶⁷

One notable study examined the factors that prompted families to file medical malpractice claims following perinatal injuries. One-half of the responding families reported that physicians would attempted to mislead them. 70% reported that physicians did not warn about long-term neurodevelopmental problems.⁶⁸

PDAs can mitigate the bad feelings that motivate claims, because PDAs improve the quality of physician-patient communication.⁶⁹ If patients are well-informed of potential risks, then they are less surprised (or angry) when those

⁶³ Michelle Mello et al., *National Costs of The Medical Liability System*, 29(9) HEALTH AFFAIRS 1569 (2010).

⁶⁴ *Id.*

⁶⁵ Robert Lowes, *Malpractice Premium Trends Belie Malpractice Crisis*, MEDSCAPE (Oct. 5, 2017) (reporting annual premium survey by Medical Liability Monitor).

⁶⁶ T. McIlraith, *Patient Satisfaction and the Cognitive vs. Emotional Disconnect*, 19(9) HOSPITALIST 22 (2015); F. Fullam, *The Link between Patient Satisfaction and Malpractice Risk* (2010), <http://www.pressganey.com-HealthCarePerformanceImprovementandPatientExperience-PressGaney>

⁶⁷ B. Huntington & N. Kuhn, *Communication Gaffes: A Root Cause of Malpractice Claims*, 16(2) BAYLOR UNIV. MED. CENTER PROC. 157 (2003); M. Colaco et al., *Influencing Factors Leading to Malpractice Litigation in Radical Prostatectomy*, 191 J. UROLOGY 1770 (2014). Policymakers have devoted substantial attention to post-injury communication like “I’m Sorry” programs. In contrast, PDAs improve communication pre-treatment.

⁶⁸ Gerald B. Hickson et al., *Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries*, 267(10) JAMA 1359 (1992).

⁶⁹ See, e.g., P. J. Moore et al., *Medical Malpractice: The Effect of Doctor-Patient Relations on Medical Patient Perceptions and Malpractice Intentions*, 173 WEST. J. MED. 244 (2000).

risks later materialize.⁷⁰ Patients using PDAs have less decisional regret and take more ownership of their own decisions.⁷¹ In short, better communication means lower liability exposure.⁷²

C. PDAs Result in Better Outcomes and Fewer Claims.

Even when patients have been injured from medical treatment, PDAs can reduce claims by setting realistic expectations and minimizing surprise. But PDAs have an even more notable liability-mitigating benefit. They can also prevent patients from getting injured in the first place. Expectedly, patients with good outcomes do not file claims.

Patient nonadherence to prescribed regimens is a common problem encountered by physicians in all specialties.⁷³ Nonadherence adversely impacts the effectiveness of the treatment and materially increases the chances of a bad outcome. Indeed, in some disease conditions, more than 40% of patients sustain significant risks by misunderstanding, forgetting, or ignoring healthcare advice.⁷⁴

Obviously, patients must understand what they are supposed to do before they can follow medical recommendations. Here, PDAs can help. For example, in a Mayo Clinic study, diabetes patients offered a PDA called Statin Choice were better informed and were more likely to adhere to their drug regimens.⁷⁵ The PDA improved the accuracy of patients' estimate of cardiovascular risk without statin therapy, improved their knowledge about statins and the potential relative merits of statin therapy, and improved the accuracy of their estimate of absolute cardiovascular risk reduction with statin therapy.⁷⁶

⁷⁰ See Ekblom, *supra* note XX (“[P]oor communication, unrealistic expectations and lack of one-on-one risk discussions are common patterns for cases in suit.”). One leading insurers advises the following as a “risk mitigation strategy.” Help patients “set reasonable expectations about outcomes by discussing the possibility of less-than-optimal results and complications that could delay recovery and affect appearance.” Doctor’s Company, *Plastic Surgery Closed Claims: What Can We Learn?* DOCTOR’S ADVOCATE (4th Quarter 2016).

⁷¹ D. Stacey et al., *Implementation of a Patient Decision Aid for Men with Localized Prostate Cancer: Evaluation of Patient Outcomes and Practice Variation*, 11(87) IMPLEMENTATION SCI. (2016).

⁷² Allen D. Spiegel & Florence Kavalier, *Better Patient Communications Mean Lower Liability Exposure*, Managed Care (Aug. 1997).

⁷³ See *supra* notes XX.

⁷⁴ Leslie R. Martin et al., *The Challenge of Patient Adherence*, 1(3) THERAPEUTICS & CLINICAL RISK MANAGEMENT 189 (2005).

⁷⁵ A.J. Weymiller et al., *Helping Patients with Type 2 Diabetes Mellitus Make Treatment Decisions Statin Choice Randomized Trial*, 167 ARCHIVES INTERNAL MED. 1076 (2007).

⁷⁶ A nearly seven-fold better understanding.

Recognizing these advantages of PDAs, some leading liability insurers advise “Written and audiovisual materials for the patient to take home are a useful supplement to the informed consent discussion. These are helpful because many patients cannot remember or explain to their families what they were told by their doctors.”⁷⁷ Indeed, some insurers include this as at the top of their list of risk mitigation strategies.

VII. New Risks Introduced by PDAs Are Minimal Relative to Benefits.

PDAs reduce the risk of liability from both negligent nondisclosure and medical malpractice claims. But they may also introduce some liability risks of their own. [EXPAND]⁷⁸

VII. CONCLUSION

Overwhelming evidence shows that PDAs hold enormous promise for improving the quality of informed consent. PDAs can reduce unwanted medical treatment and help assure that care is value-congruent. Yet, too few clinicians use PDAs with their patients. To push clinicians to use PDAs, medical malpractice insurers should offer premium discounts for using PDAs. These discounts will more than pay for themselves, because PDAs materially reduce the risk of liability.

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⁷⁷ DOCTOR’S COMPANY, WELCOME TO THE DOCTOR’S COMPANY: A SERVICE AND PATIENT SAFETY/RISK MANAGEMENT GUIDE FOR NEW MEMBERS 17 (June 2017).

⁷⁸ There may also be some legal obstacles to implementation. *See, e.g.,* Shinal v. Toms, 31 MAP 2016, 2017 Pa. LEXIS 1385 (Pa. June 20, 2017).